UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF WASHINGTON

GERI KANESTA-RYCHNER,
Plaintiff,
v.
HORIZON THERAPEUTICS USA, INC.,
Defendant.

Case No. _____

Complaint with Jury Demand

PRELIMINARY STATEMENT

1. Plaintiff Geri Kanesta-Rychner brings this action for damages caused by Defendant Horizon Therapeutics, Inc.'s wrongful conduct in connection with the development, design, testing, labeling, packaging, promoting, advertising, marketing, distribution, and selling of teprotumumab as Defendant's prescription drug Tepezza®.

2. Defendant manufactures, promotes, and sells Tepezza as a prescription drug that treats thyroid eye disease. Tepezza is manufactured as an infusion treatment given by physicians intravenously.

3. Tepezza injured Plaintiff by causing permanent hearing damage.

4. Defendant knew or should have known that Tepezza, when used as prescribed and intended, causes harmful hearing loss and other symptoms including tinnitus.

5. Numerous patient reports, including significant newly acquired reports immediately following Defendant's launch of Tepezza, scientific studies, and even

Defendant's post-marketing studies establish that Tepezza causes hearing loss and tinnitus.

6. Nevertheless, Defendant failed to warn, instruct, advise, educate, or otherwise inform Tepezza users, Tepezza prescribers, or United States governmental regulators about the risk of hearing loss, or the need for medical and/or audiological monitoring. At all relevant times, the U.S. label for Tepezza contained no warning of permanent hearing loss or tinnitus.

7. As a proximate result Defendant's wrongful actions and inactions, Plaintiff was injured and suffered damages from Plaintiff's use of Tepezza.

8. Plaintiff accordingly demands judgment against Defendant and requests, among other things, compensatory damages, statutory damages, punitive damages, attorneys' fees, and costs.

PARTIES

Plaintiff

9. Plaintiff Geri Kanesta-Rychner is a resident and a citizen of the state of Washington, Pierce County. Plaintiff suffered severe injuries as a direct result of infusion of Defendant's biological product Tepezza.

10. Plaintiff was diagnosed with thyroid eye disease and/or Graves' disease and received Tepezza infusions from a physician from April 27, 2022 through September 28, 2022.

11. During the relevant time periods, Plaintiff and Plaintiff's physicians were given no warning and had no knowledge of the serious risk of permanent hearing loss and/or tinnitus Tepezza posed. Specifically, and as discussed more fully below, there is no warning or indication that Tepezza can, and in fact does, cause permanent hearing damage. Nor are physicians directed by Defendant to conduct baseline

audiology testing before treatment with Tepezza, or monitor hearing acuity during treatment.

12. When Plaintiff complained of hearing loss to her physician during treatment, her physician advised that hearing loss is temporary, underscoring Defendant's failure to warn prescribing physicians of the true risks of Tepezza.

13. Subsequently, and as a result of Plaintiff's infusions of Tepezza, Plaintiff now suffers from permanent hearing loss and/or tinnitus.

14. As a proximate result of Defendant's acts and omissions, Plaintiff suffered the injuries described above due to Plaintiff's infusions of Tepezza. Plaintiff accordingly seeks damages associated with these injuries.

Defendant

15. Defendant Horizon Therapeutics USA, Inc. f/k/a Horizon Pharma USA, Inc. is a corporation organized under the laws of Delaware with its principal place of business at 1 Horizon Way, Deerfield, Illinois 60015.

16. Horizon Therapeutics USA, Inc. is a wholly owned subsidiary of Horizon Therapeutics PLC organized under the laws of Ireland with a principal place of business located at 70 St. Stephen's Green, Dublin 2, D02 E2X4, Ireland.

17. Defendant, together with its parent company Horizon Therapeutics PLC (collectively "Horizon") were responsible for the sales and marketing in the United States of the drug Tepezza from Horizon's U.S. headquarters in Deerfield, Illinois.

18. On information and belief, Defendant has transacted and conducted business within the State of Washington and has derived substantial revenue from goods and products disseminated and used throughout Washington and the United States.

19. Horizon held the Biologic License Application ("BLA") for Tepezza from approximately January 2020 to the present.

20. At all relevant times, Horizon was, and still is, a pharmaceutical company involved in the manufacturing, research, development, marketing, distribution, sale, and release for use to the general public of pharmaceuticals, including Tepezza, in Illinois and throughout the United States.

21. Defendant was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Tepezza, and controlling the Tepezza BLA.

22. The term "Defendant" as used in the complaint shall include any and all named or unnamed parent companies, parent corporations, subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and any organizational units of any kind, their predecessors, successors, successors in interest, assignees, and their officers, directors, employees, agents, representatives, and any and all other persons acting on their behalf.

JURISDICTION AND VENUE

23. The Court has jurisdiction under 28 U.S.C. § 1332(a)(1) because the amount in controversy exceeds $75,000, exclusive of interest and costs, and is between citizens of different states.

24. Venue is proper in this Court under 28 U.S.C. § 1391(b), because Defendant conducts business in this district and a substantial part of the acts and omissions giving rise to this complaint, including the sale and distribution of the product that injured Plaintiff, occurred in this district.

NATURE OF THE CASE

25. Plaintiff brings this case against Defendant for damages associated with Plaintiff's use of the biologic product Tepezza, which was designed, manufactured, sold, and/or distributed by Defendants. Plaintiff suffered various injuries, serious

physical pain, emotional distress, and medical expenses as a direct result of Plaintiff's use of Tepezza.

26. At all relevant times, Defendant was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and/or distribute Tepezza for the treatment of thyroid eye disease.

27. Defendant's fraudulent and illegal conduct with respect to Tepezza caused hundreds, if not thousands, of individuals—including Plaintiff—to develop severe and permanent hearing damage.

RELEVANT FACTUAL BACKGROUND

Thyroid eye disease

28. Thyroid eye disease ("TED") is characterized by progressive inflammation in the tissues around the eyes. This can cause the eyelids to become red, swollen, and uncomfortable and the eyes can push forward or bulge ("proptosis"). Notwithstanding Horizon's marketing materials suggesting vision impairment is common amongst those diagnosed with TED, that outcome is exceedingly rare—impacting a mere 3–5% of TED patients. On information and belief, Horizon was aware of these facts at all time, but nonetheless promoted Tepezza's use for anyone diagnosed with TED and for early treatment of the disease.

29. Horizon continues to maintain that "TED is a serious, progressive and *vision-threatening* rare autoimmune condition" that can "often" lead to "permanent and vision-impairing consequences." Horizon Therapeutics Form 10-K, p. 6 (filed March 1, 2023) (emphasis added) (available at https://ir.horizontherapeutics.com/static-files/ecd55c43-52e4-4fca-b907-3c2bd81ad985) (last accessed March 13, 2023).

30. TED is an autoimmune disease usually associated with hyperthyroidism. The exact mechanism of the disease is not fully understood.

31. The signs and symptoms of TED can vary greatly from one person to another. Symptoms range from mild to severe and include redness, irritation, and discomfort of the eyes and eyelids. Dry eyes and pain when moving the eyes may also occur. Eyelid retraction is also common, which is when the upper eyelid is positioned too high and/or the lower eyelid too low thus exposing the eye. The most noticeable symptom can be exophthalmos or proptosis, which means the eyes bulge or protrude outward of the eye socket. Additional symptoms and signs can include blurred vision, double vision ("diplopia"), misalignment of the eyes ("strabismus"), chronic bloody eyes, white area of eye inflamed, watery eyes due to excessive formation of tears, swelling near the upper and lower eyelids, an intolerance of bright lights, and difficulty moving the eyeballs.

32. TED is divided into two stages; the "active phase," which involves a progressive worsening of symptoms and visible inflammation followed by an "inactive phase" that is characterized by no further deterioration in the patient's condition. The active phase typically lasts for six months to two years.

33. TED mostly commonly occurs as part of Graves' disease, which is an autoimmune disease that affects the thyroid, skin, and eyes. TED can also occur in people with overactive or underactive thyroid (hyperthyroidism and hypothyroidism respectively).

34. In affected individuals who have underlying Graves' disease, treatment includes reversing hyperthyroidism. Some individuals with mild TED may be treated with supportive measures such as dark sunglasses to treat sensitivity to light, ointments, artificial tears, and/or prisms that are attached to glasses. Other therapies, such as corticosteroids, have been used to reduce inflammation and swelling in individuals with moderate-to-severe disease.

35. Some individuals with moderate-to-severe or severe disease may eventually require surgery. Generally, it is recommended to avoid surgery until after the active phase of the disease has ended.

36. According to the 2008 Consensus Statement of the European Group on Graves' Orbitopathy (EUGOGO) on Management of Graves' Orbitopathy, the disease is often mild and self-limiting, and probably declining in frequency, with only 3–5% of cases posing a threat to eyesight.

Defendant designs and seeks FDA approval for Tepezza to treat thyroid eye disease.

37. On May 6, 2013, FDA granted Orphan Drug designation for teprotumumab.

38. The FDA has authority to grant Orphan Drug designation to a drug or biological product to prevent, diagnose, or treat a rare disease or condition, with populations of under 200,000 people. Orphan Drug designation provides a separate pathway for approval and qualifies sponsors for incentives including tax credits for qualified clinical trials, exemption from user fees, and up to seven years of market exclusivity post-approval.

39. On March 9, 2015, the FDA granted a Fast Track designation for teprotumumab.

40. On July 29, 2016, the FDA granted Breakthrough Therapy Designation for teprotumumab for active TED.

41. On approximately July 6, 2019, Defendant submitted the original BLA for teprotumumab-trbw (BLA: 761143).

42. In January 2020 the FDA approved Tepezza, making it the first approved drug indicated to treat TED. Tepezza inhibits (or blocks) the activity of the protein insulin-like growth factor-1 ("IGF-1"), which is believed to a play as significant role in the development of the disorder.

43. On approval of Tepezza, the FDA Risk Assessment and Risk Mitigation Review notes:

> Severity of TED is distinct from, but related to, disease activity. Severity of TED is best defined by functional or cosmetic impairment, which can be assessed by various criteria, such as is the Clinical Measures of Severity based on the European Group on Graves' Orbitopathy (EUGOGO) Consensus Statement. Clinical activity of TED is commonly measured by the Clinical Activity Score (CAS). Both activity and severity should be considered in the treatment of TED, as the 2 measurements are not interchangeable and don't follow a linear relationship.

44. In 2021, the EUGOGO issued clinical practice guidelines for the medical management of Graves' orbitopathy, which included first- and second-line treatments for disease based on severity. The guidelines include simply that Tepezza be considered only as a second-line treatment for moderate-to-severe and active Graves' orbitopathy. In making Tepezza a second-line treatment recommendation, the 2021 EUGOGO guidelines note, "although teprotumumab has become the first drug approved by the US Food and Drug Administration for the treatment of adult GO [Graves' Orbitopathy], its incorporation into routine clinical practice is currently limited by the lack of comprehensive long-term efficacy and safety data, absence of head-to-head comparison with i.v. glucocorticoids, restricted geographical availability, reimbursement (outside the US), and costs."

Defendant's failure to test Tepezza

45. According to the Tepezza label, "Teprotumumab-trbw's mechanism of action in patients with Thyroid Eye Disease has not been fully characterized.

Teprotumumab-trbw binds to IGF-1R and blocks its activation and signaling." Defendant failed to conduct tests to determine the mechanism of action of the drug.

