BEFORE THE UNITED STATES JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

IN RE: TEPEZZA MARKETING, SALES PRACTICES, AND PRODUCTS LIABILITY LITIGATION	**MDL No. 3079**

DEFENDANT HORIZON THERAPEUTICS USA, INC.'S RESPONSE IN OPPOSITION TO PLAINTIFF'S MOTION FOR TRANSFER AND COORDINATION OR CONSOLIDATION UNDER 28 U.S.C. § 1407

Defendant Horizon Therapeutics USA Inc. ("Horizon") submits this response in opposition to the Motion for Transfer and Coordination or Consolidation Under 28 U.S.C. § 1407 ("Transfer Motion") filed by Plaintiff Kimberly Exton ("Movant"). The Panel should deny Movant's Transfer Motion because Movant has failed to satisfy her heavy burden of demonstrating that centralization would promote the just and efficient conduct of these proceedings.

INTRODUCTION

On January 21, 2020, the U.S. Food and Drug Administration approved TEPEZZA®, a prescription biologic, as a safe and effective treatment for adults with Thyroid Eye Disease, a rare condition where the muscles and fatty tissues behind the eye become inflamed, causing the eyes to be pushed forward and bulge outwards (proptosis). TEPEZZA® is the first and only FDA-approved treatment for Thyroid Eye Disease.

The lawsuits that are the subject of Movant's motion involve allegations that the plaintiffs developed permanent hearing loss and/or tinnitus after receiving TEPEZZA® infusions. TEPEZZA®'s FDA-approved labeling disclosed hearing impairment, including deafness, among the most common adverse reactions, occurring in 10% of patients participating

in clinical trials. Nevertheless, Plaintiffs allege that Horizon did not adequately warn of the risk of hearing loss associated with the use of TEPEZZA® and claim that TEPEZZA® was defectively designed.

Transfer and coordination or consolidation is unwarranted here because Movant has failed to make a particularized showing that centralization—which the Panel has described as the "last solution"—is needed. *In re Covidien Hernia Mesh Prods. Liab. Litig.*, 481 F. Supp. 3d 1348, 1349 (J.P.M.L. 2020).

First, formal centralization is inappropriate because the Transfer Motion involves only nineteen claimants[1] (half of whom are represented by the same counsel), and a single defendant represented by one law firm. And unlike many drugs involved in multi-district litigation, the number of patients treated with TEPEZZA® is limited by the fact that it is an Orphan Drug used for treatment of a rare disease and approved by the FDA just over three years ago. Thus, the number of potential plaintiffs is limited.

Second, Movant has made no showing of duplicative discovery or inconsistent pretrial rulings necessitating centralization under Section 1407. To the contrary, given the small number of actions and counsel—nineteen claims spread across five jurisdictions—the parties have already been successfully engaging in formal coordination and voluntary cooperation. Currently pending before the Northern District of Illinois is a Motion to Relate and Reassign Cases Under Local Rule 40.4, which implicates fifteen plaintiffs. Horizon opposed the motion to reassign, in part, because no Plaintiff has a viable product liability claim related to TEPEZZA® and because the cases involve substantially different facts and causation issues that directly impact the claims and defenses, rendering Local Rule 40.4 inapplicable. However, Horizon agreed that

[1] Movant's Schedule of Actions lists eighteen claims, and one "tag along" claim was filed subsequent to the Transfer Motion.

consolidation for the purposes of discovery only would be appropriate under N.D. Ill. IOP 13(e) if the cases proceed past the pending motions to dismiss. (*See* Case No. 22-cv-04518, Dkt. # 34, PageID #: 706).

In the alternative, if the Panel ultimately concludes that centralization is merited, Horizon respectfully submits that the Northern District of Illinois before the Honorable John R. Blakey, is the appropriate transferee venue. The Northern District of Illinois is the location of Horizon's U.S. headquarters and thus the location of many of the witnesses and evidence. It is also the location of the first-filed TEPEZZA® case and where fifteen of the nineteen cases are already pending. Horizon opposes transfer to the Northern District of California because there is no relationship between the parties and that venue, and it is inconvenient for counsel for both sides.

FACTUAL BACKGROUND

A. TEPEZZA®'s Development and Regulatory History

In January 2020, FDA approved TEPEZZA® as the first-ever drug for adults with Thyroid Eye Disease. Thyroid Eye Disease is rare, affecting approximately 0.25% of the population.[2] But for patients suffering from moderate-to-severe Thyroid Eye Disease, it can be incapacitating. Before TEPEZZA®'s approval, the only treatment option for severe Thyroid Eye Disease was surgery, which involves removing bone between the eye socket and the sinuses.

The FDA granted Orphan Drug designation to TEPEZZA® on May 6, 2013. Orphan Drugs treat rare diseases or conditions (those affecting fewer than 200,000 people in the U.S.). These are drugs and treatments that historically received little attention from pharmaceutical companies because the comparatively small demand for treatment provides little motive to

[2] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4655452 (last accessed 4/14/23). *See also* Transfer Motion at p. 2 ("TED and Graves' disease impact[] roughly 15,000 to 20,000 people each year in the United States.").

undertake research and development. *See* 21 U.S.C. § 360bb. The FDA also granted TEPEZZA® Priority Review, in addition to Fast Track and Breakthrough Therapy Designation—both of which expedite the review process for biologics intended to treat a serious condition and preliminarily demonstrate substantial improvement over available therapy.

B. TEPEZZA®'s FDA-approved label warned of the risk of hearing impairment, including deafness.

The FDA ultimately approved TEPEZZA® based on the results of two clinical trials. TEPEZZA®'s label discloses hearing impairment (and, specifically, deafness) as one of the most common adverse reactions observed in patients receiving the treatment. The label reads:

> **----------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 (6.1)[3]

Additionally, the label provides data concerning adverse reactions, including hearing impairment at an incidence of around 10%, documented in the clinical trials:

> **Table 1. Adverse Reactions Occurring in 5% or More of Patients Treated with TEPEZZA® and Greater Incidence than Placebo**

Adverse Reactions	TEPEZZA® N=84 N (%)	Placebo N=86 N (%)
Muscle spasms	21 (25%)	6 (7%)
Nausea	14 (17%)	8 (9%)
Alopecia	11 (13%)	7 (8%)
Diarrhea	10 (12%)	7 (8%)
Fatigue [a]	10 (12%)	6 (7%)
Hyperglycemia [b]	8 (10%)	1 (1%)
Hearing impairment [c]	**8 (10%)**	**0**
Dysgeusia	7 (8%)	0
Headache	7 (8%)	6 (7%)
Dry skin	7 (8%)	0

[3] FDA-Approved labeling for TEPEZZA® attached as Exhibit 2, at p. 8. (emphasis added).

a Fatigue includes asthenia
b Hyperglycemia includes blood glucose increase
c **Hearing impairment (includes deafness, eustachian tube dysfunction, hyperacusis, hypoacusis and autophony)**[4]

Moreover, the FDA Dermatologic and Ophthalmic Drugs Advisory Committee (the "FDA Committee") discussed the risk of hearing loss associated with TEPEZZA® and possible monitoring before FDA approved TEPEZZA® or its label.[5] Indeed, FDA Committee members considered whether to include a recommendation for audiologic testing on TEPEZZA®'s label but decided against it. In reaching this conclusion, the FDA Committee determined that it did not have enough information to make audiologic testing recommendations for TEPEZZA®. Members discussed the lack of information on the mechanism of hearing loss from TEPEZZA®, risk factors for hearing loss with TEPEZZA® use (*e.g.*, pre-existing hearing loss or tinnitus), the association of hearing loss with conditions that TEPEZZA® treats, and lack of data on how to identify and address audiologic symptoms (*e.g.*, a timeline for measuring hearing loss and how to address hearing loss symptoms). Ultimately, the FDA Committee decided to "let the individual patient and physician decide what the appropriate plan is for that patient." [6]

Between August 2022 and April 2023, nineteen Plaintiffs filed claims against Horizon asserting warnings and design defect allegations with respect to TEPEZZA®. The Complaints point to case reports and studies, as well as FDA-mandated adverse event reports as evidence that Horizon should have modified the TEPEZZA® label under the "changes being effected" ("CBE") regulation, 21 C.F.R. § 314.70(e)(6)(iii). Additionally, a few Complaints include

[4] *See* Exhibit 2, FDA-Approved labeling for TEPEZZA®, at p. 12 (emphasis added).

[5] Meeting of the Dermatologic and Ophthalmic Drugs Advisory Committee, at pp. 1-7; 79-81, 122-23, 248-49, 264-272, 295, 298-300 (December 13, 2019) ("FDA Transcript"), available at https://www.fda.gov/media/135336/download (last accessed 4/14/23), relevant portions attached as Exhibit 3).

[6] *See* Exhibit 3, FDA Transcript at 79-81, 122-23, 248-49, 264-272, 295, 298-300.

Horizon's disclosure for current and prospective investors filed in its 10-K on March 1, 2023, which indicated the following:

> [P]ost-marketing studies and pharmacovigilance reporting data have shown similar rates of hearing impairment as compared to the TEPEZZA pivotal clinical trials, which is reflected in the FDA-approved label, there have been third party reports that have purported to show higher rates of hearing impairment. In addition, 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, than those observed in the TEPEZZA pivotal clinical trials. Based on this analysis, we are discussing with the FDA potential updates to the TEPEZZA label to further characterize the range of events reported.[7]
>
> To date, FDA has taken no action with respect to the TEPEZZA® label.

C. Movant's Scheduled Actions and their Allegations

Plaintiff Kimberly Exton alleges that she was prescribed and received TEPEZZA® infusions from August 2021 through February 2022 and subsequently suffered from permanent hearing loss and tinnitus. Complaint at ¶¶ 10-11. Her Complaint alleges claims for Strict Liability – Failure to Warn, Strict Liability – Design Defect, Negligence, and Punitive Damages. The nineteen pending claims identified in the Schedule of Actions make similar products liability claims against Horizon for alleged design and warnings defects. Fifteen of the nineteen scheduled cases are pending in the Northern District of Illinois; the other four are in federal court in New York, California, Georgia, and Washington. Six law firms represent the plaintiffs in these actions, with the Johnson Becker firm representing nine of the fifteen plaintiffs who filed in the Northern District of Illinois. Frost Brown Todd, LLP in Indianapolis, Indiana and Louisville, Kentucky serves as national counsel for Horizon in these matters, with local counsel admitted to practice in the jurisdictions where the cases are pending.

All nineteen actions are in their early stages. Horizon has filed motions to dismiss in

[7] https://ir.horizontherapeutics.com/sec-filings/sec-filing/10-k/0000950170-23-005337 (last accessed 4/14/23).

response to the Complaints in twelve of the cases (and intends to file motions to dismiss in the remaining seven cases) on grounds that the claims are preempted under federal law. Plaintiffs allege that Horizon should have amended the TEPEZZA® label using the CBE regulation, but they fail to identify or allege any "newly acquired information" available during the relevant timeframe (which varies based on each Plaintiff's treatment dates) that Horizon could have used to unilaterally update the label. Likewise, FDA granted approval to TEPEZZA®'s design, and federal law prohibits a manufacturer from redesigning a biologic without FDA approval.[8] Horizon also alleged pleading insufficiencies on state law grounds based on the location of each Plaintiff's treatment and residence.[9]

No court has held a scheduling conference, other than to issue deadlines for briefing on the motions to dismiss. No party has produced or received documents or other materials through discovery, and no depositions have occurred. No court has issued any substantive ruling, let alone inconsistent pre-trial rulings. In December 2022, nine plaintiffs moved to Relate and Reassign all then-pending cases in the Northern District of Illinois pursuant to N.D. Ill. Local Rule 40.4 and Internal Operating Procedure 13(e) (the "Rule 40.4 Motion"). Horizon objected to the Rule 40.4 Motion for the same reasons it opposes the current motion: factual dissimilarities among Plaintiffs and causation issues, unique applicable case law, and lack of judicial savings and net efficiency. (Horizon's Objection and Response to Plaintiffs' Motion to Relate and

[8] Indeed, a proposed "redesign" of TEPEZZA® is impossible. TEPEZZA® is a human monoclonal antibody that is not chemically synthesized. Thus, scientifically speaking, Horizon did not design TEPEZZA® the way other manufacturers design a standard prescription drug. To change TEPEZZA®'s design by changing it in any way would be to turn it into an entirely different substance—one which would not have TEPEZZA®'s properties and would likely not even be an effective treatment for thyroid eye disease for which TEPEZZA® has been approved by the FDA.

[9] The Plaintiffs' home states are Alabama, Arizona, California, Georgia, Kentucky, Maryland, North Carolina, New York, Pennsylvania, Virginia, and Washington.

Reassign Cases Under LR 40.4 and IOP 13(e)), attached as Exhibit 1). The Rule 40.4 Motion was fully briefed in January 2023. In early February 2023, Judge Leinenweber, the judge before whom the motion is pending, advised that he would be ruling on the briefs without a hearing. To date, an Order has not yet been entered. All cases in the Northern District of Illinois have been stayed pending a ruling on the Rule 40.4 Motion, except for the *Williams v. Horizon* (N.D. Ill. Case no. 22-cv-06838) and *Fisher v. Horizon* (N.D. Ill. Case no. 23-cv-00805) in which briefing schedules on the Motion to Dismiss have been set. Responsive pleadings have not yet been filed (and are not yet due) in the remaining seven cases.

Plaintiffs' claims raise numerous fact-specific issues that necessarily require individualized inquiries. Federal preemption under the CBE regulation turns on whether and when Horizon obtained "newly acquired information" that would permit it to amend TEPEZZA®'s label. None of the Plaintiffs have demonstrated that Horizon was permitted, much less required, to amend TEPEZZA®'s label during the relevant time frame —before each Plaintiff received TEPEZZA®. Even so, Plaintiffs received infusions at different times. Some received TEPEZZA® just months after it was approved in 2020, whereas others were treated into the later part of 2022. *Compare Walker v. Horizon* (N.D. Ill. Case No. 22-cv-06375) Amended Complaint, Dkt# 23 at ¶ 10 (June 2020–November 2020 treatment dates), *with Lukowski v. Horizon* (N.D. Ill. Case No. 23-cv-01159) Complaint, Dkt# 1 at ¶ 10 (August–October 2022 treatment dates).[10] Plaintiffs' medical histories are also unique, including different pre-existing issues with hearing loss, a condition that is associated with Thyroid Eye Disease. Plaintiffs also received TEPEZZA® for different lengths of time, with different amounts and rates of infusion, and were treated by different physicians at different infusion facilities. As a result, each case presents different causation issues depending on the relative facts.

[10] Exhibit 4 is a chart listing each of the plaintiffs' treatment dates with TEPEZZA®.

Different legal standards govern each of the cases based on the location of the alleged injury. Some states apply an "unreasonably dangerous" standard for design defect claims, whereas others require proof of a feasible alternative design. The warning defect requirements also vary by state and depend on what the user and/or the learned intermediary knew about the risks of the product, and when the knowledge was acquired.

LEGAL STANDARD

Under 28 U.S.C. § 1407(a), "[w]hen civil actions involving one or more common questions of fact are pending in different districts," the Panel may transfer those actions "to any district for coordinated or consolidated pretrial proceedings." Although these actions present some common questions of fact, centralization is warranted only if doing so "would serve the convenience of the parties and witnesses or further the just and efficient conduct of this litigation." *In re TD Bank, N.A.*, 703 F.Supp. 2d 1380, 1381 (J.P.M.L. 2010); *see also In re Highway Accident Near Rockville, Conn.*, 388 F.Supp. 574, 575 (J.P.M.L. 1975) ("Before transfer will be ordered, the Panel must be satisfied that all of the statutory criteria have been met.")[11] Significantly, the moving party bears the burden of establishing that formal centralization is warranted under Section 1407(a).

[11] "Section 1407 does not, as a general rule, empower the Panel to transfer cases involving only common legal issues." *See In re Teamster Car Hauler Prod. Liab. Litig.*, 856 F.Supp. 2d 1343 (J.P.M.L. 2012) (explaining that the common issue of "complete preemption" was insufficient to justify centralization).

ARGUMENT

I. Transfer will not promote the just and efficient conduct of these proceedings.

A. Movant has failed to show that centralization is necessary for the nineteen pending federal actions.

The Transfer Motion encompasses only nineteen federal actions pending in five districts. As the Panel has long held, where only a small number of actions and districts are involved, the moving party bears a heavier burden to demonstrate the need for centralization. *See In re Transocean Ltd. Sec. Litig. (No. II)*, 753 F.Supp. 2d 1373, 1374 (J.P.M.L. 2010). And although the Panel is "disinclined to take into account the mere possibility of future filings in [the] centralization calculus[,]" the fact remains that a relatively low number of individuals have received TEPEZZA®. *See In re Qualitest Birth Control Prod. Liab. Lit.*, 38 F.Supp. 3d 1388, 1389 (J.P.M.L. 2014). As discussed, TEPEZZA® is an Orphan Drug that, by definition, treats a rare disease affecting an estimated 15,000-20,000 people in the United States. TEPEZZA® has been only available to prescribing physicians and patients for three years. Thus, while Movant would have the Panel believe that ***thousands*** of additional actions will be filed because of Horizon's "aggressive direct-to-consumer marketing campaign" (Transfer Motion, p. 1), the reality is that approximately 12,000 Americans have received TEPEZZA® since its approval in 2020.[12] And only nineteen have filed suit. As such, there exists only a discrete, low number of

[12] Movant also notes that Horizon received hundreds of adverse event reports following TEPEZZA®'s approval in 2020, (Transfer Motion, p. 3). Specifically, in the Complaints, Plaintiffs' allege: 45 adverse events in 2020; 106 adverse events in 2021; and 92 in 2022. However, these reports are not predictive of anticipated future filings, nor do they indicate risks different than what Horizon warned about on the TEPEZZA® label. FDA regulations require pharmaceutical companies to submit reports for "[a]ny adverse event associated with the use of a drug in humans, whether or not considered drug related." 21 C.F.R. § 314.80(a). Importantly, the regulation contains a disclaimer that "[a] report or information submitted by an applicant under this section (and any release by FDA of that report or information) does not necessarily reflect a conclusion by the applicant or FDA that the report or information constitutes an admission that the drug caused or contributed to an adverse effect." 21 C.F.R. § 314.80(l).

potential plaintiffs. *See also In re Belviq (Lorcaserin HCl)*, 555 F.Supp. 3d 1369, 1370 (J.P.M.L. 2021) (denying centralization where there were only "at most, twenty actions" pending, despite the plaintiffs' prediction that the litigation would encompass "hundreds or thousands of cases.").

Centralization is unnecessary for the additional reason that there are "limited number of involved counsel" in the litigation. *See In re Cordarone (amiodarone Hydrochloride) Mktg. Sales Prac. & Prod. Liab. Litig.*, 190 F.Supp. 3d 1346, 1348 (J.P.M.L. 2016); *In re Mirena IUS Levonorgestrel-Related Prod. Liab. Litig.*, 38 F.Supp. 3d 1380, 1381 (J.P.M.L. 2014). Horizon—the sole defendant in all nineteen actions—has retained Frost Brown Todd LLP as national counsel. There are six firms representing the plaintiffs, with one firm—Johnson Becker—representing nine Plaintiffs in the Northern District of Illinois.[13]

B. Informal coordination can be achieved through voluntary cooperation.

The small number of actions and law firms involved allows for informal cooperation, which warrants denial of the Transfer Motion at this time. The Panel has emphasized that where at all possible, informal coordination is "preferable to formal centralization." *In re Adderall XR (Amphetamine/Dextroamphetamine) Mktg., Sales Prac. & Antitrust Litig.*, 968 F.Supp. 2d 1343, 1344-45 (J.P.M.L. 2013). Here, half of the cases involve common plaintiffs' counsel, with whom Horizon's national counsel is already cooperating with informally. Horizon's national

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Adverse event reports also cannot demonstrate a greater frequency of adverse events because the database may contain duplicate reports where the same report was submitted by a consumer and by the sponsor. "Therefore, FAERS data cannot be used to calculate the incidence of an adverse event … in the U.S. population." Questions and Answers on FDA's Adverse Event Reporting System (FAERS) https://www.fda.gov/drugs/surveillance/questions-and-answers-fdas-adverse-event-reporting-system-faers (last accessed 4/14/23).

[13] The remaining plaintiffs are represented by Simmons Hanly Conroy (*Lucci*, N.D.Ill.; *Perez*, N.D.Ill.; and *Lukowski*, N.D.CA.), Peiffer Wolf Carr (*Diaz*, N.D.Ill.; *Klostermann*, N.D.Ill.; *Pledger*, N.D.Ill.; and *Kanester-Rychner*, W.D.WA), Dicello Levitt (*Snyder*, N.D.Ill.), Childers Schlueter & Smith (*Simpson*, M.D. Ga.), and Levin Papantonio (*Exton*, N.D.N.Y.).

counsel will continue to cooperate and efficiently coordinate discovery (if needed) and other pretrial matters as appropriate. *See In re OxyElite Pro & Jack3d Prod. Liab. Litig. (No. II)*, 65 F.Supp. 3d 1412, 1413-14 (J.P.M.L. 2014) ("Informal cooperation among the involved attorneys and coordination between the involved courts . . . remains practicable and preferable to formal centralization of this litigation.").

Given the low number of claimants and counsel, Movant fails to demonstrate why formal centralization is necessary in this instance. Instead, Movant relies on conclusory assertions and rote generalizations, such as a "risk" of inconsistent rulings and "serial litigation." (Transfer Motion pp. 7-8). Rather than highlight real disputes regarding informal coordination (which do not exist),[14] Movant offers only perfunctory statements that apply to every would-be MDL, like the threat of duplicative discovery,[15] the danger of inconsistent rulings, and the interests of judicial economy. (*Id.* at pp. 11-12). On this record, Movant has not shown that centralization of these cases would "promote the just and efficient conduct of [these] actions." 28 U.S.C. § 1407.

At a minimum, Movant's request for centralization is premature and contrary to the Panel's guidance that the parties should first seek alternatives to centralization before asking the Panel to intervene. *See In re Best Buy Co. Inc., Cal. Song-Beverly Credit Cart Act Litig.*, 804 F.Supp. 2d 1376, 1379 (J.P.M.L. 2011). As the Panel has recognized, centralization of products liability actions has the unintended consequence of attracting more new case filings. Indeed,

[14] As discussed, Horizon opposed formal reassignment but agreed to work with the Court and counsel to coordinate discovery proceedings in response to Plaintiffs' Rule 40.4 Motion.