46. Further, the Tepezza label admits "[n]o formal pharmacodynamic studies have been conducted with teprotumumab-trbw."

47. According to its label, "[t]he safety of TEPEZZA was evaluated in two randomized, double-masked, placebo-controlled clinical studies (Study 1 [NCT:01868997] and Study 2 [NCT:03298867]) consisting of **170** patients with Thyroid Eye Disease (**84** received TEPEZZA and **86** received placebo)." (*See* **6.1 Clinical Trials Experience**) (emphasis added).

48. Elsewhere on the label, it reports that "TEPEZZA was evaluated in 2 randomized, double-masked, placebo-controlled studies in **171** patients with Thyroid Eye Disease: Study 1 (NCT01868997) and Study 2 (NCT03298867)." Of those patients, "[a] total of **84** patients were randomized to TEPEZZA and **87** patients were randomized to placebo." (*See* 14 **CLINICAL STUDIES**) (emphasis added).

49. Regardless of which representation on the Tepezza label regarding the total number of study participants is accurate, Tepezza was submitted to FDA for approval with less than 100 patients enrolled in clinical trials actually receiving the drug.

50. The label for Tepezza contains warnings for "Infusion Reactions" (*see* 5.1), "Exacerbation of Preexisting Inflammatory Bowel Disease" (*see* 5.2), and "Hyperglycemia" (*see* 5.3).

51. The only reference on the Tepezza label related to hearing loss is listed among the "adverse reactions:" "Most common adverse reactions (incidence greater than 5%) are muscle spasm, nausea, alopecia, diarrhea, fatigue, hyperglycemia, hearing impairment, dry skin, dysgeusia and headache." In a table listing the incidence of the adverse reactions in the experimental versus the control group of the clinical

trials, "hearing impairment" was noted to have occurred in 8 Tepezza users and 0 of the placebo group (*see* 6.1, Table 1). Hearing impairment was noted to include "deafness, eustachian tube dysfunction, hyperacusis, hypoacusis, and autophony." Nothing on the label suggests that *any* of the adverse events might be of extended duration (e.g., permanent diarrhea). Nor does the label mention tinnitus.

The dangers of Tepezza — Post-marketing

52. Despite study after study providing clear evidence of the dangers of Tepezza, Defendant failed to adequately investigate the threat that Tepezza poses to patients' ears and hearing or warn patients of the risk that they would suffer ear injury and permanent or extended hearing impairment.

53. According to Defendant's 2021 Annual Report, it "delayed the start of an FDA-required post-marketing study to evaluate safety of TEPEZZA in a larger patient population and retreatment rates relative to how long patients receive the medicine. The FDA-required post-marketing study was initiated in the fourth quarter of 2021." Defendant continued to market and sell Tepezza in the interim.

54. On February 22, 2022, Defendant issued a press release announcing results from a new post-marketing safety analysis of hearing events associated with Tepezza for the treatment of TED.

55. These findings were also presented at the 48th Annual Meeting of the North American Neuro-Ophthalmology Society (NANOS 2022), Feb. 12–17, in Austin, Texas.

56. Thousands of patients were included in this 19-month analysis and demonstrated approximately **10%** of all cases reported to the safety database have included a hearing-related event.

57. The most frequently reported hearing event was hypoacusis (reduction in hearing), followed by tinnitus (ringing in the ears).

58. Defendant continues to represent the majority of hearing-related adverse events in the pivotal trials and post-approval have been mild to moderate and reversible.

59. In contrast to the public statements, almost immediately after the FDA approved Tepezza, patients and doctors began reporting serious complications relating to ear and permanent hearing problems in patients taking Tepezza.

Adverse events related to Tepezza

60. As noted above, Plaintiff was treated with Tepezza between April 27, 2022 and September 28, 2022. On information and belief, before the completion of Plaintiff's treatment, Horizon self-reported (or consumers reported) the following newly acquired information to the FDA, but Horizon took no action to seek a label change under the FDA's Changes Being Effected ("CBE") regulation (21 C.F.R. § 314.70(c)(3)):

a. On May 13, 2020, the FDA received a report of a consumer experiencing tinnitus following use of Tepezza;

b. On June 2, 2020, Horizon notified the FDA of a consumer reporting experiencing tinnitus following use of Tepezza;

c. On June 4, 2020, Horizon notified the FDA of a consumer reporting experiencing hypoacusis following use of Tepezza;

d. On June 8, 2020, Horizon notified FDA of a report from a healthcare professional of a patient experiencing tinnitus following use of Tepezza;

e. On June 15, 2020, Horizon notified FDA of a report from a healthcare professional of a patient experiencing tinnitus following use of Tepezza;

f. On July 1, 2020, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing tinnitus and hypoacusis following use of Tepezza;

g. On July 14, 2020, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing deafness following use of Tepezza;

h. On July 28, 2020, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing tinnitus following use of Tepezza;

i. On August 6, 2020, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing hypoacusis following use of Tepezza;

j. On August 14, 2020, Horizon notified the FDA of a report from a patient experiencing hypoacusis following use of Tepezza;

k. On August 20, 2020, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing bilateral deafness following use of Tepezza;

l. On September 1, 2020, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing tinnitus following use of Tepezza;

m. On September 7, 2020, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing hypoacusis following use of Tepezza;

n. On September 8, 2020, Horizon notified the FDA of two separate reports—one from a consumer and one from a healthcare professional—of patients experiencing hypoacusis following use of Tepezza;

o. On September 9, 2020, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing deafness following use of Tepezza;

p. On September 10, 2020, Horizon notified the FDA of a report from a consumer of experiencing hypoacusis following use of Tepezza;

q. On September 11, 2020, Horizon notified the FDA of a report from a consumer of experiencing hypoacusis following use of Tepezza;

r. On September 15, 2020, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing hypoacusis following use of Tepezza;

s. On September 18, 2020, Horizon notified the FDA of a report from a consumer of experiencing hypoacusis and tinnitus following use of Tepezza;

t. On September 18, 2020, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing deafness following use of Tepezza;

u. On September 25, 2020, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing hypoacusis following use of Tepezza;

v. On September 28, 2020, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing hypoacusis following use of Tepezza;

w. On September 30, 2020, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing deafness following use of Tepezza;

x. On September 30, 2020, Horizon notified the FDA of a report from a consumer of experiencing hypoacusis and tinnitus following use of Tepezza;

y. On October 9, 2020, Horizon notified the FDA of a report from a consumer of experiencing deafness following use of Tepezza;

z. On October 16, 2020, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing hypoacusis following use of Tepezza;

aa. On October 21, 2020, the FDA received a report of a consumer experiencing deafness following use of Tepezza;

bb. On October 27, 2020, Horizon notified the FDA of two separate reports from consumers of experiencing deafness following use of Tepezza;

cc. On November 2, 2020, Horizon notified the FDA of a report from a consumer of experiencing tinnitus following use of Tepezza;

dd. On November 10, 2020, Horizon notified the FDA of a report from a consumer of experiencing hypoacusis following use of Tepezza;

ee. On November 16, 2020, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing deafness following use of Tepezza;

ff. On November 19, 2020, Horizon notified the FDA of a report from a consumer of experiencing dysacusis and tinnitus following use of Tepezza;

gg. On December 4, 2020, Horizon notified the FDA of a report from a consumer of experiencing tinnitus following use of Tepezza;

hh. On December 17, 2020, Horizon notified the FDA of a report from a consumer of experiencing hypoacusis following use of Tepezza;

ii. On December 28, 2020, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing deafness following use of Tepezza; and

jj. On December 30, 2020, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing hypoacusis following use of Tepezza.

61. On information and belief, FDA received 45 adverse-event reports in 2020 related to Tepezza for ear and labyrinth disorders, which include tinnitus, hypoacusis, and deafness.

62. The adverse-event reports continued in 2021:

a. On January 13, 2021, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing dysphonia and hypoacusis following use of Tepezza;

b. On January 14, 2021, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing deafness following use of Tepezza;

c. On January 19, 2021, Horizon notified the FDA of a report from a consumer of experiencing hypoacusis following use of Tepezza;

d. On February 9, 2021, Horizon notified the FDA of a report from a consumer of experiencing tinnitus following use of Tepezza;

e. On March 11, 2021, Horizon notified the FDA of a report from a consumer of experiencing hypoacusis following use of Tepezza;

f. On April 9, 2021, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing hypoacusis following use of Tepezza;

g. On April 20, 2021, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing tinnitus following use of Tepezza;

h. On May 17, 2021, Horizon notified the FDA of nine separate reports of adverse events following use of Tepezza:

i. One from a consumer reporting hypoacusis and tinnitus;

ii. One from a consumer reporting hypoacusis;

iii. One from a healthcare provider reporting a patient experiencing hypoacusis and tinnitus;

iv. Two from healthcare providers reporting a patient experiencing hypoacusis; and

v. Four from healthcare providers reporting a patient experiencing deafness following use of Tepezza;

i. On May 18, 2021, Horizon notified the FDA of a report from a consumer of experiencing hypoacusis following use of Tepezza;

j. On May 19, 2021, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing hypoacusis following use of Tepezza;

k. On May 20, 2021, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing deafness following use of Tepezza;

l. On May 20, 2021, Horizon notified the FDA of a report from a consumer experiencing deafness following use of Tepezza;

m. On May 31, 2021, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing hypoacusis following use of Tepezza;

n. On June 17, 2021, the FDA received a report from a consumer experiencing deafness following use of Tepezza;

o. On July 7, 2021, Horizon notified the FDA of a report from a consumer of experiencing deafness following use of Tepezza;

p. On July 13, 2021, the FDA received a report from a consumer of experiencing hypoacusis following use of Tepezza; and

q. On July 14, 2021, the FDA received a report from a consumer of experiencing tinnitus following use of Tepezza.

r. One July 21, 2021, the FDA received a report of a consumer experiencing deafness following use of Tepezza;

s. On August 2, 2021, the FDA received a report from a consumer of experiencing tinnitus following use of Tepezza;

t. On August 10, 2021, Horizon notified the FDA of 16 separate reports of adverse events following use of Tepezza:

i. Four from consumers of experiencing hypoacusis;

ii. One from a consumer of experiencing hypoacusis and tinnitus;

iii. One from a consumer of experiencing deafness;

iv. Four from healthcare professionals of a patient experiencing deafness;

v. Four from healthcare professionals of a patient experiencing hypoacusis; and

vi. Two from healthcare professionals of a patient experiencing tinnitus.