[15] While Horizon believes that Plaintiffs' claims should not proceed to discovery, there are many mechanisms available to the parties to minimize the possibility of duplicative discovery short of Section 1407 transfer. *In re Eli Lily & Co., (Cephalexin Monohydrate) Patent Litig.*, 446 F.Supp. 242, 244 (J.P.M.L. 1978). "[N]otices of deposition can be filed in all related actions; the parties can stipulate that any discovery relevant to more than one action can be used in all those actions; or the involved courts may direct the parties to coordinate their pretrial activities." *In re Adderall*, 968 F.Supp. 3d at 1345.

MDLs often attract cases based not on their merits, but instead because they can be easily filed, escape individual scrutiny, and inflate case counts in an effort to inflict settlement pressure. *In re Mentor Corp. Obtape Transobturator Sling Prod. Liab. Litig.* 2016 WL 4705827, at *2 (M.D. Ga. Sept 7, 2016); *see also In re Uponor, Inc., F1960 Plumbing Fittings Prod. Liab. Litg.*, 895 F.Supp. 2d 1346, 1348 (J.P.M.L. 2012) (noting the risks of "added inconvenience, confusion and cost" with premature centralization). Informal alternatives to centralization are possible and preferable in these cases. The Panel need not order formal centralization and impose "the last solution" for a problem that Movant has not tried to solve or even shown to exist.

In sum, Plaintiff has failed to carry her burden to show that a transfer would "promote the just and efficient conduct of [these] actions," and seeks to impose the "last solution"—coordination—instead of informal cooperation, which is possible and preferable here. The Transfer Motion should be denied.

II. If the Panel determines that centralization is warranted, then the Northern District of Illinois, with the Honorable John R. Blakey presiding, would be the most appropriate transferee court.

For the reasons stated above, Horizon does not believe centralization under Section 1407 is merited. However, if there is to be an MDL, the Northern District of Illinois with Judge Blakey presiding over the litigation is the most appropriate transferee forum.

In determining the most appropriate transferee forum under Section 1407, the Panel considers (among other things), the location of the parties, witnesses, and documents; the convenience of the parties and witnesses; the progress achieved in the pending actions; the resources and experience of the transferee forum; and the preference of the parties. *See In re Mirena IUS Levonorgestrel-Related Prod. Liab. Litig. (No. II)*, 249 F.Supp. 3d 1357, 1360 (J.P.M.L. 2017) (ordering transfer and considering parties' convenience); *In re Sprint Premium*

Data Plan Mktg. & Sales Prac. Litig., 777 F.Supp. 2d 1349, 1351 (J.P.M.L. 2011) (a district is an "appropriate transferee district" if it "has a great deal of experience serving as a transferee court yet has a manageable MDL docket"). All of these factors weigh in favor of selecting the Northern District of Illinois as the transferee forum.

The Northern District of Illinois is the location of the first-filed action, *Weibel v. Horizon* (N.D.Ill. Case no. 22-cv-04518), and the location of the majority of the currently pending actions. The Northern District of Illinois has a meaningful nexus to the parties, witnesses, and documents. Horizon's U.S. headquarters are just outside of Chicago in Deerfield—and thus many of the witnesses and relevant documents are located in the Northern District of Illinois. *See In re Profemur Hip Implant Prod. Liab. Litig.*, 481 F.Supp. 3d 1350, 1353 (J.P.M.L. 2020) (centralizing related actions in the district court "located near the Wright and Microport defendants' Memphis headquarters, where relevant documents and witnesses may be found"); *In re Farxiga (Dapagliflozin) Prod. Liab. Litig.*, 273 F.Supp. 3d 1380, 1382 (J.P.M.L. 2017) (centralizing related actions in the S.D.N.Y. because the defendant "is headquartered in New York, and thus many witnesses and relevant documents are likely to be found in or near the district"); *In re Procter & Gamble Aerosol Prod., Mktg. & Sales Litig.*, 600 F.Supp. 3d 1343, 1344 (J.P.M.L. 2022) (centralizing related actions where "P&G has its headquarters" because "common witnesses and other evidence likely will be located in or near this district"). The Northern District of Illinois is also the only forum that has jurisdiction over all of the related actions. Because Horizon's principal place of business is in Illinois, it is subject to general personal jurisdiction in the Northern District of Illinois. Additionally, Chicago is geographically accessible and convenient for parties, witnesses, and counsel. Counsel for both sides are located in or near the Midwest United States, and there are many direct flights to Chicago's two airports

from counsel's homebase locations. Finally, the Northern District of Illinois has the resources and expertise to manage coordinated litigation. The district has extensive experience handling MDLs, including several product liability MDLs involving drugs and medical devices. *E.g., In re Zimmer NexGen Knee Implant Prods. Liab. Litig.*, MDL No 2272; *In re Testosterone Replacement Therapy Prods. Liab. Litig.*, MDL No. 2545).

Judge Blakey's distinguished and wide-ranging legal career followed by nearly a decade on the federal bench presiding over complex and substantial litigation, makes him an ideal candidate to preside over these cases. He is already handling two of the fifteen cases pending in the Northern District of Illinois and is thus familiar with the litigation. (*See Lucci v. Horizon*, N.D.Ill. Case no. 22-cv-07351 and *Pledger v. Horizon*, N.D.Ill. Case no. 22-cv-06562). Judge Blakey is also an experienced transferee judge, who is efficiently and effectively presiding over MDL 3009 *In re Seresto Flea and Tick Collar Marketing, Sales Practices and Products Liability Litigation*, in which the parties are actively participating in settlement negotiations before Magistrate Judge Heather K. McShain. He has authored numerous opinions on product liability claims, including design and warnings defects issues, and he will therefore be well-versed with the legal issues involved in these cases. Finally, Judge Blakey has the experience and disposition to deftly manage this litigation.

In contrast, the Northern District of California is already overtaxed and has no nexus to the parties. It is currently the home of 17 active MDLs, the most of any district in the United States, despite the fact that there are two current judicial vacancies in the district deemed judicial emergencies.[16] Further, three plaintiffs allege that they are California residents, but two of those plaintiffs—*Perez* and *Diaz*—chose to file in the Northern District of Illinois. And, as already

[16] https://www.uscourts.gov/judges-judgeships/judicial-vacancies/judicial-emergencies (last accessed 4/14/23).

noted, the majority of counsel for both sides are located in the Midwest region: counsel for Horizon are located in Indiana and Kentucky; Johnson Becker, which represents half of the plaintiffs, is located in Minnesota; Simmons Hanly Conroy is located in Illinois; Peiffer Wolf Carr is in Ohio; and Dicello Levitt is also in Ohio. The two remaining plaintiffs' firms are also both much closer to Chicago than California with Childers Schlueter & Smith in Georgia and Levin Papantonio in Florida. The factors of location of the parties, witnesses, and documents, the convenience of the parties and witnesses, and available judicial resources all weigh against the Northern District of California.

CONCLUSION

Horizon respectfully requests that the Panel deny the Transfer Motion. In the alternative, if the Panel believes that centralization is warranted now, Horizon requests that the Panel select the Northern District of Illinois for coordinated pretrial proceedings before the Honorable John R. Blakey.

Respectfully submitted,

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EXHIBIT 1

Horizon's Objection and Response to Plaintiffs' Motion to Relate and Reassign Cases Under LR 40.4 and IOP 13(e)

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS

DANIEL WEIBEL, Plaintiff, v. HORIZON THERAPEUTICS USA, INC. Defendant.	Civil Action No. 1:22-cv-4518
LISA CHRISTIAN NETHERY Plaintiff, v. HORIZON THERAPEUTICS USA, INC. Defendant.	Civil Action No. 1:22-cv-5005
DONNA WALKER Plaintiff, v. HORIZON THERAPEUTICS USA, INC. Defendant.	Civil Action No. 1:22-cv-6375
GLORIA PLEDGER Plaintiff, v. HORIZON THERAPEUTICS USA, INC. Defendant.	Civil Action No. 1:22-cv-6562

JOHN INGRAM Plaintiff, v. HORIZON THERAPEUTICS USA, INC. Defendant.	Civil Action No. 1:22-cv-6836
ANDREA LEEDS Plaintiff, v. HORIZON THERAPEUTICS USA, INC. Defendant.	Civil Action No. 1:22-cv-6837
RACHEL SNYDER Plaintiff, v. HORIZON THERAPEUTICS USA, INC. Defendant.	Civil Action No. 1:22-cv-6747
CYNTHIA WILLIAMS Plaintiff, v. HORIZON THERAPEUTICS USA, INC. Defendant.	Civil Action No. 1:22-cv-6838

KIMBERLY PEREZ Plaintiff, v. HORIZON THERAPEUTICS USA, INC. Defendant.	Civil Action No. 1:22-cv-6718

DEFENDANT HORIZON THERAPEUTICS USA, INC.'S OBJECTION AND RESPONSE TO PLAINTIFFS' MOTION TO RELATE AND REASSIGN CASES UNDER LOCAL RULE 40.4 AND INTERNAL OPERATING PROCEDURE 13(e)

Defendant, Horizon Therapeutics USA, Inc. ("Horizon") objects to the reassignment of cases proposed by Plaintiffs. Local Rule 40.4 requires proof of relatedness, substantial saving in judicial time and effort, and that the cases are subject to disposition in a single proceeding. Plaintiffs can satisfy none of these essential elements. The cases involve substantially different facts that directly impact the claims and defenses in each case. The applicable law in each case is unique due to choice of law principles. There would be little or no judicial savings in efficiency because of the different issues of law and fact applicable to each case. For the same reasons, the cases cannot be determined in a single proceeding, as individual determinations are necessary. In fact, distinct motions to dismiss – based on differing facts and laws – are being filed in each case.[1]

Though the cases are fundamentally inappropriate for reassignment under LR 40.4, Horizon believes that coordination of certain discovery, pursuant to a uniform case management plan governing written discovery, company witness depositions, and expert discovery, to the extent there is commonality concerning specific issues, would promote judicial efficiency.

[1] On January 9, 2023, Horizon filed motions to dismiss in the *Weibel* (case no. 1:22-cv-4518, Dkt. Nos. 32 and 33) and *Nethery* No. (case no. 1:22-cv-5005, Dkt. Nos. 25 and 26) cases pending before this Court, as well as in the *Walker* (case no. 1:22-cv-6375, Dkt. Nos. 17 and 18) case, pending before Judge Mondalvo. Horizon will be filing additional motions to dismiss in the remaining cases by the end of January.

LEGAL STANDARD

"To have a case reassigned based on relatedness, the movant must satisfy **both** Local Rule 40.4(a) and (b)." *Donahue v. Elgin Riverboat Resort*, No. 04 C 816, 2004 WL 2495642, at *1 (N.D. Ill. Sept. 28, 2004) (emphasis added)(citing *Lawrence E. Jaffe Pension Plan v. Household Int'l, Inc.*, No. 02 C 5893, 2003 U.S. Dist. LEXIS 7466, at *3 (N.D. Ill. May 5, 2003)).

LR 40.4(a) provides as follows:

> (a) Definitions. Two or more civil cases may be related if one or more of the following conditions are met:
>
> (1) the cases involve the same property;
>
> (2) the cases involve some of the same issues of fact or law;
>
> (3) the cases grow out of the same transaction or occurrence; or
>
> (4) in class action suits, one or more of the classes involved in the cases is or are the same.

"The fact that the cases are brought against the same defendant and generally involve the same types of allegations are not sufficient to show the cases are related pursuant to Local Rule 40.4(a)." *Donahue*, 2004 WL 2495642 at *1).