u. On August 18, 2021, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing tinnitus following use of Tepezza;

v. On August 18, 2021, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing autophony, deafness, and hypoacusis following use of Tepezza;

w. On August 18, 2021, Horizon notified the FDA of two separate reports from healthcare professionals of a patient experiencing hypoacusis following use of Tepezza;

x. On September 7, 2021, the FDA received a report from a consumer of experiencing deafness following use of Tepezza;

y. On September 10, 2021, the FDA received a report from a healthcare professional of a patient experiencing deafness following use of Tepezza;

z. On October 5, 2021, the FDA received a report from a consumer of experiencing tinnitus following use of Tepezza;

aa. On October 7, 2021, the FDA received a report from a consumer experiencing hypoacusis following use of Tepezza;

bb. On October 15, 2021, the FDA received a report from a healthcare professional of a patient experiencing deafness following use of Tepezza;

cc. On October 20, 2021, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing tinnitus following use of Tepezza;

dd. On October 29, 2021, Horizon notified the FDA of three separate reports from a consumer of experiencing deafness following use of Tepezza;

ee. On October 29, 2021, Horizon notified the FDA of a report from a consumer of experiencing tinnitus following use of Tepezza;

ff. On October 29, 2021, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing deafness following use of Tepezza;

gg. On November 3, 2021, Horizon notified the FDA of a report from a consumer of experiencing tinnitus following use of Tepezza;

hh. On November 3, 2021, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing hypoacusis following use of Tepezza;

ii. On November 4, 2021, Horizon notified the FDA of a report from a consumer of experiencing tinnitus following use of Tepezza;

jj. On November 4, 2021, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing hypoacusis following use of Tepezza;

kk. On November 4, 2021, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing tinnitus following use of Tepezza;

ll. On November 5, 2021, Horizon notified the FDA of four separate reports from healthcare professionals of a patient experiencing hypoacusis following use of Tepezza;

mm. On November 8, 2021, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing hypoacusis following use of Tepezza;

nn. On November 8, 2021, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing tinnitus following use of Tepezza;

oo. On November 9, 2021, the FDA received a report from a consumer experiencing tinnitus following use of Tepezza;

pp. On November 10, 2021, Horizon notified the FDA of a report from a consumer of experiencing tinnitus and hypoacusis following use of Tepezza;

qq. On November 10, 2021, Horizon notified the FDA of three separate reports from a consumer of experiencing hypoacusis following use of Tepezza;

rr. On November 10, 2021, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing deafness following use of Tepezza;

ss. On November 10, 2021, Horizon notified the FDA of three separate reports from healthcare professional of a patient experiencing hypoacusis following use of Tepezza;

tt. On November 10, 2021, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing tinnitus following use of Tepezza;

uu. On November 11, 2021, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing tinnitus following use of Tepezza;

vv. On November 11, 2021, Horizon notified the FDA of a report from a consumer experiencing deafness following use of Tepezza;

ww. On November 12, 2021, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing deafness following use of Tepezza;

xx. On November 12, 2021, Horizon notified the FDA of two separate reports from healthcare professionals of a patient experiencing hypoacusis following use of Tepezza;

yy. On November 12, 2021, Horizon notified the FDA of a report from a consumer of experiencing tinnitus following use of Tepezza;

zz. On November 15, 2021, Horizon notified the FDA of a report from a consumer of experiencing deafness following use of Tepezza;

aaa. On November 15, 2021, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing tinnitus and deafness following use of Tepezza;

bbb. On November 17, 2021, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing deafness and tinnitus following use of Tepezza;

ccc. On November 17, 2021, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing deafness following use of Tepezza;

ddd. On December 6, 2021, the FDA received a report from a consumer of experiencing deafness and tinnitus following use of Tepezza;

eee. On December 12, 2021, the FDA received a report from a consumer of experiencing hypoacusis following use of Tepezza;

63. On information and belief, FDA received 91 adverse-event reports in 2021 related to Tepezza for ear and labyrinth disorders, which include tinnitus, hypoacusis, and deafness.

64. The adverse-event reports continued in 2022:

a. On January 7, 2022, Horizon notified the FDA of a report from a consumer of experiencing bilateral deafness following use of Tepezza;

b. On January 19, 2022, the FDA received a report from a healthcare professional of a patient experiencing tinnitus following use of Tepezza;

c. On January 21, 2022, the FDA received a report from a healthcare professional of a patient experiencing tinnitus following use of Tepezza;

d. On February 4, 2022, Horizon notified the FDA of a report from a consumer of experiencing deafness following use of Tepezza;

e. On February 4, 2022, Horizon notified the FDA of a report from a consumer of experiencing tinnitus following use of Tepezza;

f. On February 7, 2022, Horizon notified the FDA of a report from a consumer of experiencing deafness following use of Tepezza;

g. On February 8, 2022, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing hypoacusis following use of Tepezza;

h. On February 9, 2022, Horizon notified the FDA of a report from a consumer of experiencing tinnitus following use of Tepezza;

i. On February 14, 2022, Horizon notified the FDA of a report from a consumer of experiencing tinnitus following use of Tepezza;

j. On February 15, 2022, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing tinnitus and hypoacusis following use of Tepezza;

k. On February 15, 2022, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing hypoacusis following use of Tepezza;

l. On February 15, 2022, Horizon notified the FDA of a report from a consumer of experiencing hypoacusis following use of Tepezza;

m. On February 16, 2022, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing tinnitus following use of Tepezza;

n. On February 21, 2022, Horizon notified the FDA of a report from a consumer of experiencing hypoacusis following use of Tepezza;

o. On February 22, 2022, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing hypoacusis following use of Tepezza;

p. On March 2, 2022, the FDA received a report from a consumer of experiencing hypoacusis, tinnitus, and bilateral deafness following use of Tepezza;

q. On March 9, 2022, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing deafness following use of Tepezza;

r. On March 11, 2022, Horizon notified the FDA of a report from a consumer of experiencing deafness following use of Tepezza;

s. On March 23, 2022, Horizon notified the FDA of a report from a consumer of experiencing hypoacusis following use of Tepezza;

t. On March 24, 2022, Horizon notified the FDA of a report from a consumer of experiencing hypoacusis following use of Tepezza;

u. On March 28, 2022, the FDA received a report from a consumer of experiencing hypoacusis following use of Tepezza;

v. On April 4, 2022, Horizon notified the FDA of a report from a consumer of experiencing deafness following use of Tepezza;

w. On April 7, 2022, Horizon notified the FDA of a report from a consumer of experiencing deafness and hypoacusis following use of Tepezza;

x. On April 11, 2022, Horizon notified the FDA of a report from a consumer of experiencing tinnitus following use of Tepezza;

y. On April 18, 2022, Horizon notified the FDA of a report from a consumer of experiencing deafness following use of Tepezza;

z. On April 18, 2022, the FDA received a report from a healthcare professional of a patient experiencing deafness following use of Tepezza;

aa. On April 22, 2022, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing deafness and tinnitus following use of Tepezza;

65. Each of the 27 reports noted in the paragraph above were received by the FDA before Plaintiff's treatment with Tepezza began.

66. The adverse-event reports continued after Plaintiff had her first Tepezza infusion on April 27, 2022, but before her course of eight infusions concluded on September 28, 2022:

a. On May 3, 2022, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing tinnitus following use of Tepezza;

b. On May 5, 2022, Horizon notified the FDA of a report from a consumer of experiencing hypoacusis following use of Tepezza;

c. On May 5, 2022, Horizon notified the FDA of a report from a consumer of experiencing tinnitus following use of Tepezza;

d. On May 6, 2022, Horizon notified the FDA of a report from a consumer of experiencing hypoacusis following use of Tepezza;

e. On May 6, 2022, Horizon notified the FDA of two separate reports from a healthcare professional of a patient experiencing hypoacusis following use of Tepezza;

f. On May 8, 2022, the FDA received a report from a consumer of experiencing hypoacusis following use of Tepezza;

g. On May 9, 2022, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing deafness following use of Tepezza;

h. On May 9, 2022, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing hypoacusis following use of Tepezza;

i. On May 9, 2022, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing tinnitus following use of Tepezza;

j. On May 10, 2022, Horizon notified the FDA of two separate reports from a consumer of experiencing hypoacusis following use of Tepezza;

k. On May 10, 2022, Horizon notified the FDA of a report from a consumer of experiencing tinnitus following use of Tepezza;

l. On May 10, 2022, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing deafness following use of Tepezza;

m. On May 11, 2022, Horizon notified the FDA of a report from a consumer of experiencing hypoacusis following use of Tepezza;

n. On May 11, 2022, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing autophony following use of Tepezza;

o. On May 12, 2022, the FDA received a report from a consumer of experiencing deafness following use of Tepezza;

p. On May 15, 2022, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing tinnitus following use of Tepezza;

q. On May 15, 2022, Horizon notified the FDA of three separate reports from a healthcare professional of a patient experiencing hypoacusis following use of Tepezza;

r. On May 17, 2022, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing deafness following use of Tepezza;

s. On May 17, 2022, Horizon notified the FDA of a report from a consumer of experiencing hypoacusis following use of Tepezza;

t. On May 17, 2022, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing hypoacusis following use of Tepezza;

u. On May 18, 2022, Horizon notified the FDA of four separate reports from a healthcare professional of a patient experiencing deafness following use of Tepezza;

v. On May 18, 2022, Horizon notified the FDA of two separate reports from a consumer of experiencing deafness following use of Tepezza;

w. On June 1, 2022, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing deafness following use of Tepezza;

x. On June 28, 2022, Horizon notified the FDA of a report from a consumer of experiencing hypoacusis and tinnitus following use of Tepezza;

y. On June 28, 2022, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing deafness and tinnitus following use of Tepezza;

z. On July 13, 2022, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing tinnitus following use of Tepezza;

aa. On July 18, 2022, the FDA received a report from a consumer of experiencing deafness and autophony following use of Tepezza;

bb. On August 4, 2022, Horizon notified the FDA of a report from a consumer of experiencing tinnitus and hypoacusis following use of Tepezza;

cc. On August 5, 2022, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing deafness following use of Tepezza;

dd. On August 8, 2022, Horizon notified the FDA of a report from a consumer of experiencing hypoacusis following use of Tepezza;

ee. On August 10, 2022, Horizon notified the FDA of a report from a consumer of experiencing deafness following use of Tepezza;

ff. On August 11, 2022, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing deafness following use of Tepezza;

gg. On August 12, 2022, Horizon notified the FDA of three separate reports from a healthcare professional of a patient experiencing deafness following use of Tepezza;

hh. On August 16, 2022, Horizon notified the FDA of two separate reports from a consumer of experiencing deafness following use of Tepezza;

ii. On August 16, 2022, Horizon notified the FDA of three separate reports from a healthcare professional of a patient experiencing hypoacusis following use of Tepezza;

jj. On August 16, 2022, Horizon notified the FDA of three separate reports from a healthcare professional of a patient experiencing deafness following use of Tepezza;

kk. On August 16, 2022, Horizon notified the FDA of three separate reports from a consumer of experiencing tinnitus following use of Tepezza;

ll. On August 16, 2022, Horizon notified the FDA of two separate reports from a healthcare professional of a patient experiencing tinnitus following use of Tepezza;

mm. On August 16, 2022, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing tinnitus and hypoacusis following use of Tepezza;

nn. On August 16, 2022, Horizon notified the FDA of a report from a consumer of experiencing auditory disorder following use of Tepezza;

oo. On August 17, 2022, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing tinnitus following use of Tepezza;

pp. On August 17, 2022, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing deafness following use of Tepezza;

qq. On August 17, 2022, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing hypoacusis following use of Tepezza;

rr. On August 18, 2022, Horizon notified the FDA of a report from a consumer of experiencing deafness following use of Tepezza;

ss. On August 30, 2022, Horizon notified the FDA of a report from a healthcare professional of a patient experiencing tinnitus, hypoacusis, and deafness following use of Tepezza;

tt. On September 6, 2022, the FDA received a report from a healthcare professional of a patient experiencing tinnitus and deafness following use of Tepezza;

uu. On September 21, 2022, Horizon notified the FDA of a report from a consumer of experiencing hypoacusis and tinnitus following use of Tepezza;

vv. On September 22, 2022, Horizon notified the FDA of a report from a consumer of experiencing hypoacusis following use of Tepezza;

67. Each of the 66 reports referenced in the prior paragraph were received by the FDA during the period of Plaintiff's infusions.

68. On information and belief, FDA received 93 adverse-event reports in 2022 related to Tepezza for ear and labyrinth disorders, which include tinnitus, hypoacusis, and deafness (*see* FAERS Public Dashboard, *available at* https://fis.fda.gov/sense/app/95239e26-e0be-42d9-a960-9a5f7f1c25ee/sheet/6b5a135f-f451-45be-893d-20aaee34e28e/state/analysis (last accessed December 29, 2022) either before or during Plaintiff's treatment with Tepezza.

Reports in the published medical literature

69. The FDA has established reporting categories for post-approval changes to a drug's label. The Changes Being Effected or CBE supplement allows for changes in the labeling of a drug product to reflect newly acquired information without prior

approval from the FDA. 21 C.F.R. § 314.70(c)(3). The manufacturer may make these changes based on newly acquired information, which can include reevaluation of prior clinical trials, mounting adverse-event reports, and the peer-reviewed literature. The manufacturer is, at all times, responsible for the content of its label and may execute a CBE to the label *with or without* FDA approval.

70. The CBE process allows for drug manufacturers to change a drug label more quickly than the supplemental new drug application ("sNDA") process based on newly acquired information about the drug.

71. FDA has routinely approved manufacturers' CBEs imposing testing regimes for harms associated with a drug's use.

72. Before and during Plaintiff's treatment, the peer-reviewed literature, together with the mounting adverse event reports, and Horizon's own clinical trial data, required Defendant to implement a CBE warning physicians and consumers of the risk of irreversible hearing loss and tinnitus. To date, Horizon has failed to utilize the CBE process to modify the label to warn of risks associated with long-term hearing loss and/or impose a baseline testing regime to monitor patients for hearing loss.

73. Before and during Plaintiff's treatment, the peer-reviewed literature established that Horizon possessed newly acquired information sufficient to trigger its CBE obligations. For example:

a. In April 2021, an e-publication of a pooled analysis *from the clinical trials* was funded and published by Horizon. Kahaly GJ, Douglas RS, Holt RJ, Sile S, and Smith TJ. *Teprotumumab for patients with active thyroid eye disease: a pooled data analysis, subgroup analyses, and off-treatment follow-up results from two randomised, double-masked, placebo-controlled, multicentre trials.* Lancet Diabetes Endocrinol

2021;9:360–72 (e-pub April 15, 2021). These data were available to Horizon at all times before and during Plaintiff's treatment. The authors include Horizon employee Saba Sile. The article notes that Horizon funded the study and played a pivotal role in constructing the analysis plan, study design, data collection, data analysis, data interpretation, and writing of the publication. The paper reported the hearing events in the clinical trials as: "[h]earing impairment events, reported as deafness, eustachian tube dysfunction, hyperacusis, hypoacusis, or autophony, were all classified as non-serious and all patients continued in the study without event worsening. No patients discontinued treatment because of these events. One hearing event continued but improved and was lost to follow-up, while another patient with a history of loud noise-induced tinnitus continued at the time of last-post study follow-up report." In other words, the authors' reanalysis of the clinical trial data could not rule out ongoing hearing issues after patients discontinued the treatment.

b. In October 2021, Douglas et al., published a follow-up open-label extension clinical trial report of the OPTIC-X study. Douglas RS, Kahaly, GJ, Ugradar S, Elflein H, Ponto KA, Fowler BT, Dailey R, Harris, GJ, Schiffman J, Tang R, Wester S, Patel Jain A, Marcocci C, Marinò M, Antonelli A, Eckstein A, Führer-Sakel D., Salvi M, Sile S, Francis-Sedlak M, Holt RJ, Smith TJ. *Teprotumumab efficacy, safety, and durability in longer-duration thyroid eye disease and re-treatment: OPTIC-X*. Ophthalmology 2022;129:438–449 (e-pub October 2021). As with the April 2021 publication, much, if not all, of

the data from the study existed before Plaintiff's treatment and/or discontinuation of use. The authors include three Horizon employees: Saba Sile, Megan Francis-Sedlak, and Robert J. Holt. The authors reported four patients experiencing hearing loss or tinnitus, *one of which continued through the last visit*. On information and belief, Horizon failed to conduct any additional follow-on investigation for the patient with ongoing hearing loss at the time of the clinical trials.

c. Teprotumumab (Tepezza) is an insulin-like growth factor I receptor (IGF-IR) inhibitor. On information and belief, Horizon knew when developing Tepezza that it was an IGF-IR inhibitor.

d. It has been known since the early 2000s that IGF-1 is associated with mammalian hearing and deficiencies result in hearing loss. On information and belief, it was well known in the medical literature that IGF-1 plays a central role in hearing and low levels of IGF-I had been shown to correlate with human syndromes associated with hearing loss. *See e.g.,* Murillo-Custa, S et al., *The role of insulin-like growth factor-I in the pathophysiology of hearing*. Front. Mol. Neurosci. 2011;4–11; Varela-Nieto I, Murillo-Cuesta S, Rodriguez de la Rosa L, Lassatetta L, Contreras J. *IGF-1 deficiency and hearing loss: molecular clues and clinical implications.* Pediatr. Endocrinol. Rev. 2013 Jul; 10(4):460–72; Varela-Nieto I, Morales-Garcia JA, Vigil P, Diaz-Casares A, Gorospe, I, Sanchez-Galiano S, Canon S, Camarero G, Contreras J, Cediel R,

Leon Y. *Trophic effects of insulin-like growth factor-I (IGF-I) in the inner ear*. Hear Res. 2004 Oct;196(102):19–25; Cediel R, Riquelme R, Contreras J, Diaz A, Varela-Nieto I. *Sensorineural hearing loss in*

insulin-like growth factor I-null mice: a new model of human deafness. Eur J. Neurosci. 2006 Jan;23(2):587–90.

e. Inhibition of IGF-1R as a mechanism for teprotumumab-induced ototoxicity has been reported in the medical literature. *See e.g.*, Winn BJ, Kersten RC. *Teprotumumab: interpreting the clinical trials in the context of thyroid eye disease pathogenesis and current therapies*. Ophthalmology. 2021 Nov;128(11):1627–1651 (e-pub April 28, 2021); Teo HM, Smith TJ, Joseph SS. *Efficacy and safety of teprotumumab in thyroid eye disease*. Ther. Clin. Risk. Manag. 2021 Nov 25;17:1219–1230; Chern A, Dagi Glass LR, Gudis DA. *Thyroid eye disease, teprotumumab, and hearing loss: an evolving role for otolaryngologists*. Otolaryngol Head Neck Surg. 2021 Dec;165(6):757–758; Girnita L, Smith TJ, Janssen JAML. *It takes two to tango: IGF-I and TSH receptors in thyroid eye disease*. J. Clin. Endocrinol. Metab. 2022 Aug 8;107(Supplement _1):S1–S12.

74. These data, coupled with the fact that IGF-1Rs are well known to adversely impact cochlear development and maintenance, triggered Horizon's obligation to implement a CBE to warn of the risks of long-term hearing loss and tinnitus. To date, Horizon has yet to execute a CBE warning patients and their doctors that Tepezza may cause ongoing hearing loss and tinnitus after discontinuation of use and/or completion of treatment.

75. Beyond the information set forth above, there is mounting evidence in the peer-reviewed literature establishing that long-term hearing loss can occur following discontinuation of Tepezza treatments. In August 2021, e-published February 2021, Chern et al. published an article titled *Teprotumumab and hearing loss: hear the warnings*. Orbit. 2021 Aug;40(4):355–56.

76. In August 2021, Highland et al. published an article titled *Ototoxicity and Teprotumumab* reporting a case of a 61-year-old female with "one of the first descriptive cases of ototoxicity resulting in irreversible sensorineural hearing loss in the setting of treatment with teprotumumab." The authors suggested that audiologic evaluations should be recommended to patients on teprotumumab. Highland et al., *Ototoxicity and Teprotumumab*. Ann. Otol. Rhinol. Laryngol. 2022 Aug; 131(8):910–913) (e-pub August 27, 2021).

77. In September 2021, Yu et al. reported a case series of two cases of subjective and objective hearing function changes associated with teprotumumab treatment for thyroid eye disease, including hearing loss and tinnitus. The authors noted that the potential for a risk of long-term irreversible hearing loss may exist. Yu et al., *Audiology findings in patients with teprotumumab associated otologic symptoms.* Am. J. Ophthalmol. Case Rep. 2021 Sep 16;24:101202.

78. Chern et al. also published an article in December 2021 stating "clinicians who prescribe teprotumumab should strongly consider monitoring patients' hearing with an audiologist and otolaryngologist." Chern et al., *Thyroid eye disease, teprotumumab, and hearing loss: an evolving role for otolaryngologists.* Otolaryngol. Head Neck Surg. 2021 Dec;165(6):757–758.

79. In January 2022, an additional case series of four cases of Tepezza-associated hearing loss was reported based upon patients of three doctors who treated 28 patients. The authors proposed a mechanism and concluded:

> Teprotumumab may cause a spectrum of potentially irreversible hearing loss ranging from mild to severe, likely resulting from the inhibition of the insulin-like growth factor-1 and the insulin-like growth factor-1 receptor pathway. Due to the novelty of teprotumumab and the lack of a comprehensive understanding of its effect on hearing, the

> authors endorse prospective investigations of hearing loss in the setting of teprotumumab treatment. Until the results of such studies are available, the authors think it prudent to adopt a surveillance protocol to include an audiogram and tympanometry before, during and after infusion, and when prompted by new symptoms of hearing dysfunction.

Belinsky et al., *Teprotumumab and Hearing Loss: Case Series and Proposal for Audiologic Monitoring*. Ophthalmic Plast. Reconstr. Surg. 2022 Jan–Feb 01;38(1):73–78.

80. In February 2022, another case report noted that while hearing loss was noted as a side effect in clinical trials, no formal audiometric investigations of these patients had been reported, and the manufacturer offered no formal guidelines for audiometric monitoring. The authors concluded that, because guidelines exist for other known ototoxic medications, patients undergoing treatment with Tepezza should receive similar audiometric monitoring. Ding et al., *Sensorineural Hearing Loss After Teprotumumab Therapy for Thyroid Eye Disease: A Case Report*. Otol. Neurotol. 2022 Feb 1;43(2):e148–e152.

81. In February 2022, Sears et al. reported on a prospective observational case series. In this series, 27 patients were analyzed (24 females, 3 males, average 56.3 years old). Twenty-two patients (81.5%) developed new subjective otologic symptoms. The results revealed three of the five patients with teprotumumab-related hearing loss had persistent subjective hearing loss at last follow-up. The authors also concluded that clinicians need screening, monitoring, and prevention guidelines for teprotumumab-related hearing loss. Sears et al., *Hearing dysfunction after treatment with teprotumumab for thyroid eye disease*. Am. J. Ophthalmol. 2022 Feb 25;240:1–13.