LR 40.4(b) imposes even stricter requirements before reassignment is permissible. *See Williams v. Walsh Const.*, No. 05 C 6807, 2007 WL 178309, at *2 (N.D. Ill. Jan. 16, 2007)("Once the cases are determined to be related under LR 40.4(a), LR 40.4(b) requires more stringent criteria for the case to qualify for reassignment."). LR 40.4(b) reads as follows:

> (b) Conditions for Reassignment. A case may be reassigned to the calendar of another judge if it is found to be related to an earlier-numbered case assigned to that judge and **each of the following criteria is met**:
>
> (1) both cases are pending in this Court;
>
> (2) **the handling of both cases by the same judge is likely to result in a substantial saving of judicial time and effort**;

(3) the earlier case has not progressed to the point where designating a later filed case as related would be likely to delay the proceedings in the earlier case substantially; **and**

(4) **the cases are susceptible of disposition in a single proceeding**.

(Emphasis added). All four criteria under LR 40.4(b) must be satisfied for a related case to be reassigned.

In addition to the requirements in sections (a) and (b) of the Rule, LR 40.4(c) requires a moving party to set forth the points of commonality in sufficient detail for relatedness under section (a) and "indicate the extent to which the conditions required by section (b) will be met" as well. These provisions "impose an obligation on the moving party to specifically identify why each of the four conditions under LR 40.4(b) is met." *Williams v. Walsh Const.*, No. 05 C 6807, 2007 WL 178309, at *2 (N.D. Ill. Jan. 16, 2007) (citations omitted). Additionally, "[i]n order that all parties to a proceeding be permitted to respond on the questions of relatedness and possible reassignment, such motions should not generally be filed until after the answer or motions in lieu of answer have been filed in each of the proceedings involved." LR 40.4(c).

ARGUMENT

A. The requirements of LR 40.4 cannot be met and the cases should not be reassigned.

1. *Plaintiffs failed to satisfy the requirements of LR 40.4(a).*

First, Plaintiffs cannot meet their burden under LR 40.4(a). As this Court has held, "[t]he fact that the cases are brought against the same defendant and generally involve the same types of allegations are not sufficient to show the cases are related pursuant to Local Rule 40.4(a)." *Donahue*, 2004 WL 2495642 at *1.

In *Donahue*, defendant moved to reassign racial discrimination claims filed by several employees. First, evaluating the motion under LR 40.4(a), the court pointed out that the individual

claims lacked commonality, as the plaintiffs' claims involved different decisionmakers and their cases each involved a unique set of facts specific to each plaintiff. "The fact that the cases are brought against the same defendant and generally involve the same types of allegations are not sufficient to show the cases are related pursuant to Local Rule 40.4(a). Therefore, Elgin's motion must be denied on this basis alone." *Id.* at *2.

Like *Donahue*, the factual and legal differences in these cases make reassignment improper here. In their Motion, Plaintiffs have relied almost exclusively upon the argument that their lawsuits are against the same defendant and their own allegations are similar in the cases they filed against Horizon. However, Plaintiffs' argument ignores the significant differences in each of those lawsuits which render them inappropriate for reassignment under LR 40.4. As discussed in further detail below, Horizon's defenses, the applicable law, the facts concerning each individual plaintiff, and the analysis necessary to resolve each case present substantial differences. The cases are not sufficiently related to meet the requirements of LR 40.4, and reassignment should not be permitted.

2. *Plaintiffs cannot satisfy their burden under LR 40.4(b).*

Nor can Plaintiffs meet the stringent requirements of LR 40.4(b). Here, the cases present differences in the applicable law, differences in fact, and differences in the application of law to fact which prohibit reassignment under LR 40.4.

a. Reassignment of the cases would not result in "substantial saving of judicial time and effort" as required by LR 40.4(b)(2).

"Under 40.4(b)(2), the judicial savings alleged by the moving party **must be substantial**; a mere assertion that some judicial time and effort would be saved by reassignment is insufficient." *Williams v. Walsh Const.*, No. 05 C 6807, 2007 WL 178309, at *2 (emphasis added) (quoting *Hollinger Int'l, Inc. v. Hollinger, Inc.*, No. 04 C 0698, 2004 WL 1102327, at *2 (N.D. Ill. May 5, 2004)). "Likewise, if the cases will require different discovery, legal findings, defenses or

summary judgment motions, it is unlikely that reassignment will result in a substantial judicial savings." *Id*. (citing *Hollinger*, 2004 WL 1102327 at *2; *Donahue*, 2004 WL 2495642 at *1).

In *Donahue*, the court held that, even if the cases had been sufficiently related under LR 40.4(a), reassignment was nonetheless improper under LR 40.4(b), because the moving party could not satisfy the second and fourth provision of the Rule. The movant failed to show that reassignment would result in "substantial saving of judicial time and effort" because "each plaintiff's claim required individualized proof and was subject to unique defenses." *Id*. at *3. Therefore, each plaintiff's claim would have to be separately litigated, whether in one proceeding or in several.

In their Motion, Plaintiffs cited to *Blair v. Equifax Check Servs., Inc.*, 181 F.3d 832, 839 (7th Cir. 1999), claiming that "the Seventh Circuit has instructed, '[b]y far the best means of avoiding wasteful overlap when related suits are pending in the same court is to consolidate all before a single judge.'" However, that case has no application here. *Blair* involved an interlocutory appeal of a ***class certification*** for multiple overlapping class actions in against Equifax related to the check-verification service that allegedly violated Fair Debt Collection Practices Act. *Blair* concerned an analysis under Rule 23; it had nothing to do with reassignment of cases pursuant to LR 40.4. *Blair* is completely distinctive from a products liability cases involving alleged medical injuries to different plaintiffs based on different facts and under different state laws.

Here, the cases cannot meet the requirements of substantial saving in judicial efficiency as set forth in LR 40.4(b)(2). In each case, the court will be faced with different analyses under the laws of different states to determine the legal issues and the merits of each case. For example, Plaintiffs' warning defect claims depend on what the user and consumer and/or learned intermediary knew about the risks of the product, and when this knowledge was acquired. Here,

there are different legal standards for warning defect claims depending on which state's law applies; different facts depending on when the drug infusions took place; and different risk/benefit analyses for the different patients, depending on their respective conditions and disease states. Not even the analysis of the federal preemption arguments will be the same in each case due to the related facts of each case. Application of preemption principles will vary from case to case depending on when the plaintiffs' respective infusions occurred. Design defect claims will vary from state to state (if not preempted) depending on the legal standard for proving defect. Finally, the *Twombly-Iqbal* analysis is dependent on the substantive law of the state where the infusions occurred.

Though reassignment might afford *Plaintiffs* some reduction in their own time and effort, the relevant focus under the Rule is whether the ***Court*** will have "substantial" saving in its time and effort. Due to their many significant differences, the reassignment of these cases would result in minimal, if any, savings in judicial time and effort. *See e.g., Teamsters Loc. 705 Pension v. A.D. Conner, Inc.*, No. 10 C 6352, 2011 WL 1674839, at *2 (N.D. Ill. May 4, 2011)("Although there would be some saving of judicial time and effort because there are some common issues of fact regarding damages, such saving would be minimal at best because ultimately each case will require different discovery, legal findings and damages calculations.").

The factual and legal distinctions – and differing state law for each case – will require separate analyses for each case.[2] Plaintiffs cannot prove – and did not even attempt to do so in their motion – that savings in judicial time and effort would result from reassignment – let alone

[2] *Cf. BP Corp. N. Am. Inc. v. N. Tr. Invs., N.A.*, No. 08-CV-6029, 2009 WL 1684531, at *2 (N.D. Ill. June 15, 2009), relied upon by Plaintiffs, which involved claims of breach of fiduciary duties by an investment company, requiring the court to "**interpret the same provisions in ERISA and will apply the same case law regarding fiduciary duties and prohibited transactions under ERISA**." (Emphasis added).

"substantial" saving as required by the Rule. Should the cases survive Rule 12 motion practice, the cases here "will require different discovery, legal findings, defenses or summary judgment motions," and other dispositive motions – as already demonstrated by Horizon's pending motions to dismiss. *Williams v. Walsh Const.*, No. 05 C 6807, 2007 WL 178309, at *2. Reassignment would not result in "substantial saving in judicial time and effort" because "each plaintiff's claim require[s] individualized proof and [is] subject to unique defenses." *Donahue*, 2004 WL 2495642 at *3. Accordingly, reassignment of these cases is prohibited by LR 40.4(b)(2).

b. The cases are not susceptible to disposition in one proceeding as required by LR 40.4(b)(4).

For the same reasons, Plaintiffs cannot meet their burden under LR 40.4(b)(4) because resolution of common issues would not be "outcome determinative" for all cases. *Donahue*, 2004 WL 2495642 at *2. "[C]ases are rarely susceptible to disposition in one proceeding pursuant to 40.4(b)(4) where the cases involve unique issues of law and fact and those unique characteristics are dominant." *Williams*, 2007 WL 178309, at *2(citations omitted); *see also Donahue*, 2004 WL 2495642 at *2 ("In this case, each individual case relies on different set of facts, and a finding in one case would not be dispositive of any issues in the other cases.").

Plaintiffs relied upon *Pactiv Corp. v. Multisorb Techs., Inc.*, No. 10 C 461, 2011 WL 686813, at *5 (N.D. Ill. Feb. 15, 2011), for their argument in favor of reassignment. Importantly, however, *Pactiv* is a patent infringement case involving the same plaintiff and defendant and nearly identical allegations related to the patents – all of which present crucial differences from the cases at hand. Patent infringement cases are uniquely suitable to meet the requirements for reassignment of LR 40.4. The *Pactiv* court found that the cases involved common issues of fact and law and the same transaction or occurrence. Most patent cases are principally focused on patent validity and/or whether that patent was infringed by a competitor. If a patent is invalid, it is invalid against the

world. The outcome of one case is often determinative of all, satisfying LR 40.4(b)(4). Further, the risk of inconsistent rulings runs high if patent cases are not reassigned, and substantial judicial savings results from reassignment.[3]

Patent infringement cases are fundamentally different from state tort cases such as these, where the laws vary from state to state, and the defenses and claims turn on the individual facts. Additionally, in these cases, every Plaintiff's alleged damages, if any are allowed, are different and vary for each case. Further, patent cases do not involve the type of complex causation issues that are central to the subject cases. Here, causation will be disputed in all cases, and substantially different amongst them.

As set forth above, contrary to *Pactiv*, the factual and legal issues in each case here present significant differences that make a unified resolution of the defenses and claims impossible. Each Plaintiff will have different underlying medical conditions at different stages, different prognoses, different learned intermediaries, different infusion regiments, different treatment facilities, different treatment protocols, different results, different alleged adverse effects, different causation issues, different damages – and different drug infusion dates, which significantly impacts the legal merits and the facts of each case. Horizon will have different defenses to each claim.

LR 40.4(b)(4) cannot be satisfied here because the legal and factual issues are not similar such that resolution of common issues would be "outcome determinative" for all cases. Here, as in *Donahue,* "each individual case relies on different set of facts, and a finding in one case would not be dispositive of any issues in the other cases." *Donahue*, 2004 WL 2495642 at *2. Horizon has multiple motions to dismiss pending in the earlier-filed cases, including two before this Court,

[3] For the same reasons, Plaintiffs' reliance on *21 srl v. Enable Holdings, Inc.*, No. 09 Civ. 3667, 2009 U.S. Dist. LEXIS 115530, *6–7 (N.D. Ill. Dec. 9, 2009), another patent infringement case, is similarly misplaced and unpersuasive here.

and each one is unique, based on the law of different states, and turns on different facts. Resolution of these motions, and even resolution of any of the issues within the motions, will not be determinative of all cases. Thus, the cases are neither related, nor "susceptible of disposition in a single proceeding." The fourth factor cannot be satisfied.

3. *Plaintiffs have not satisfied the requirements of LR 40.4(c).*

Under LR 40.4(c), the moving party is required to "indicate the extent to which the conditions required to section (b) will be met" and "specifically identify why each of the four conditions under LR 40.4(b) is met." *Williams v. Walsh Const.*, No. 05 C 6807, 2007 WL 178309, at *2 (N.D. Ill. Jan. 16, 2007) (citations omitted); *see also Lawrence E. Jaffe Pension Plan v. Household Int'l, Inc.*, No. 02 C 5893, 2003 WL 21011757, at *3 (N.D. Ill. May 5, 2003) ("Moreover, even if the movant could satisfy LR 40.4(b)(4) on the merits, under LR 40.4(c), a motion to reassign must explicitly indicate how conditions required by section (b) will be met if the cases are found to be related."). Conclusory allegations that the LR 40.4(b) requirements are met are insufficient to satisfy a movant's obligations. *See Lawrence E. Jaffe Pension Plan,* 2003 WL 21011757, at *3 (citing *Daniels v. Pipefitters' Ass'n Local Union No. 597,* 174 F.R.D. 408, 411 (N.D.Ill.1997)).

Plaintiffs' motion falls short on explaining specifically how a reassignment would substantially save judicial time and effort or how LR 40.4(b)(4) is met, *i.e.*, how the cases could be determined in a single proceeding. Indeed, Plaintiffs dedicate only one paragraph and a few conclusory sentences to these two crucial factors under the Rule.[4] This lack of specificity alone is fatal to their motion.

[4] *See* DN 24, Plaintiffs' Memorandum in Support of Motion to Relate and Reassign Cases Under Local Rule 40.4 and Internal Operating Procedure 13(e) at p. 8.

B. Limited coordination of discovery may be appropriate under IOP 13.

As an alternative, Plaintiffs request the cases to be "consolidated" under IOP 13(e), describing this IOP as "another vehicle for consolidation of cases." As spelled out in its Introduction, however, the Internal Operating Procedures of the court "does not confer rights upon litigants." *Brieger v. Tellabs*, Inc., 434 F.Supp.2d 567, 569 (N.D. Ill. 2006).

The IOP Introduction states,

> These are procedures for the court's internal operations. They are intended to supplement the Guide to Judiciary Policies and Procedures and the local rules. They set out the procedures generally to be used by chambers and the clerk's office in performing certain administrative tasks. While the procedures are public and available on request, **litigants acquire no rights under them**.

(emphasis added). As in this case, the *Brieger* court noted that the motions to dismiss for the respective cases would have to be assessed under completely different standards, so it would not be more efficient for one judge to deal with the allegedly related cases. *See Brieger*, 434 F.Supp.2d at 569. Thus, even if IOP did confer rights on the moving party, it would still not warrant reassignment of the cases. The court did note, however, that while reassignment was not proper, it was likely that a significant amount of discovery would overlap in the subject cases. *See id*. If discovery proceeded in those cases, the court believed that reassignment ***for the purposes of discovery only***, pursuant to N.D. Ill. IOP 13(e) would be appropriate. *See id*. at 569-70.

Although reassignment of the cases is not appropriate under LR 40.4, a limited coordination of discovery could be appropriate in these cases under IOP 13(e). The provision reads,

> (e) COORDINATED PRETRIALS IN COMPLEX CASES NOT INVOLVING MULTI-DISTRICT LITIGATION. The Executive Committee may determine that it would be in the best interests of efficient judicial administration to hold a coordinated pretrial proceeding in a group of cases which either (1) are not related within the meaning of LR40.4(a) or (2) are related within the meaning of LR40.4(a) but reassignment is not appropriate under LR40.4(b). Where such a determination

> is made, the Committee will designate a judge to hold such a proceeding. The cases shall remain on the calendars of the judges to whom they were assigned at the start of the coordinated proceeding and only matters specified in the order of coordination shall be brought before the designated judge. All judges affected by such a coordinated pretrial proceeding shall be notified by the clerk.

Coordination of certain portions of the discovery in these cases could allow the parties to more efficiently conduct discovery concerning the product – such as Horizon's discovery responses, document production, testimony of company witnesses, and avoid the need for duplicative efforts or unnecessarily subjecting witnesses to multiple depositions concerning the product at issue. Additionally, certain expert discovery could also be part of the plan, to the extent there is commonality.

Although the precise scope of any discovery coordination has not been specified, Horizon believes a plan to maximize judicial efficiencies could be crafted, in the event that any of the cases survive the pending Rule 12 dispositive motions.

CONCLUSION

For the reasons set forth above, reassignment of these cases is improper as Plaintiffs cannot satisfy the requirements of LR 40.4. Horizon concurs that depending upon the scope and the terms, coordination of certain discovery in the cases may be appropriate.

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 13th day of January, 2023, a copy of the foregoing was filed electronically. Notice of this filing will be sent to the following parties by operation of the Court's electronic filing system.

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0133648.0761386 4867-6281-1974v6

EXHIBIT 2

TEPEZZA® FDA-Approved Labeling

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use TEPEZZA safely and effectively. See full prescribing information for TEPEZZA.

TEPEZZA (teprotumumab-trbw) for injection, for intravenous use
Initial U.S. Approval: 2020

----------INDICATIONS AND USAGE----------
TEPEZZA is an insulin-like growth factor-1 receptor inhibitor indicated for the treatment of Thyroid Eye Disease (1)

----------DOSAGE AND ADMINISTRATION----------
- Initiate dosing with 10 mg/kg for first infusion, followed by 20 mg/kg every 3 weeks for 7 additional infusions (2.1)
- Administer TEPEZZA by intravenous infusion over 60 to 90 minutes (2.3)

----------DOSAGE FORMS AND STRENGTHS----------
For Injection: 500 mg lyophilized powder in a single-dose vial for reconstitution (3)

----------CONTRAINDICATIONS----------
None (4)

----------WARNINGS AND PRECAUTIONS----------
- Infusion reactions: If an infusion reaction occurs, interrupt or slow the rate of infusion and use appropriate medical management (5.1)
- Exacerbation of Preexisting Inflammatory Bowel Disease (IBD) : Monitor patients with preexisting IBD for flare of disease; discontinue TEPEZZA if IBD worsens (5.2)
- Hyperglycemia: Monitor glucose levels in all patients; treat hyperglycemia with glycemic control medications (5.3)

----------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 (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Horizon at 1-866-479-6742 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

----------USE IN SPECIFIC POPULATIONS----------
Females of Reproductive Potential: Appropriate forms of contraception should be implemented prior to initiation, during treatment and for 6 months following the last dose of TEPEZZA (8.3)

See 17 for PATIENT COUNSELING INFORMATION.

Revised: 1/2020

FULL PRESCRIBING INFORMATION: CONTENTS*

* Sections or subsections omitted from the full prescribing information are not listed.

EXHIBIT B
TEPEZZA® FDA APPROVED LABELING

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

TEPEZZA is indicated for the treatment of Thyroid Eye Disease.

2 DOSAGE AND ADMINISTRATION

2.1 Recommended Dosing

The recommended dose of TEPEZZA is an intravenous infusion of 10 mg/kg for the initial dose followed by an intravenous infusion of 20 mg/kg every three weeks for 7 additional infusions.

2.2 Reconstitution and Preparation

Step 1: Calculate the dose (mg) and determine the number of vials needed for the 10 or 20 mg/kg dosage based on patient weight. Each TEPEZZA vial contains 500 mg of the teprotumumab antibody.

Step 2: Using appropriate aseptic technique, reconstitute each TEPEZZA vial with 10 mL of Sterile Water for Injection, USP. Ensure that the stream of diluent is not directed onto the lyophilized powder, which has a cake-like appearance. Do not shake, but gently swirl the solution by rotating the vial until the lyophilized powder is dissolved. The reconstituted solution has a volume of 10.5 mL. Withdraw 10.5 mL of reconstituted solution to obtain 500 mg. After reconstitution, the final concentration is 47.6 mg/mL.

Step 3: The reconstituted TEPEZZA solution must be further diluted in 0.9% Sodium Chloride Injection, USP prior to infusion. To maintain a constant volume in the infusion bag, a sterile syringe and needle should be used to remove the volume equivalent to the amount of the reconstituted TEPEZZA solution to be placed into the infusion bag. Discard the 0.9% Sodium Chloride, USP volume withdrawn.

Step 4: Withdraw the required volume from the reconstituted TEPEZZA vial(s) based on the patient's weight (in kg) and transfer into an intravenous bag containing 0.9% Sodium Chloride Solution, USP to prepare a diluted solution with a total volume of 100 mL (for less than 1800 mg dose) or 250 mL (for 1800 mg and greater dose). Mix diluted solution by gently inversion. Do not shake.

The product does not contain any preservative. The combined storage time of reconstituted TEPEZZA solution in the vial and the diluted solution in the infusion bag containing 0.9% Sodium Chloride Injection, USP is a total of 4 hours at room temperature 20°C to 25°C (68°F to 77°F) or up to 48 hours under refrigerated conditions 2°C to 8°C (36°F to 46°F) protected from light. If refrigerated prior to administration, allow the diluted solution to reach room temperature prior to infusion.

EXHIBIT B
TEPEZZA® FDA APPROVED LABELING

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Upon reconstitution, TEPEZZA is a colorless or slightly brown, clear to opalescent solution which is free of foreign particulate matter. Discard the solution if any particulate matter or discoloration are observed.

Do not freeze the reconstituted or diluted solution.

Discard vial(s) and all unused contents.

No incompatibilities between TEPEZZA and polyethylene (PE), polyvinyl chloride (PVC), polyurethane (PUR) or polyolefin (PO) bags and intravenous administration sets have been observed.

2.3 Administration

Administer the diluted solution intravenously over 90 minutes for the first two infusions. If well tolerated, the minimum time for subsequent infusions can be reduced to 60 minutes. If not well tolerated, the minimum time for subsequent infusions should remain at 90 minutes.

Do not administer as an intravenous push or bolus. TEPEZZA should not be infused concomitantly with other agents.

3 DOSAGE FORMS AND STRENGTHS

For injection (intravenous infusion): 500 mg of teprotumumab as a white to off-white lyophilized powder in a single-dose vial for reconstitution and dilution.

4 CONTRAINDICATIONS

None

5 WARNINGS AND PRECAUTIONS

5.1 Infusion Reactions

TEPEZZA may cause infusion reactions. Infusion reactions have been reported in approximately 4% of patients treated with TEPEZZA. Signs and symptoms of infusion-related reactions include transient increases in blood pressure, feeling hot, tachycardia, dyspnea, headache and muscular pain. Infusion reactions may occur during any of the infusions or within 1.5 hours after an infusion. Reported infusion reactions are usually mild or moderate in severity and can usually be successfully managed with corticosteroids and antihistamines. In patients who experience an infusion reaction, consideration should be given to pre-medicating with an antihistamine, antipyretic, corticosteroid and/or administering all subsequent infusions at a slower infusion rate.