82. In March 2022, the e-publication of an Expert Consensus on the use of teprotumumab was released. Douglas RS, Kossler AL, Abrams J, Briceño, CA, Gay D, Harrison A, Lee M, Nguyen J, Joseph SS, Schlachter D, Tan J, Lynch J, Oliver L, Perry R, Ugradaron, S. *Expert consensus on the use of teprotumumab for the management of thyroid eye disease using a modified-Delphi approach*. J Neuro-Ophthalmol. 2022;42:334–339 (e-pub March 24, 2022). The authors reported the results of three rounds of surveys taken between October 2020 and February 2021. Nine of the fifteen authors reported being consultants, speakers, or owners of Defendant in the publication. The consensus recommendations include: (1) a medical history including history of hearing loss *must be* completed before initiation of treatment (emphasis in original) because conditions can worsen during treatment; (2) baseline audiogram and patulous eustachian tube testing *may be* conducted before the initiation of treatment with teprotumumab to ensure patients undergo minimal adverse events (emphasis in original); and (3) hearing-impairment adverse effects *should be* discussed with patients before initiating treatment (emphasis in original).

83. In April 2022, Chow and Silkiss published a case report of a woman in her 50s who developed tinnitus after the third dose of Tepezza, followed by frank hearing loss after the fifth dose. Repeat audiogram six weeks later showed no improvement in the hearing loss. The authors concluded "[g]iven potentially irreversible sensorineural hearing loss, we recommend close monitoring with regular audiometric testing before, during[,] and after teprotumumab therapy and propose potential treatment to reverse its effects in the ear." Chow & Silkiss, *Teprotumumab-associated chronic hearing loss screening and proposed treatments.* BMJ Case Rep. 2022 Apr 13;15(4):e248335.

84. In April 2022, an additional case report of a woman with tinnitus and hearing loss was published by Najjar and Yu. The woman reported tinnitus after the second infusion and hearing loss by the fifth infusion. Audiograms after discontinuation revealed no improvement. The authors recommended a new prospective clinical trial be performed with comprehensive pretreatment audiologic testing and ongoing audiologic monitoring. Najjar & Yu, *Audiologic Demonstration of Ototoxicity from Teprotumumab Treatment in a Patient with Thyroid Eye Disease.* OTO Open. 2022 Apr 29;6(2):2473974X221097097.

85. In July 2022, Bartalena et al. continued the publication of reports in a peer-reviewed journal article titled to distill the danger to its essence: *Teprotumumab for Graves' orbitopathy and ototoxicity: moving problems from eyes to ears?* J. Endocrinol. Invest. 2022 Jul;45(7):1455–57. (This article was e-published April 11, 2022.)

86. At all relevant times, Defendant failed to adequately warn or instruct patients, the medical community, or prescribers in the United States that Tepezza causes, is linked to, and is associated with permanent hearing loss and/or tinnitus.

87. At all relevant times, Defendant failed to adequately warn or instruct patients, the medical community, or prescribers in the United States that patients receiving Tepezza should undergo regular audiological testing to detect hearing loss.

88. At all relevant times, the labeling for Tepezza failed to provide adequate warnings and instructions, failed to caution that patients should be closely monitored, and failed to adequately inform patients and physicians that permanent hearing loss and/or tinnitus is associated with Tepezza use.

89. At all relevant times, Defendant also failed to alert patients of the need for audiological monitoring while receiving Tepezza and whether risks for hearing-related injuries increase with higher doses or longer durations.

90. Other mediations affecting hearing have included instructions and warnings for users and prescribers. For example, the chemotherapeutic drug cisplatin is likewise associated with ototoxicity. In the labeling for cisplatin, the manufacturer provides the following warning:

> Cisplatin for injection can cause ototoxicity, which is cumulative and may be severe. Consider audiometric and vestibular function monitoring.
>
> Ototoxicity is manifested by tinnitus, hearing loss in the high frequency range (4,000 to 8,000 Hz) and/or decreased ability to hear normal conversational tones. Ototoxicity can occur during or after treatment and can be unilateral or bilateral. Deafness after the initial dose of cisplatin for injection has been reported. Vestibular toxicity has also been reported.
>
> Ototoxic effects can be more severe and detrimental in pediatric patients, particularly in patients less than 5 years of age. The prevalence of hearing loss in pediatric patients is estimated to be 40-60%. Additional risk factors for ototoxicity include simultaneous cranial irradiation, treatment with other ototoxic drugs and renal impairment. Consider audiometric and vestibular testing in all pediatric patients receiving cisplatin [see Use in Specific Populations (8.4)].
>
> Genetic factors (e.g. variants in the thiopurine S-methyltransferase [TPMT] gene) may also contribute to the cisplatin-induced ototoxicity; although this association has not been consistent across populations and study designs.

91. The American Speech-Language-Hearing Association 2020 guidelines also suggest that baseline audiological monitoring should occur when using ototoxic medications. Specifically, the guidelines state:

> When possible, the baseline record should include (1) an audiologic hearing test focused on your ability to hear very high-pitched sounds; (2) word recognition tests; and (3) other tests. This information can help you and your doctor make any important decisions to stop or change the medication therapy before your hearing is affected.

92. As explained above, the FDA has established reporting categories for post-approval changes to a drug's label. The CBE supplement allows for changes in the labeling of a drug product to reflect newly acquired information without prior approval from the FDA.

93. The CBE process allows for drug manufacturers to change a drug label more quickly than the supplemental new drug application ("sNDA") process based on newly acquired information about the drug.

94. Defendant should have changed the Tepezza label to include warnings and instructions addressing the risk of injury associated with the drug as soon as it had notice of adverse reports relating to the same.

95. By failing to use the FDA's CBE supplement to warn Plaintiff, consumers, and physicians of the risk of permanent hearing loss associated with using Tepezza, Defendant acted in a gross and flagrant character, evincing reckless disregard of the safety and welfare of persons exposed to its dangerous drug.

96. Additionally, by failing to use the FDA's CBE supplement to warn Plaintiff, consumers, and physicians of the risk of permanent hearing loss and/or tinnitus associated with using Tepezza, Defendant showed wantonness, recklessness, or a grossly careless disregard for the public's safety and welfare.

Rather than warn of the dangers of Tepezza, Horizon implemented an aggressive marketing campaign to encourage its use.

97. As noted above, less than 5% of all persons with TED suffer *any* form of vision impairment. In this sense, Tepezza was, and in, a drug in search of a disease given that more than 95% of all users will experience *no benefit* related to vision impairment.

98. As a drug in search of a disease, Horizon launched an aggressive marketing campaign to fuel sales of its blockbuster drug. For example, according to Horizon's 2021 Annual report, "Our comprehensive post-launch commercial strategy for TEPEZZA aims to enable more TED patients to benefit from TEPEZZA. We are doing this by: (i) facilitating continued TEPEZZA uptake in the treatment of TED through continued promotion of TEPEZZA to treating physicians; (ii) continuing to develop the TED market by increasing physician awareness of the disease severity and the urgency to diagnose and treat it, as well as the benefits of treatment with TEPEZZA; (iii) driving accelerated disease identification and time to treatment through our digital and broadcast marketing campaigns; (iv) enhancing the patient journey with our high-touch, patient-centric model as well as support for the patient and site-of-care referral processes; and (v) pursuing more timely access to TEPEZZA for TED patients."

99. Similarly, Horizon's 2021 Annual Report reiterates: "It bears repeating: 2021 was a record-breaking year for Horizon. Full-year 2021 net sales were $3.23 billion, representing year-over-year growth of 47 percent, and our full-year 2021 adjusted EBITDA [earnings before interest, taxes, depreciation, and amortization] was $1.28 billion, representing year-over-year growth of 33 percent. Driving much of this growth was TEPEZZA®, which boasted one of the most successful rare disease

medicine launches in history, and had full-year 2021 net sales of $1.66 billion, representing year-over-year growth of 103 percent."

100. Additionally, in the wake of the global COVID pandemic, Horizon launched an aggressive campaign to convert physician use. On May 14, 2021, PM360 reported the following:

> Within three months of its launch, 95% of target physicians were aware of the brand and more than 65% said they were highly likely to prescribe TEPEZZA. Due to COVID, the team also had to find ways to reach HCPs without an in-person sales force. **The team developed a booth (TEPEZZAexperience.com) for virtual medical congresses that allows visitors to take a quiz about TED, tour the TEPEZZA data, hear real patient stories, and connect with a Horizon representative.** In just the month of November, the booth received over 2,800 visits and over 550 unique HCP engagements.
>
> As TEPEZZA is an infusion medication and the core prescriber base did not have infusion experience, a new field team was also developed to build a site of care network. The marketing team developed customized materials for the infusion center clinical and administrative staff to support rapid uptake at launch.

See https://www.pm360online.com/elite-2021-marketing-team-tepezza-marketing-team/ (last visited November 16, 2022) (emphasis in original). On information and belief, this aggressive marketing campaign drove, in part, the astonishing Tepezza sales that followed.

101. But that was not all. At the same time, Horizon launched a massive direct-to-consumer campaign whose sole purpose was to build brand awareness and promote sales. Specifically, PM360 reported:

> On the patient front, the team launched a DTC campaign that spotlighted the extremely challenging symptoms of TED that cannot be ignored. Within a month, TEPEZZA achieved 82% aided awareness among patients, an increase of 68% prior to the campaign. Combined communication efforts also drove 157K unique visitors to TreatTED.com, a page created for the TEPEZZA.com website.

Id. On information and belief, the direct-to-consumer campaign included the development of websites masquerading as support groups for persons suffering from TED, promotion of the drug on Graves' disease websites, the creation of "more than 1,000 infusion centers," and a massive unbranded and branded televised direct-to-consumer advertisement campaign. *See generally* *https://www.fiercepharma.com/marketing/horizon-uses-eye-catching-animation-for-ted-ads* (last accessed November 16, 2022).

102. At the time of approval, a spokesperson for the company said teprotumumab would cost $14,900 per vial, with full treatment over six months consisting of approximately 23 vials, and that the wholesale acquisition cost for that amount is $343,000, with an annual net realized price of $200,000. As a result, the cost of a course of treatment of Tepezza is hundreds of thousands of dollars per patient.

103. As a direct result of these efforts, annual sales of Tepezza soared. According to Horizon's April 28, 2022 Proxy Statement, the company's "excellence in commercial execution" continued for this dangerous drug, evidenced by "more than doubl[ing] the full-year net sales of TEPEZZA … to $1.7 billion in its second year post-launch, representing impressive growth of 103 percent."

104. In that 2022 Proxy Statement, Horizon continued to tout its "initiatives to drive increased awareness of TEPEZZA and TED…" and reported that it has "generated cumulative net sales of $2.5 billion, despite the negative impact of the

COVID-19 pandemic, representing exceptional value creation for our shareholders" and sees "opportunities for continued growth for TEPEZZA, projecting peak global annual net sales of more than $3.5 billion."

105. On March 1, 2023, Horizon issued a press release touting its 2022 results including "Record Net Sales of $3.63 Billion." *See* Form 8-K for Horizon Therapeutics (available at https://ir.horizontherapeutics.com/static-files/77b26fd6-263d-4d52-b74f-05b143d39c02) (last accessed Mar. 13, 2023). Horizon reported that this represented a year-over-year increase of 12%. *Id*. Horizon also reported that its record-breaking sales for 2022 included "Record TEPEZA Net Sales of $1.97 Billion" and that this represented a year-over-year increase of 18%. *Id*.