EXHIBIT B
TEPEZZA® FDA APPROVED LABELING

5.2 Exacerbation of Preexisting Inflammatory Bowel Disease

TEPEZZA may cause an exacerbation of preexisting inflammatory bowel disease (IBD). Monitor patients with IBD for flare of disease. If IBD exacerbation is suspected, consider discontinuation of TEPEZZA.

5.3 Hyperglycemia

Hyperglycemia or increased blood glucose may occur in patients treated with TEPEZZA. In clinical trials, 10% of patients (two thirds of whom had pre-existing diabetes or impaired glucose tolerance) experienced hyperglycemia. Hyperglycemic events should be controlled with medications for glycemic control, if necessary.

Monitor patients for elevated blood glucose and symptoms of hyperglycemia while on treatment with TEPEZZA. Patients with pre-existing diabetes should be under appropriate glycemic control before receiving TEPEZZA.

6 ADVERSE REACTIONS

The following clinically significant adverse reactions are described elsewhere in the labeling:

- Infusion Reactions *[see Warnings and Precautions (5.1)]*
- Exacerbation of Inflammatory Bowel Disease *[see Warnings and Precautions (5.2)]*
- Hyperglycemia *[see Warnings and Precautions (5.3)]*

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The 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). Patients were treated with TEPEZZA (10 mg/kg for first infusion and 20 mg/kg for the remaining 7 infusions) or placebo given as an intravenous infusion every 3 weeks for a total of 8 infusions. The majority of patients completed 8 infusions (89% of TEPEZZA patients and 93% of placebo patients).

The most common adverse reactions (≥5%) that occurred at greater incidence in the TEPEZZA group than in the control group during the treatment period of Studies 1 and 2 are summarized in Table 1.

Table 1. Adverse Reactions Occurring in 5% or More of Patients Treated with TEPEZZA and Greater Incidence than Placebo

Adverse Reactions	TEPEZZA N=84 N (%)	Placebo N=86 N (%)
Muscle spasms	21 (25%)	6 (7%)
Nausea	14 (17%)	8 (9%)
Alopecia	11 (13%)	7 (8%)
Diarrhea	10 (12%)	7 (8%)
Fatigue[a]	10 (12%)	6 (7%)
Hyperglycemia[b]	8 (10%)	1 (1%)
Hearing impairment[c]	8 (10%)	0
Dysgeusia	7 (8%)	0
Headache	7 (8%)	6 (7%)
Dry skin	7 (8%)	0

[a] Fatigue includes asthenia
[b] Hyperglycemia includes blood glucose increase
[c] Hearing impairment (includes deafness, eustachian tube dysfunction, hyperacusis, hypoacusis and autophony)

6.2 Immunogenicity

As with all therapeutic proteins, there is potential for immunogenicity. The detection of antibody formation is highly dependent on the sensitivity and specificity of the assay.

In a placebo-controlled study with TEPEZZA, 1 of 42 patients treated with placebo had detectable levels of antidrug antibodies in serum. In the same study, none of the 41 patients treated with TEPEZZA had detectable levels of antidrug antibodies in serum.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Based on findings in animals and its mechanism of action inhibiting insulin-like growth factor 1 receptor (IGF-1R), TEPEZZA may cause fetal harm when administered to a pregnant woman. Adequate and well-controlled studies with TEPEZZA have not been conducted in pregnant women. There are insufficient data with TEPEZZA use in pregnant women to inform any drug associated risks for adverse developmental outcomes. In utero teprotumumab exposure in cynomolgus monkeys dosed once weekly with teprotumumab throughout pregnancy resulted in external and skeletal abnormalities. Teprotumumab exposure may lead to an increase in fetal loss *[see Data]*. Therefore, TEPEZZA should not be used in pregnancy, and appropriate forms of contraception should be implemented prior to initiation, during treatment and for 6 months following the last dose of TEPEZZA. If the patient becomes pregnant during treatment, TEPEZZA should be discontinued and the patient advised of the potential risk to the fetus.

The background rate of major birth defects and miscarriage is unknown for the indicated population. In the U.S. general population, the estimated background risks of major birth defects and miscarriage in clinically recognized pregnancies are 2-4% and 15-20%, respectively.

Data

Animal Data
In an abridged pilot embryofetal development study, seven pregnant cynomolgus monkeys were dosed intravenously at one dose level of teprotumumab, 75 mg/kg (2.8-fold the maximum recommended human dose (MRHD) based on AUC) once weekly from gestation day 20 through the end of gestation. The incidence of abortion was higher for the teprotumumab treated group compared to the control group. Teprotumumab caused decreased fetal growth during pregnancy, decreased fetal size and weight at caesarean section, decreased placental weight and size, and decreased amniotic fluid volume. Multiple external and skeletal abnormalities were observed in each exposed fetus, including: misshapen cranium, closely set eyes, micrognathia, pointing and narrowing of the nose, and ossification abnormalities of skull bones, sternebrae, carpals, tarsals and teeth. The test dose, 75 mg/kg of teprotumumab, was the maternal no observed adverse effect level (NOAEL).

Based on mechanism of action inhibiting IGF-1R, postnatal exposure to teprotumumab may cause harm.

8.2 Lactation

Risk Summary
There is no information regarding the presence of TEPEZZA in human milk, the effects on the breast-fed infant or the effects on milk production.

8.3 Females and Males of Reproductive Potential

Contraception
Females
Based on its mechanism of action inhibiting IGF-1R, TEPEZZA may cause fetal harm when administered to a pregnant woman *[see Use in Specific Populations (8.1)]*. Advise females of reproductive potential to use effective contraception prior to initiation, during treatment with TEPEZZA and for 6 months after the last dose of TEPEZZA.

8.4 Pediatric Use

Safety and effectiveness have not been established in pediatric patients.

8.5 Geriatric Use

Of the 171 patients in the two randomized trials, 15% were 65 years of age or older; the number of patients 65 years or older was similar between treatment groups. No overall differences in efficacy or safety were observed between patients 65 years or older and younger patients (less than 65 years of age).

10 OVERDOSAGE

No information is available for patients who have received an overdosage.

11 DESCRIPTION

Teprotumumab-trbw, an insulin-like growth factor-1 receptor inhibitor (IGF-1R), is a fully human IgG1 monoclonal antibody produced in Chinese hamster ovary (CHO-DG44) cells. It has a molecular weight of approximately 148 kilodaltons.

TEPEZZA (teprotumumab-trbw) for injection is supplied as a sterile, preservative-free, white to off-white, lyophilized powder for intravenous infusion. Each single-dose vial contains 500 mg of teprotumumab-trbw, L-histidine (7.45 mg), L-histidine hydrochloride monohydrate (31.8 mg), polysorbate 20 (1 mg), and trehalose dihydrate (946 mg). After reconstitution with 10 mL of Sterile Water for Injection, USP, the final concentration is 47.6 mg/mL with a pH of 5.5.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

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.

12.2 Pharmacodynamics

No formal pharmacodynamic studies have been conducted with teprotumumab-trbw.

12.3 Pharmacokinetics

The pharmacokinetics of teprotumumab-trbw was described by a two compartment population PK model based on data from 40 patients with Thyroid Eye Disease receiving an initial intravenous infusion of 10 mg/kg, followed by infusions of 20 mg/kg TEPEZZA every 3 weeks in two clinical trials. Following this regimen, the mean (± standard deviation) estimates for steady-state area under the concentration curve (AUC), peak (Cmax), and trough (Ctrough) concentrations of teprotumumab-trbw were 138 (± 34) mg•hr/mL, 632 (± 139) mcg/mL, and 176 (± 56) mcg/mL, respectively.

Distribution
Following the recommended TEPEZZA dosing regimen, the population PK estimated mean (± standard deviation) for central and peripheral volume of distribution of teprotumumab-trbw were 3.26

(±0.87) L and 4.32 (± 0.67) L, respectively. The mean (± standard deviation) estimated inter-compartment clearance was 0.74 (± 0.16) L/day.

Elimination
Following the recommended TEPEZZA dosing regimen, the population PK estimated mean (± standard deviation) for the clearance of teprotumumab-trbw was 0.27 (± 0.08) L/day and for the elimination half-life was 20 (± 5) days.

Metabolism
Metabolism of teprotumumab-trbw has not been fully characterized. However, teprotumumab-trbw is expected to undergo metabolism via proteolysis.

Specific Populations
No clinically significant differences in the pharmacokinetics of teprotumumab-trbw were observed following administration of TEPEZZA based on patient's age (18-80 years), gender, race/ethnicity (103 White, 10 Black, and 3 Asian), weight (46-169 kg), mild to moderate renal impairment (creatinine clearance 30 to 89 mL/min estimated by Cockcroft-Gault Equation), bilirubin levels (2.7-24.3 mcmol/L), aspartate aminotransferase (AST) levels (11-221 U/L), or alanine aminotransferase (ALT) levels (7-174 U/L). The effect of hepatic impairment on the pharmacokinetics of teprotumumab-trbw is unknown.

Drug Interactions
No studies evaluating the drug interaction potential of TEPEZZA have been conducted.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis
The carcinogenic potential of TEPEZZA has not been evaluated in long-term animal studies.

Mutagenesis
The genotoxic potential of TEPEZZA has not been evaluated.

Impairment of Fertility
Fertility studies have not been performed with TEPEZZA.

14 CLINICAL STUDIES

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). Patients were randomized to receive TEPEZZA or placebo in a 1:1 ratio. Patients were given intravenous infusions (10 mg/kg for first infusion and 20 mg/kg for the remaining 7 infusions) every 3 weeks for a total of 8 infusions. Patients had a clinical diagnosis of Thyroid Eye Disease with symptoms and were euthyroid or had thyroxine and free triiodothyronine levels less than 50% above or below normal

limits. Prior surgical treatment for Thyroid Eye Disease was not permitted. Proptosis ranged from 16 to 33 mm and 125 patients (73%) had diplopia at baseline.

A total of 84 patients were randomized to TEPEZZA and 87 patients were randomized to placebo. The median age was 52 years (range 20 to 79 years), 86% were White, 9% were Black or African-American, 4% were Asian and 1% identified as Other. The majority (73%) were female. At baseline, 27% of patients were smokers.

The proptosis responder rate at week 24 was defined as the percentage of patients with ≥2 mm reduction in proptosis in the study eye from baseline, without deterioration in the non-study eye (≥2 mm increase) in proptosis. Additional evaluations included signs and symptoms of Thyroid Eye Disease including pain, gaze evoked orbital pain, swelling, eyelid erythema, redness, chemosis, inflammation, clinical activity score and assessments of functional vision and patient appearance. Results for proptosis are found in Table 2.