106. In short, Horizon's collective marketing efforts worked, resulting in nearly $6 billion in sales in less than three years (for a drug supposedly designed to treat a "rare" disease).

Defendant had a duty to protect American consumers, but failed to fulfill it.

107. At all relevant times, Defendant had a duty to craft an adequate label with respect to Tepezza.

108. At all relevant times, Defendant had a duty to ensure that the warnings in the Tepezza label were adequate—at all times—for as long as the drug remained available for sale in the United States.

109. At all relevant times, Defendant had a responsibility to conduct post-marketing surveillance and to continue to study the safety and efficacy of Tepezza, after the Tepezza BLA was approved, for as long as the drug remained available for sale in the United States.

110. At all relevant times, Defendant had a duty to revise the Tepezza label to include a warning regarding the risk of serious and permanent hearing-related

injuries as soon as there was reasonable evidence of a causal association between such injuries and Tepezza use.

111. On information and belief, despite understanding Tepezza could cause hearing-related injuries, Defendant knowingly withheld and/or misrepresented information required to be submitted under FDA BLA regulations concerning the safety and efficacy of Tepezza, including, but not limited to, raw data sets, documents, data analyses, and/or other information related to the risk of Tepezza users suffering hearing-related injuries as a result of their Tepezza use. Such information was material and relevant to the risk of patients, like Plaintiff, developing serious hearing-related injuries as a result of taking Tepezza.

112. In a recent SEC filing, Defendant acknowledged its awareness of the true hearing-related consequences of Tepezza. *See* Horizon Therapeutics Form 10-K, p. 75 (submitted March 1, 2023) ("[A] recent analysis of safety data as part of our ongoing pharmacovigilance program indicated a signal of hearing impairment events of greater severity, in limited cases, then those observed in the TEPEZZA pivotal clinical trials.") (available at https://ir.horizontherapeutics.com/static-files/ecd55c43-52e4-4fca-b907-3c2bd81ad985) (last accessed March 13, 2023). Yet still Horizon has not warned the public or prescribing physicians of the true risks of using this drug.

How Horizon's misconduct endangered American consumers

113. On information and belief, had Defendant exercised reasonable care in testing and studying Tepezza, it would have discovered—prior to seeking FDA approval—that Tepezza use can cause serious and irreversible hearing loss and/or tinnitus.

114. On information and belief, despite post-approval adverse-event reports and other clinical evidence, Defendant failed to continue to test and study the safety and efficacy of Tepezza.

115. On information and belief, from the date Defendant received FDA approval to market Tepezza in the United States, Defendant made, distributed, marketed, and sold Tepezza without adequate warning to Plaintiff's prescribing physicians or Plaintiff that Tepezza was associated with and/or could cause serious hearing loss in patients who used it, and that Defendant had not adequately conducted complete and proper testing and studies of Tepezza with regard to hearing loss and/or tinnitus, including as to duration.

116. On information and belief, Defendant concealed and/or failed to completely disclose its knowledge that Tepezza was associated with and/or could cause hearing loss and/or tinnitus, including as to duration, as well as its knowledge that it had failed to fully test or study said risk.

117. On information and belief, Defendant ignored the association between the use of Tepezza and the risk of developing permanent hearing loss, including, but not limited to, hearing loss and tinnitus.

118. On information and belief, Defendant failed to warn Plaintiff and Plaintiff's healthcare providers regarding true risk of hearing damage of Tepezza, but similar efficacy compared to other products and/or treatment options.

119. On information and belief, Defendant failed to provide adequate instructions to healthcare professionals and patients in the United States regarding how to safely monitor and identify signs of potentially serious audiological complications associated with Tepezza infusions.

120. On information and belief, Defendant failed to warn healthcare professionals and patients in the United States, including Plaintiff's prescribing physicians and Plaintiff, regarding how to safely monitor and identify signs of potentially serious hearing complications associated with Tepezza infusions.

121. On information and belief, Defendant failed to warn and/or to provide adequate instructions to healthcare professionals and patients in the United States, including Plaintiff's prescribing physicians and Plaintiff, regarding how to safely stop receiving Tepezza when potentially serious hearing complications developed while using Tepezza.

122. On information and belief, Defendant failed to warn healthcare professionals and patients in the United States, including Plaintiff's prescribing physicians and Plaintiff, of the *true* risk of auditory damage to patients receiving Tepezza as compared to other similarly efficacious pharmaceutical products or treatment options.

123. Defendant's failures to provide adequate instructions and/or disclose information—which Defendant possessed regarding the failure to adequately test and study Tepezza for the risk of serious hearing complications—further, rendered the Tepezza Package Insert, and other educational and/or promotional materials, inadequate.

124. Despite adverse-event reports from healthcare professionals and consumers around the world, Defendant never adequately warned of the risk of serious and irreversible hearing loss, including, but not limited to, hearing loss and tinnitus, associated with using Tepezza.

125. Rather than warning the public and the medical community about the permanent hearing-related consequences of Tepezza, Defendant significantly expanded the size of its Tepezza sales force in the second half of 2022. Horizon Therapeutics Form 10-K, p. 48 (submitted March 1, 2023) (available at https://ir.horizontherapeutics.com/static-files/ecd55c43-52e4-4fca-b907-3c2bd81ad985) (last accessed March 13, 2023).

126. Rather than warning the public and the medical community about the permanent hearing-related consequences of Tepezza, Defendant continues to invest significantly in direct-to-consumer advertising based on the returns it has seen to date. *Id*.

Equitable tolling of statutes of limitations

127. Defendant willfully, wantonly, and intentionally conspired, and acted in concert, to withhold information from Plaintiff, Plaintiff's healthcare providers, and the general public concerning the known hazards associated with the use of Tepezza.

128. Defendant willfully, wantonly, and intentionally conspired, and acted in concert, to withhold safety-related warnings from Plaintiff, Plaintiff's healthcare providers, and the general public concerning the known hazards associated with the use of Tepezza.

129. Defendant willfully, wantonly, and intentionally conspired, and acted in concert, to withhold instructions from Plaintiff, Plaintiff's healthcare providers, and the general public concerning how to identify, mitigate, and/or treat known hazards associated with the use of Tepezza.

130. Defendant willfully, wantonly, and intentionally conspired, and acted in concert, to ignore relevant safety concerns and to deliberately *not* study the safety and efficacy of Tepezza.

131. Defendant failed to disclose a known risk and, instead, affirmatively misrepresented that Tepezza was safe for its intended use. Defendant disseminated labeling, marketing, promotion, and/or sales information to Plaintiff, Plaintiff's healthcare providers, and the general public regarding the safety of Tepezza knowing such information was false, misleading, and/or inadequate to warn of the safety risks associated with Tepezza use. Defendant did so willfully, wantonly, and with the

intent to prevent the dissemination of information known to it concerning Tepezza's safety.

132. Further, Defendant actively concealed the true risks associated with the use of Tepezza, particularly as they relate to the risk of serious hearing-related injuries, by affirmatively representing in numerous communications that there were no hearing-loss warnings required to safely prescribe and take Tepezza and no permanent hearing-related adverse side effects associated with use of Tepezza. These communications were disseminated to Plaintiff, Plaintiff's healthcare providers, and the general public and included, without limitation, the Package Insert.

133. Due to the absence of any warning by Defendant as to the significant permanent health and safety risks posed by Tepezza, Plaintiff was unaware that Tepezza could cause serious and permanent hearing-related injuries, as this danger was not known to Plaintiff, Plaintiff's healthcare providers, or the general public.

134. Due to the absence of any instructions for how to identify and/or monitor Tepezza patients for potential hearing-related complications, Plaintiff was unaware that Tepezza could cause serious and permanent hearing-related injuries, as this danger was not known to Plaintiff, Plaintiff's healthcare providers, or the general public.

135. Given Defendant's conduct and deliberate actions designed to deceive Plaintiff, Plaintiff's healthcare providers, and the general public with respect to the safety and efficacy of Tepezza, Defendant is estopped from relying on any statute-of-limitations defenses.

CLAIM 1: STRICT LIABILITY FAILURE TO WARN

136. Plaintiff incorporates all prior allegations.

137. At all relevant times, Defendant engaged in the business of researching, testing, developing, manufacturing, labeling, marketing, selling, inspecting, handling, storing, distributing, and/or promoting Tepezza and placed it into the stream of commerce in a defective and unreasonably dangerous condition. These actions were under the ultimate control and supervision of Defendant.

138. Defendant, as a manufacturer and distributer of pharmaceutical drugs, is held to the level of knowledge of an expert in the field, and further, Defendant knew or should have known that warnings and other clinically relevant information and data that it distributed regarding the risks associated with the use of Tepezza were inadequate.

139. Plaintiff did not have the same knowledge as Defendant, and no adequate warning or other clinically relevant information and data was communicated to Plaintiff or to Plaintiff's treating physicians.

140. Defendant had a duty to provide adequate warnings and instructions for Tepezza, to use reasonable care to design a product that is not unreasonably dangerous to users, and to adequately understand, test, and monitor its product.

141. Defendant had a continuing duty to provide consumers, including Plaintiff and Plaintiff's physicians, with warnings and other clinically relevant information and data regarding the risks and dangers associated with Tepezza as it became or could have become available to Defendant.

142. Defendant marketed, promoted, distributed, and sold an unreasonably dangerous and defective prescription drug, Tepezza, to health care providers empowered to prescribe and dispense Tepezza to consumers, including Plaintiff, without adequate warnings and other clinically relevant information and data.

Through both omission and affirmative misstatements, Defendant misled the medical community about the risk and benefit balance of Tepezza, which resulted in injury to Plaintiff.

143. Defendant knew or should have known through testing, scientific knowledge, advances in the field, published research in major peer-reviewed journals, and its own post-marketing studies, that Tepezza created a risk of serious and potentially irreversible hearing issues, and/or could interfere with normal hearing.

144. Despite the fact that Defendant knew or should have known that Tepezza caused unreasonable and dangerous side effects, it continued to promote and market Tepezza without stating that there existed safer and more or equally effective alternative drug products and/or providing adequate clinically relevant information and data.

145. Defendant knew or should have known that consumers, Plaintiff specifically, would foreseeably and needlessly suffer injury as a result of Defendant's failures.

146. The Tepezza supplied to Plaintiff by Defendant was defective, unreasonably dangerous, and had inadequate warnings or instructions at the time it was sold, and Defendant also acquired additional knowledge and information confirming the defective and unreasonably dangerous nature of Tepezza. Despite this knowledge and information, Defendant failed and neglected to issue adequate warnings that Tepezza causes serious and potentially irreversible hearing issues and/or instructions concerning the need for audiological monitoring and potential discontinuation of use of Tepezza.

147. Defendant's failure to provide adequate warnings or instructions rendered Tepezza unreasonably dangerous in that it failed to perform as safely as an ordinary patient, prescriber, and/or other consumer would expect when used as intended

and/or in a manner reasonably foreseeable by Defendant, and in that the risk of danger outweighs the benefits.

148. Defendant failed to provide timely and adequate warnings to physicians and consumers, including Plaintiff and to Plaintiff's intermediary physicians, in the following ways:

a. Defendant failed to include adequate warnings and/or provide adequate clinically relevant information and data that would alert Plaintiff and Plaintiff's physicians to the dangerous risks of Tepezza including, among other things, potentially irreversible hearing issues;

b. Defendant failed to provide adequate post-marketing warnings and instructions after Defendant knew or should have known of the significant risks of, among other things, potentially irreversible hearing issues; and

c. Defendant continued to aggressively promote and sell Tepezza, even after it knew or should have known of the unreasonable risks of potentially irreversible hearing issues from the drug.