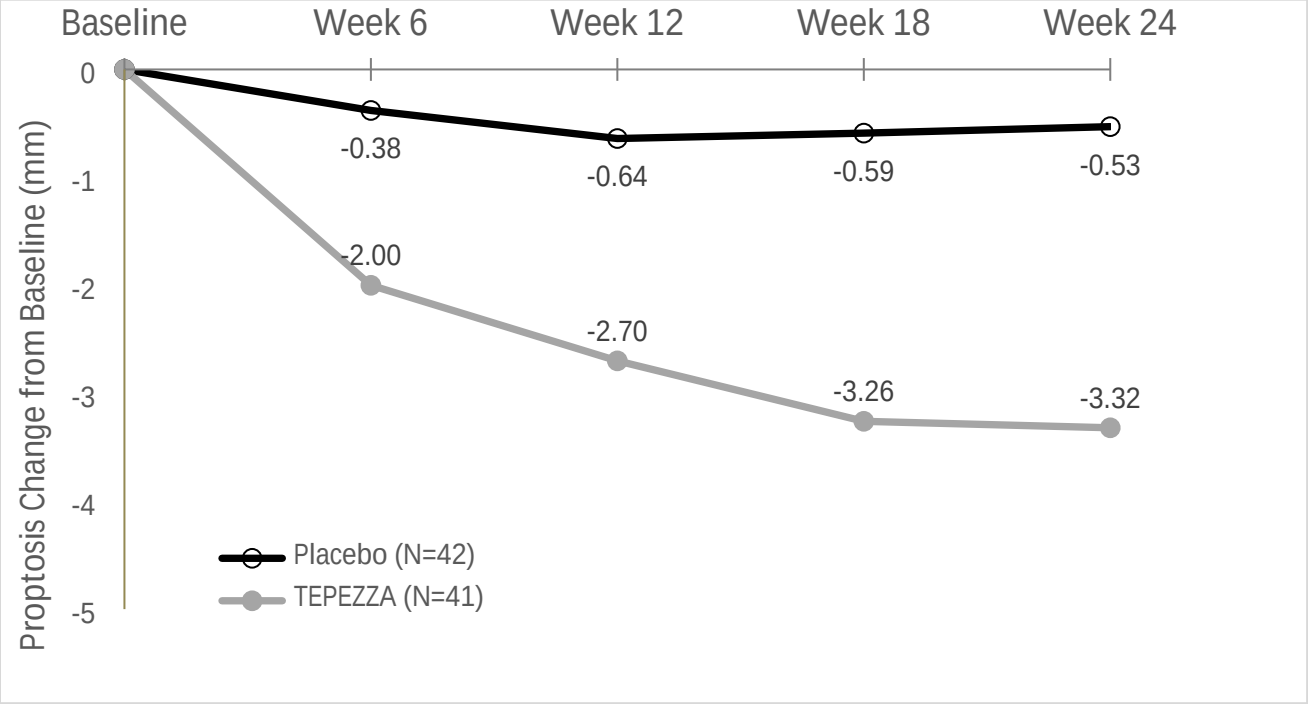
Table 2. Efficacy Results in Patients with Thyroid Eye Disease in Study 1 and 2

	Study 1			Study 2		
	Teprotumumab (N=42)	Placebo (N=45)	Difference (95% CI)	Teprotumumab (N=41)	Placebo (N=42)	Difference (95% CI)
Proptosis responder rate at week 24, % (n) [1]	71% (30)	20% (9)	51% (33, 69)	83% (34)	10% (4)	73% (59, 88)
Proptosis (mm) average change from baseline through week 24, LS Mean (SE) [2]	-2.5 (0.2)	-0.2 (0.2)	-2.3 (-2.8, -1.8)	-2.8 (0.2)	-0.5 (0.2)	-2.3 (-2.8, -1.8)

[1] Difference and its corresponding 95% Confidence Interval (CI) is based on a weighted average of the difference within each randomization stratum (tobacco user, tobacco non-use) using CMH weights.
[2] Results were obtained from an MMRM with an unstructured covariance matrix and including treatment, smoking status, baseline value, visit, treatment by visit, and visit by baseline value interaction as fixed effects. A change from Baseline of 0 was imputed at the first post-Baseline visit for any subject without a post-Baseline value.

In Study 2, improvement of proptosis as measured by mean change from Baseline was observed as early as 6 weeks and continued to improve through week 24 as shown in Figure 1. Similar results were seen in Study 1.

Figure 1. Change from Baseline in Proptosis over 24 Weeks in Study 2



P<0.01 at each timepoint

TEPEZZA also led to improvement in the less severely impacted "fellow" eye**.**

Diplopia (double vision) was evaluated in a subgroup of patients that had diplopia at baseline in Study 1 and 2. Results are shown in Table 3.

Table 3. Diplopia in Patients with Thyroid Eye Disease in Study 1 and 2

Parameter	TEPEZZA (n=66)	Placebo (n=59)
Diplopia Responder rate[a] at week 24, % (n)	53% (35)	25% (15)

P<0.01

[a] Diplopia was evaluated on a 4-point scale where scores ranged from 0 for no diplopia to 3 for constant diplopia. A diplopia responder was defined as a patient with baseline diplopia >0 and a score of 0 at week 24.

Following discontinuation of treatment in Study 1, 53% of patients (16 of 30 patients) who were proptosis responders at week 24 maintained proptosis response 51 weeks after the last TEPEZZA infusion. 67% of patients (12 of 18) who were diplopia responders at week 24 maintained diplopia response 51 weeks after the last TEPEZZA infusion.

Subgroups

Examination of age and gender subgroups did not identify differences in response to TEPEZZA among these subgroups. Reduction in proptosis was similar between smokers and non-smokers in both studies.

16 HOW SUPPLIED/STORAGE AND HANDLING

TEPEZZA (teprotumumab-trbw) for injection is a sterile, preservative-free, white to off-white lyophilized powder available as follows:

Carton containing one 500 mg single-dose vial	NDC 75987-130-15

Refrigerate at 2°C to 8°C (36°F to 46°F) in original carton until time of use to protect from light. Do not freeze.

17 PATIENT COUNSELING INFORMATION

Embryo-Fetal Toxicity

- Advise females of reproductive potential that TEPEZZA can cause harm to a fetus and to inform their healthcare provider of a known or suspected pregnancy.
- Educate and counsel females of reproductive potential about the need to use effective contraception prior to initiation, during treatment with TEPEZZA and for 6 months after the last dose of TEPEZZA.

Infusion-related reactions

- Advise patients that TEPEZZA may cause infusion reactions that can occur at any time. Instruct patients to recognize the signs and symptoms of infusion reaction and to contact their healthcare provider immediately for signs or symptoms of potential infusion-related reactions.

Exacerbation of Inflammatory Bowel Disease

- Advise patients on the risk of inflammatory bowel disease (IBD) and to seek medical advice immediately if they experience diarrhea, with or without blood or rectal bleeding, associated with abdominal pain or cramping/colic, urgency, tenesmus or incontinence.

Hyperglycemia

- Advise patients on the risk of hyperglycemia and, if diabetic, discuss with healthcare provider to adjust glycemic control medications as appropriate. Encourage compliance with glycemic control.

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EXHIBIT B
TEPEZZA® FDA APPROVED LABELING

EXHIBIT 3

FDA Transcript Excerpts

FOOD AND DRUG ADMINISTRATION

CENTER FOR DRUG EVALUATION AND RESEARCH

DERMATOLOGIC AND OPHTHALMIC DRUGS

ADVISORY COMMITTEE (DODAC)

Friday, December 13, 2019

8:01 a.m. to 3:22 p.m.

FDA White Oak Campus

White Oak Conference Center

Building 31, The Great Room

10903 New Hampshire Avenue

Silver Spring, Maryland

Meeting Roster

ACTING DESIGNATED FEDERAL OFFICER (Non-Voting)

Jay Fajiculay, PharmD

Division of Advisory Committee and

Consultant Management

Office of Executive Programs, CDER, FDA

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DR. YOO: David Yoo, associate professor of ophthalmology at Loyola University, director of oculoplastic surgery.

DR. BRITTAIN: Erica Brittain. I'm a statistician, National Institute of Allergy and Infectious diseases, NIH.

DR. WENG: Christina Weng, associate professor of ophthalmology at Baylor college of Medicine in Houston, Texas.

DR. MURRAY: Tim Murray, Miami Ocular Oncology and Retina.

DR. FAJICULAY: Jay Fajiculay, acting designated federal officer for the DODAC.

DR. CHODOSH: Jim Chodosh. I'm professor of ophthalmology at Harvard Medical School, Mass Eye and Ear.

DR. KING: Tonya King. I'm professor of biostatistics at Penn State College of Medicine.

DR. STAMLER: John Stamler, clinical instructor, University of Iowa, Iowa City.

The event was treated with IV steroids and antihistamines but not epinephrine. The event was noted as resolved approximately 2 hours after onset. Approximately 3 and a half hours post-dose, serum tryptase levels were normal. The patient withdrew from the study and was not rechallenged with study drug.

In all of these cases, patients were managed with symptomatic treatment and all resolved the same day without sequelae. One patient was able to receive the rest of the doses of study drug using premedication and a slower infusion rate. No patient received epinephrine.

Let's now look at hearing impairment. Literature suggests a 14 times increase in hearing impairment related to a diagnosis of Graves' disease. That said, there is an imbalance relative to placebo. The term "hearing impairment" here comprises a broad range of terms such as eustachian tube dysfunction, tinnitus, and deafness.

In the double-masked population, 8 patients treated with teprotumumab experienced events of

hearing impairment. Specifically, this included 3 cases from study 1. One patient has resolved, one was improving on last contact, and the third was noted as ongoing in a patient who had preexisting tinnitus related to loud-noise exposure. All cases in study 2 have resolved.

An additional 5 patients in OPTIC-X, who are ongoing in the study, have experienced events of hearing impairment. All of these have been graded as mild, and three have either fully or partially resolved to date, and the others are ongoing in the study.

All events were non-serious and were graded as mild or moderate in intensity. To date, the majority have resolved or improved, and most others are in an ongoing follow-up. Of the 13 patients with hearing impairment, 8 underwent audiology testing by judgment of the investigator, including all patients with events that the investigator considered to be of moderate intensity, and let's look at these in more detail.

The majority of patients' audiograms

revealed mild to moderate sensory neural hearing loss. The events of hearing impairments seen with teprotumumab do not appear progressive. There were 2 cases that were unilateral. While it's not definitive, it is unlikely that this is associated with ototoxicity from a systemically administered agent.

Four patients exhibited high frequency hearing loss. Ototoxicity typically begins in the frequencies above 8,000 hertz and later affects lower frequencies; however, this is also the pattern associated with age-related hearing loss. Although these data are confounded by hearing impairment that is associated with Graves' disease and advancing age, there is a clear numerical imbalance in the teprotumumab group relative to placebo.

Now, let's look at inflammatory bowel disease or IBD. In study 1, 2 patients experienced serious events related to inflammatory bowel disease. One was a serious adverse event of IBD exacerbation and the other was a serious adverse

minutes. Panel members, please remember there should be no discussion of the meeting topic during the break amongst yourselves or with any member of the audience, and we're going to reconvene at 10:20 a.m. For those panel members still hoping to ask questions, we have you on our list, and we'll get to them in the next bit. Thank you.

(Whereupon, at 10:05 a.m., a recess was taken.)

DR. CHODOSH: We're going to get started again. This meeting is back in order. If Dr. Weng would ask her question, please?

DR. WENG: Thank you very much for the introductory presentations. I just have two quick questions. The first is regarding the hearing-related adverse effects that were noted in approximately 10 percent of the study patients.

You showed us, Dr. Thompson, some of the adverse effects from the nine other oncology studies, but I didn't notice any hearing loss or tinnitus-related adverse events in those studies. Were those looked at, and were the proportions

similar?

My second question is in regard to the efficacy and outcomes here with teprotumumab. Were the outcomes stratified by initial CAS? For instance, if someone was more severe coming into the study, was that reflected in the amount of decrease in CAS or proptosis that was observed?

DR. THOMPSON: With respect to hearing in oncology, in 6 of 9 studies -- and actually I'll just project this -- there were adverse events of hearing impairment that were reported. These were generally actually at lower rates. Only one of the studies has a rate of 13 percent. In the other three studies, there were no hearing impairment events noted.