149. Defendant had an obligation to provide Plaintiff and Plaintiff's physicians with adequate clinically relevant information and data and warnings regarding the adverse health risks associated with exposure to Tepezza, and/or that there existed safer and more or equally effective alternative drug products.

150. By failing to provide Plaintiff and Plaintiff's physicians with adequate clinically relevant information, data, and warnings regarding the adverse health risks associated with exposure to Tepezza, and/or that there existed safer and more or equally effective alternative drug products, Defendant breached its duty of reasonable care and safety.

151. By failing to adequately test and research harms associated with Tepezza, and by failing to provide appropriate warnings and instructions about Tepezza use, patients and the medical community—including Plaintiff and Plaintiff's prescribing doctors—were inadequately informed about the true risk-benefit profile of Tepezza and were not sufficiently aware that serious and potentially irreversible hearing issues might be associated with use of Tepezza. Nor were the medical community, patients, patients' families, or regulators appropriately informed that serious and potentially irreversible hearing issues might be a side effect of Tepezza and should or could be reported as an adverse event.

152. The Tepezza designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendant was defective due to inadequate post-marketing surveillance and/or warnings because, even after Defendant knew or should have known of the risks and severe and permanent hearing injuries from receiving Tepezza, it failed to provide adequate warnings to users or consumers of the product and continued to improperly advertise, market and/or promote Tepezza.

153. Tepezza is defective and unreasonably dangerous to Plaintiff and other consumers regardless of whether Defendant had exercised all possible care in its preparation and sale.

154. The foreseeable risk of serious and potentially irreversible hearing issues caused by Tepezza could have been reduced or avoided by Plaintiff, prescribers, and/or other consumers if Defendant had provided reasonable instructions or warnings of these foreseeable risks of harm.

155. Defendant's actions described above were performed willfully, intentionally, and with reckless disregard of the health and safety of Plaintiff and the general public.

156. As a direct and proximate result of Defendant's conduct, including the inadequate warnings, dilution or lack of information, lack of adequate testing and research, and the defective and dangerous nature of Tepezza, Plaintiff suffered bodily injury and resulting pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expense of medical and nursing care and treatment, loss of earnings, loss of ability to earn money and other economic losses, and aggravation of previously existing conditions. The losses are either permanent or continuing, and Plaintiff will suffer the losses in the future.

CLAIM 2: NEGLIGENT FAILURE TO WARN

157. Plaintiff incorporates all prior allegations.

158. At all relevant times, Defendant had a duty to exercise reasonable care and had the duty of an expert in all aspects of the warning and post-sale warning to assure the safety of Tepezza when used as intended or in a way that Defendant could reasonably have anticipated, and to assure that the consuming public, including Plaintiff and Plaintiff's physicians, obtained accurate information and adequate instructions for the safe use or non-use of Tepezza.

159. Defendant's duty of care was that a reasonably careful designer, manufacturer, seller, importer, distributor, and/or supplier would use under like circumstances.

160. Defendant had a duty to warn Plaintiff, Plaintiff's physicians, and consumers of Tepezza's dangers and serious side effects, including serious and potentially irreversible hearing loss and other clinically relevant information, as it was reasonably foreseeable to Defendant that Tepezza could cause such injuries.

161. At all relevant times, Defendant failed to exercise reasonable care and knew, or in the exercise of reasonable care should have known, that Tepezza had inadequate instructions and/or warnings.

162. Defendant's actions and omissions were negligent and careless, resulting in a breach of the duties set forth above. These acts and omissions include, but are not limited to:

a. Failing to accompany its product with proper and adequate warnings, labeling, or instructions concerning the potentially dangerous, defective, unsafe, and deleterious propensity of Tepezza and of the risks associated with its use, including the severity and potentially irreversible nature of such adverse effects;

b. Disseminating information to Plaintiff and Plaintiff's physicians that was negligently and materially inaccurate, misleading, false, and unreasonably dangerous to patients such as Plaintiff;

c. Failing to provide warnings or other information that accurately reflected the symptoms, scope, severity, and permanence of the side effects and health risks;

d. Failure to accompany its product with proper or adequate rate of incidence or prevalence of hearing-related injuries;

e. Failing to adequately test and/or warn about the use of Tepezza, including, without limitations, the possible adverse side effects and health risks caused by using Tepezza;

f. Failure to adequately warn of the risks that Tepezza could interfere with the normal health and hearing;

g. Failure to adequately warn of the risk of serious and potentially irreversible hearing loss;

h. Failure to adequately warn and advise of adverse reactions involving hearing, tinnitus, and other audiologic symptoms;

i. Failure to instruct patients, prescribers, and consumers of the need for audiological monitoring when receiving Tepezza;

j. Failing to provide instructions on ways to safely use Tepezza to avoid injury;

k. Failing to explain the mechanism, mode, and types of adverse events associated with Tepezza;

l. Failing to provide adequate training or information to medical care providers for appropriate use of Tepezza and patients receiving Tepezza;

m. Failing to provide patients and/or physicians with adequate clinically relevant information, data, and warnings regarding the adverse health risks associated with exposure to Tepezza, as it became or could have become known to Defendant;

n. Failing to advise patients and/or physicians that there existed safer and more or equally effective alternative products or treatment options that do not carry the risks posed by Tepezza; and

o. Representing to physicians, including but not limited to Plaintiff's prescribing physicians, that this drug was safe and effective for use.

163. Tepezza was defective and unreasonably dangerous when it left the possession of Defendant in that it contained warnings insufficient to alert patients and prescribing physicians of the dangerous risks associated with Tepezza, including but not limited to the risk of serious and potentially irreversible hearing loss and tinnitus despite Defendant's knowledge of the risk of these injuries over other TED therapies available.

164. Tepezza was defective due to inadequate post-marketing warnings and instruction because Defendant knew or should have known of the risk and danger of

serious bodily harm from the use of Tepezza but failed to provide adequate warning to patients and prescribing physicians of the product, including Plaintiff and Plaintiff's prescribing physician, knowing the product could cause serious injury.

165. Plaintiff was prescribed and used Tepezza for its intended purpose.

166. Plaintiff could not have known about the dangers and hazards presented by Tepezza.

167. The warnings given by Defendant were not accurate, clear, or complete and/or were ambiguous.

168. The warnings, or lack thereof, that were given by Defendant failed to properly warn prescribing physicians, including Plaintiff's prescribing physician, of the risk of serious and potentially irreversible hearing loss and tinnitus, and failed to instruct prescribing physicians to test and monitor for the presence of the injuries for which Plaintiff and others had been placed at risk by using Tepezza.

169. The warnings that were given by Defendant failed to properly warn Plaintiff and prescribing physicians of the prevalence of permanent hearing loss.

170. Plaintiff and Plaintiff's prescribing physicians reasonably relied upon the skill, superior knowledge, and judgment of Defendant. Defendant had a continuing duty to warn Plaintiff and prescribing physicians of the dangers associated with Tepezza. Had Plaintiff received adequate warnings regarding the risks of Tepezza, Plaintiff would not have used Tepezza. But Defendant failed to communicate adequate warnings and/or instruction for use of Tepezza.

171. Defendant's failure to exercise reasonable care in the design, dosing information, marketing, warnings, and/or manufacturing of Tepezza was a proximate cause of Plaintiff's injuries and damages, which were foreseeable.

172. Plaintiff's injuries and damages are severe and permanent and will continue into the future. As a result, Plaintiff seeks actual and punitive damages from Defendant.

173. As a direct and proximate result of Defendant's negligence, Plaintiff suffered bodily injury and resulting pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expense of medical and nursing care and treatment, loss of earnings, loss of ability to earn money and other economic losses, and aggravation of previously existing conditions. The losses are either permanent or continuing, and Plaintiff will suffer the losses in the future.

CLAIM 3: STRICT LIABILITY DESIGN DEFECT

174. Plaintiff incorporates all prior allegations.

175. At all relevant times, Defendant engaged in the business of researching, testing, developing, manufacturing, labeling, marketing, selling, inspecting, handling, storing, distributing, and/or promoting Tepezza, and placed it into the stream of commerce in a defective and unreasonably dangerous condition. These actions were under the ultimate control and supervision of Defendant.

176. Defendant, as a manufacturer, designer, distributer, marketer, and promoter of pharmaceutical drugs, had a duty to design a product free from a defective condition that was unreasonably dangerous to Plaintiff.

177. Defendant breached this duty by designing Tepezza in such a way that posed an unreasonable risk of permanent hearing injuries and by placing and keeping Tepezza on the market despite Tepezza's defective condition.

178. Defendant had a duty to create a product that was not unreasonably dangerous for its normal, intended, and foreseeable use. Defendant knew or should have known that Tepezza, which it developed, manufactured, labeled, marketed,

sold, and/or promoted, was defectively designed in that it posed a serious risk of severe and permanent hearing injuries.

179. Defendant had a continuing duty to use reasonable care to design a product that is not unreasonably dangerous to users and to adequately understand, test, and monitor its product.

180. Defendant breached that duty when it created a product unreasonably dangerous for its intended and foreseeable use.

181. Defendant designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed a defective product that created an unreasonable risk to the health of consumers, and Defendant is therefore strictly liable for the injuries sustained by Plaintiff.

182. The Tepezza supplied to Plaintiff by Defendant was defective in design or formulation because, when it left the hands of the manufacturer or supplier, it was in an unreasonably dangerous and defective condition because it failed to perform as safely as an ordinary consumer would expect when used as intended or in a manner reasonably foreseeable to Defendant, posing a risk of serious and potentially irreversible hearing damage to Plaintiff and other consumers.

183. The Tepezza administered to Plaintiff was expected to, and did, reach Plaintiff without substantial change in the condition in which it is sold.

184. The Tepezza administered to Plaintiff was in a condition not contemplated by Plaintiff in that it was unreasonably dangerous, posing a serious risk of permanent hearing damage.

185. Tepezza is a medication prescribed primarily for TED.

186. Tepezza causes serious and potentially irreversible hearing issues, and/or could interfere with normal health and hearing, thus harming Plaintiff and other consumers.

187. Plaintiff, ordinary consumers, and prescribers would not expect a TED drug designed, marketed, and labeled for eye disease treatment to cause irreversible hearing loss.

188. The Tepezza supplied to Plaintiff by Defendant was defective in design or formulation in that, when it left the hands of the manufacturer or supplier, it had not been adequately tested, was in an unreasonably dangerous and defective condition, and posed a risk of serious and potentially irreversible hearing issues to Plaintiff and other consumers.

189. The Tepezza supplied to Plaintiff by Defendant was defective in design or formulation in that its limited and unproven effectiveness and low efficacy did not outweigh the risks of serious and potentially irreversible hearing issues posed by the drug. Balancing the limited utility and high risk of the drug's use, the design of the Tepezza drug makes the product unreasonably dangerous.

190. The design defects render Tepezza more dangerous than other drugs and therapies designed to treat TED and causes an unreasonable increased risk of injury, including but not limited to potentially irreversible hearing loss.

191. Defendant knew or should have known through testing, scientific knowledge, advances in the field, published research in major peer-reviewed journals, its own post-marketing studies, or otherwise, that Tepezza created a risk of serious and potentially irreversible hearing loss and/or could interfere with normal health and hearing.

192. Tepezza is defective and unreasonably dangerous to Plaintiff and other consumers in that, despite early indications and concerns that Tepezza use could result in permanent hearing damage, Defendant failed to adequately test or study the drug, including but not limited to: pharmacokinetics and pharmacodynamics of the drug, its effects on hearing, the potential effects and risks of long-term use, the

potential for inter-patient variability, and/or the potential for a safer effective dosing regimen.

193. Defendant knew or should have known that consumers, and Plaintiff specifically, would foreseeably and needlessly suffer injury as a result of Tepezza's defective design.

194. Tepezza is defective and unreasonably dangerous to Plaintiff and other consumers even if Defendant had exercised all possible care in the preparation and sale of Tepezza.

195. Defendant's actions described above were performed willfully, intentionally, and with reckless disregard of the life and safety of Plaintiff and the general public.

196. As a direct and proximate result of Defendant's conduct, including the lack of adequate testing and research and the defective and dangerous nature of Tepezza, Plaintiff suffered bodily injury and resulting pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expense of medical and nursing care and treatment, loss of earnings, loss of ability to earn money and other economic losses, and aggravation of previously existing conditions. The losses are either permanent or continuing, and Plaintiff will suffer the losses in the future.

CLAIM 4: NEGLIGENT DESIGN DEFECT

197. Plaintiff incorporates all prior allegations.

198. At all relevant times, Defendant had a duty to exercise reasonable care and had the duty of an expert in all aspects of the design, formulation, manufacture, compounding, testing, inspection, packaging, labeling, distribution, marketing, promotion, advertising, sale, testing, and research to assure the safety of Tepezza when used as intended or in a way that Defendant could reasonably have anticipated, and to assure that the consuming public, including Plaintiff and

Plaintiff's physicians, obtained accurate information and adequate instructions for the safe use or non-use of Tepezza.

199. At all relevant times, Defendant failed to exercise reasonable care and meet the duties of an expert and knew, or in the exercise of reasonable care should have known, that Tepezza was not properly manufactured, designed, compounded, tested, inspected, packaged, distributed, marketed, advertised, formulated, promoted, examined, maintained, sold, prepared, monitored, or a combination of these acts.

200. Defendant's actions and omissions were negligent and careless, resulting in a breach of the duties set forth above. These acts and omissions include, but are not limited to:

a. Failing to use due care in developing, testing, designing, monitoring, and manufacturing Tepezza so as to avoid the aforementioned risks to individuals when Tepezza was being used for treatment;

b. Failing to conduct adequate pre-clinical and clinical testing and post-marketing surveillance to determine the safety of Tepezza;

c. Failing to adequately test or study Tepezza, including but not limited to pharmacokinetics and pharmacodynamics of the drug, its effects on hearing, the potential effects of long-term use, the potential for inter-patient variability, and/or the potential for a safer effective dosing regimen;

d. Failing to independently and vigilantly protect against unreasonable health risks posed by Tepezza;

e. Promoting, advertising, marketing, and selling Tepezza without advising that there existed safer and more or equally effective alternative drug products or treatment options; and

f. Designing, manufacturing, and placing into the stream of commerce a product that was unreasonably dangerous for its reasonably foreseeable use, which Defendant knew or should have known could cause injury to Plaintiff.

201. Defendant's negligence and Tepezza's failures arise under circumstances precluding any other reasonable inference other than a defect in Tepezza.

202. Defendant's failure to exercise reasonable care in the design, dosing information, marketing, warnings, and/or manufacturing of Tepezza was a proximate cause of Plaintiff's injuries and damages, which were foreseeable.

203. Plaintiff's injuries and damages are severe and permanent and will continue into the future. As a result, Plaintiff seeks actual and punitive damages from Defendant.

204. As a direct and proximate result of Defendant's negligence, Plaintiff suffered bodily injury with resulting pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expense of medical and nursing care and treatment, loss of earnings, loss of ability to earn money and other economic losses, and aggravation of previously existing conditions. The losses are either permanent or continuing, and Plaintiff will suffer losses in the future.

CLAIM 5: PUNITIVE DAMAGES

205. Plaintiff incorporates all prior allegations.

206. Defendant's acts and omissions constituted oppression, fraud, malice, and/or recklessness and were done with advance knowledge, conscious disregard of the safety of others, and/or ratification by Defendant's officers, directors, and/or managing agents.

207. Defendant's actions amounted to actual malice or reckless indifference to the likelihood of harm associated with its acts and omissions.

208. Defendant misled both the medical community and the public, including Plaintiff and Plaintiff's physicians, by making false, misleading, or incomplete representations about the safety and effectiveness of Tepezza and by failing to provide adequate instructions and training concerning its use.

209. Defendant marketed, promoted, distributed, and sold an unreasonably dangerous and defective prescription drug to healthcare providers empowered to prescribe and dispense Tepezza to consumers, including Plaintiff, without adequate warnings and other clinically relevant information and data and misled the medical community about the need for and the risk-benefit balance of Tepezza, which resulted in injury to Plaintiff.

210. Defendant downplayed, understated, and/or disregarded its knowledge of the serious and permanent side effects and risks associated with the use of Tepezza despite available information demonstrating that drug could interfere with normal health and hearing and cause potentially irreversible hearing loss and tinnitus.

211. Defendant were or should have been in possession of evidence demonstrating that Tepezza use could interfere with the normal health and hearing, cause irreversible damage to hearing, and cause tinnitus. Nevertheless, Defendant continued to market Tepezza by providing false and misleading information regarding its safety and effectiveness.

212. Defendant failed to provide warnings that would have dissuaded health care professionals from using Tepezza, thus preventing health care professionals, including Plaintiff's prescribing physician, and consumers, including Plaintiff, from weighing the true risks against the benefits of using Tepezza.

213. Defendant knew or should have known that consumers, and Plaintiff specifically, would foreseeably and needlessly suffer injury as a result of Tepezza's negligent failure to warn, negligent design, and/or negligent marketing, and

consciously, deliberately and callously disregarded that knowledge in favor of maximizing sales and profits.

214. As a direct and proximate result of Defendant's acts and omissions, Plaintiff suffers from hearing loss and other auditory symptoms caused by Plaintiff receiving Tepezza.

215. As a result of Plaintiff's injuries, Plaintiff has endured substantial pain and suffering, has incurred significant expenses for medical care, and will remain economically challenged and emotionally harmed.

216. Plaintiff has suffered and will continue to suffer economic loss and emotional harm.

217. Defendant's actions were performed willfully, intentionally, and with reckless disregard for the rights of Plaintiff and the public.

218. Plaintiff's injuries and damages are severe, permanent, and will continue into the future. As a result, Plaintiff seeks actual and punitive damages from Defendant.

219. Defendant's conduct was committed with knowing, conscious, deliberate, or reckless disregard for the rights and safety of consumers, including Plaintiff, thereby entitling Plaintiff to punitive damages in an amount appropriate to punish the Defendant and deter it from similar conduct in the future.

220. Consequently, Defendant is liable for punitive damages in an amount to be determined by the jury:

PRAYER FOR RELIEF

Plaintiff respectfully prays for the following relief:

a. Enter judgment in Plaintiff's favor on each claim;

b. Award Plaintiff compensatory damages for each of the following categories of harm:

i. Medical expenses (both to purchase Tepezza and resulting from its use);

ii. Pain and suffering;

iii. Mental anguish, anxiety, and discomfort;

iv. Physical impairment; and

v. Loss of enjoyment of life;

c. Award Plaintiff pre- and post-judgment interest;

d. Award exemplary and punitive damages;

e. Award reasonable and necessary attorneys' fees, costs, and expenses, of suit along with pre-judgment interest on those sums; and

f. Award such other relief to which Plaintiff may be justly entitled.

JURY DEMAND

Plaintiff demands a trial by jury.

Dated: March 15, 2023 Respectfully submitted,

/s/ Catherine Cabalo

Catherine Cabalo
PEIFFER WOLF CARR KANE CONWAY & WISE, LLP
4 Embarcadero Center, Suite 1400
San Francisco, California 94111
(415) 766-3544
ccabalo@peifferwolf.com

Ashlie Case Sletvold (*pro hac vice* to be filed)
Marilyn Eble (*pro hac vice* to be filed)
PEIFFER WOLF CARR KANE CONWAY & WISE, LLP
6370 SOM Center Road, Suite 108
Cleveland, Ohio 44139
216-589-9280
asletvold@peifferwolf.com
meble@peifferwolf.com

Attorneys for Plaintiff

JS 44 (Rev. 10/20)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

Geri Kanesta-Rychner

(b) County of Residence of First Listed Plaintiff Pierce County, WA
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Ashlie Case Sletvold and Marilyn K. Eble; Peiffer Wolf Carr Kane Conway & Wise, LLP (216) 589-9280
6370 SOM Center Rd., Suite 108, Cleveland, OH 44139

DEFENDANTS

Horizon Therapeutics USA, Inc.

County of Residence of First Listed Defendant Lake County, IL
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

Eric A. Riegner; Frost Brown Todd LLC, (317) 237-3800
201 North Illinois Street, Suite 1900, Indianapolis, IN 46204

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☒ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☒ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

Click here for: Nature of Suit Code Descriptions.

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
- ☒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 835 Patent - Abbreviated New Drug Application
- ☐ 840 Trademark
- ☐ 880 Defend Trade Secrets Act of 2016

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit (15 USC 1681 or 1692)
- ☐ 485 Telephone Consumer Protection Act
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding | ☐ 2 Removed from State Court | ☐ 3 Remanded from Appellate Court | ☐ 4 Reinstated or Reopened | ☐ 5 Transferred from Another District *(specify)* | ☐ 6 Multidistrict Litigation - Transfer | ☐ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
28 USC 1332

Brief description of cause:
Diversity - Product Liability Action re Tepezza

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER _____

DATE
3/15/2023

SIGNATURE OF ATTORNEY OF RECORD
/s/ Catherine Cabalo

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I.(a) Plaintiffs-Defendants. Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) County of Residence. For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) Attorneys. Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. Jurisdiction. The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below**; NOTE: federal question actions take precedence over diversity cases.**)

III. Residence (citizenship) of Principal Parties. This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. Nature of Suit. Place an "X" in the appropriate box. If there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: Nature of Suit Code Descriptions.

V. Origin. Place an "X" in one of the seven boxes.
Original Proceedings. (1) Cases which originate in the United States district courts.
Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441.
Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
Multidistrict Litigation – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407.
Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket.
PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7. Origin Code 7 was used for historical records and is no longer relevant due to changes in statue.

VI. Cause of Action. Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service.

VII. Requested in Complaint. Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. Related Cases. This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Western District of Washington

Geri Kanesta-Rychner

Plaintiff(s)

v.

Horizon Therapeutics USA, Inc.

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Horizon Therapeutics USA, Inc.
c/o Eric Anthony Riegner
Frost Brown Todd LLC
201 North Illinois Street, Suite 1900
Indianapolis, IN 46204

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Ashlie Case Sletvold
Jessica S. Savoie
Marilyn K. Eble
Peiffer Wolf Carr Kane Conway & Wise, LLP
6370 SOM Center Rd., Suite 108
Cleveland, OH 44139

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

Print