The caveat here is, of course, the fact that these patients have generally -- most of them have received prior chemotherapies, including platinum-based chemotherapy; so the nature of hearing impairment in these patients is a little difficult to understand, but it is here, though, at lower rates.

DR. CHODOSH: Dr. King?

DR. KING: Tonya King. Along with the question of potential safety concern with repeated courses of treatment, it sounds, based on hearing the stories of the patients in the public open session, that even the potential side effects of therapy that we've learned about don't compare to living with the disease, that sounds much worse than the potential side effects that could occur. This is something, as was mentioned, that we'll learn more from OPTIC-X and any potential long-term studies that can be done after approval.

DR. CHODOSH: If I can comment, I would like to say that the patient testimonies were very important. I think the data on muscle spasms not incurring at an increased rate, as the treatment progresses, is encouraging but can really only be applied to muscle spasms. I retain some concern -- I don't think that this is a quantifying concern -- about the side effects like loss of hearing, which obviously can have profound impact on those who have it.

Some would say that hearing loss is worse than blindness for some populations. So I think we have to keep those in mind. As I said, those aren't necessarily qualifying statements for me in terms of my decision about how to vote later in this meeting, but I think we shouldn't ignore those. I agree with what you said, that, clearly, having this disease is bad, to put it very simply, and it seems that the side effects might be less bad. Let's keep it simple.

Mary? Dr. Hartnett?

DR. HARTNETT: Thank you. I agree with what has been said. I just want to, as a comment, remember that this has only fewer the 90 patients, so I would hope that we continue to learn more and that a lot of effort is put forth to learn more about the potential side effects going forward.

DR. CHODOSH: Dr. Low Wang?

DR. LOW WANG: Thank you. I was so struck, as I think many of us are, by how well this drug works, and I think, of course, the safety database is incredibly limited. I agree with what's been

know, but theoretically, there might be a concern. I wonder how many patients there are with both diseases in the world. Probably very, very few. Any idea?

(No response.)

DR. CHODOSH: Okay. I think Dr. Stamler had a question.

DR. STAMLER: John Stamler. I'm a bit more concerned about hearing loss, and I wonder if we should monitor hearing, perhaps a hearing test, before treatment starts.

DR. CHODOSH: Other comments about that? Yes, Dr. Weng?

DR. WENG: Christina Weng. I agree with that comment. I think that was one of the adverse effects that I really noted; first of all, the stark difference between that and the placebo group. Second, it's much more specific than some of the adverse events that we see with other drugs, like fatigue, that are more generalizable and may not be attributable; so you really can't ignore that difference.

Not to mention that there was a proportion of patients that did not recover, at least during the observation period thus far, who are still dealing with impacts, even though they might be improving. So if there's a potential for irreversible change in one sense, I don't want to trade one sense for another sense, especially one that's very valuable to many people.

DR. CHODOSH: Thank you. Jim Chodosh. I'm going to recognize you, Dr. Chambers, in a second. It is, I think, a fair burden that audiology is a much more complex thing to request of every patient receiving the treatment than a blood test.

Dr. Chambers, can you comment?

DR. CHAMBERS: Wiley Chambers. I'm just playing devil's advocate. What would you do with the information; if you test somebody and they have hearing loss? As we've heard, there is some suggestion that people with thyroid disease may have a higher rate of hearing loss. Certainly as you get older, there are hearing loss issues.

Would you not treat them? Would you treat

them with a less dose? Would you treat them for a shorter period of time? What would you do? I'm concerned about putting things in label if you don't know what to do with it.

DR. CHODOSH: Dr. Weng?

DR. WENG: Christina Weng. I don't know that it would -- I think that's going to be left up to the provider and the patient. What I think is more important is that there is very discrete awareness that is shared with the patient in knowing what risk to take. I think all of us on an individual level are willing to take -- some of us are willing to take more risks than others. Depending on how severe the disease state is, I think that changes whether or not you would be willing to undergo that.

So I don't think it's a matter of monitoring so much as it is with the glucose issue. I think it's a matter of knowing that that's a possibility, so perhaps with the labeling.

DR. CHODOSH: Dr. Chambers?

DR. CHAMBERS: Wiley Chambers. So the usual

way we would do that would be to identify it either in the adverse reaction section of the label or in the precaution warning so that people are aware it's an event that's been associated, at least temporally, with the product, but not necessarily advocate testing or monitoring. But again, you've identified that it's a potential issue, and let the individual patient and physician decide what the appropriate plan is for that patient.

DR. CHODOSH: Dr. Brittain? Identify yourself.

DR. BRITTAIN: Just a quick comment. If the cases were 8 to 0, I think we have to feel pretty confident that that is not a chance finding, even if there's no understanding of why there would be an effect.

DR. CHODOSH: This is Jim Chodosh again. I'm not sure about that because the numbers are still very small, and if you flip a coin 10 times, you might get 8 hits, but I do think it's a major concern.

The question I would have -- I'm thinking

this through as we're talking about it -- would be what would you do with the patient who already has hearing loss, and would you worry about making it worse? I think that possibly the labeling could include extra precautions in patients who are already aware of hearing loss.

We don't know the mechanism. Assuming that it's a real effect, we don't know the mechanism. It would be really helpful to have some idea about the mechanism because, then, maybe we could predict if you had a certain type of hearing loss already, and you already had damage in some way, from a drug, from sound, from whatever the mechanism is and the problem, that you might be more susceptible or less susceptible. Maybe some patients with hearing loss have no risk with the drug and maybe some without hearing loss do.

So we don't really have enough information, but I think in the post-approval marketing phase, if it gets that far, it would be great to have some way to understand this because I think this hearing issue, if it turns out to be a real effect, could

be very important. I'm sure there's something there, some molecular explanation for this, and we'd want to know it at that point because there are many forms of hearing loss, and they have very distinct mechanisms.

We wouldn't want to dump all -- as an example, patients come in all the time and they want to know whether they can take a drug because they have glaucoma, when in reality, 90 percent of those patients have open-angle glaucoma, and the drug is associated with narrowing a glaucoma. So that specificity is important, however it would be decided to take care of that.

Dr. Low Wang had another comment.

DR. LOW WANG: Yes. Cecilia Low Wang. I was also struck by the incidence of hearing loss and muscle spasms. But I think that the question of monitoring versus not and doing baseline hearing tests, I don't know that that would help because we really don't know the time course, and we don't know the cause.

We don't know that if you have some hearing

loss at baseline, does that mean that you're more likely to get more hearing loss or it's more likely to worsen? We really don't know. If you have baseline tinnitus, does that increase your risk? We don't know that either. I think that if we did have those results, I think it would be hard to really use them.

I think just a strong caution on the label. I guess the one argument for patients with preexisting hearing loss is that if you already have some degree of hearing loss and you also get this and develop hearing loss, then you're losing more hearing, potentially. So I think that would be the one precaution there.

I think that from the information that we already have from the trials that have been done, I think those cases of hearing loss can be characterized further to try to answer this, at least preliminarily, and figure out what needs to be set on the label about hearing loss. I don't know that we've heard enough details today about the patients who are on the trial.

DR. CHODOSH: Ms. Schwartzott?

MS. SCHWARTZOTT: Jennifer Schwartzott. I agree that in the post-approval studies, they should follow the hearing loss and the tinnitus. But really, a hearing test is very easy, so to me, that would be a step that I would be willing to take if they did that before we started this treatment. I would not see a problem with that.

DR. CHODOSH: Jim Chodosh. It strikes me that if this drug were approved, there would be centers that would be interested in undertaking independent studies of hearing loss in treated patients, and that that could be done outside of the sponsor's responsibility, and probably would be of interest to independent investigators.

Dr. Murray had a question or a comment.

DR. MURRAY: Just to echo your comment, it seems that requiring hearing testing when we don't understand mechanism is really not appropriate at this point, but it would be nice to understand the mechanisms so that we could better target labeling going forward or better discussion with our

patients.

DR. CHODOSH: I summarized this already, but I will add that I think everybody thinks that hearing loss is potentially important. There were some differences of opinion in how that should be addressed. Whether it should be mandatory testing before the drug is given, I think was a minority opinion. But I think the majority felt that at some level, hearing should be studied, but whether that's the responsibility of the sponsor or the FDA, I didn't hear a consensus for that.

We're going to go to the next question. This is question number 3 for discussion. Please discuss whether the term "active" as used in the proposed indication is informative to clinicians and patients considering use of the product. I don't think we have questions about the wording, so we'll take comments from the committee.

Dr. Burman?

DR. BURMAN: Thank you. Ken Burman. The Clinical Activity Score, which I'm looking at now, takes into account symptoms, signs of eyelids, and

DR. CHODOSH: Dr. Hartnett?

DR. HARTNETT: Yes. I thought that the industry mentioned that even after the first infusion, there were episodes of hyperglycemia. I wonder if we know exactly when they occurred, and then it would be helpful to know when to actually test.

DR. CHODOSH: Thank you. Jim Chodosh. Dr. Chambers, perhaps a closer perusal of that data would be informing.

The next question of discussion, which I think some of which has been answered, is please discuss your level of concern with the episodes and frequency of reported: A, muscle spasms; B, hypoacusis/loss of hearing; C, diarrhea/inflammatory bowel disease; D, infection rate; E, alopecia.

We can take these in turn. Muscle spasms, any comments? Dr. Hartnett?

DR. HARTNETT: I was concerned about muscle spasms, and I felt there were some areas that I'd like more information. For example, if there was

patients read the labeling, when they do, and when physicians read it, they note that muscle spasms will occur more commonly in patients on the drug, or did in the trial, than those on the placebo, and I think that's enough. So I'll leave the summary for muscle spasms at that.

Then hyperacusis, loss of hearing, I heard more concern about ongoing, and I personally would elevate it into the second tier that you mentioned because I think people really should and do need to be aware of it.

For example, the prescribing physician I think needs to have a heightened awareness that hearing loss is still this -- again, particularly because we don't have a good characterization of the mechanism, this unknown-unknown, and to be sure to ask patients about it, and that patients who have hearing loss in the family or a preexisting hearing loss should know about this because it might influence their interest in participating in the study.

Again, if you take the extreme example of

someone who's barely active, if you want to use that word, and there's a question about whether they should receive the agent or not, and then they have preexisting hearing loss or a family history of hearing loss, they might say, "You know, maybe the symptoms I'm having are not that bad, and I don't want to take a chance on losing my hearing."

So my personal feeling is that it's potentially important, but we don't have enough information to elevate it to the third level, and I wouldn't do that at this point, personally.

Other comments? Dr. Brittain?

DR. BRITTAIN: I would just say I agree with you.

DR. CHODOSH: Thank you. Ms. Schwartzott?

MS. SCHWARTZOTT: What I will say is that these are things that are on pretty much most of my medications. These are on the list of symptoms, so it's nothing that we're going to be all that surprised at anyway.

DR. CHODOSH: It's a very good point. As a matter of fact, most systemic medications -- I

don't know. I've never done this survey, but I bet if you did, you could find a -- let's put it this way. A high proportion of medications in their labeling mention hearing loss because it's a common thing. So if during any trial a patient developed hearing loss on the drug, it's going to be listed if it's at any significant percentage.

DR. CHAMBERS: Move on.

DR. CHODOSH: Got it. The next one is diarrhea, inflammatory bowel disease. We heard earlier -- I think it was Dr. Burman who suggested that patients with inflammatory bowel disease not receive the therapy or perhaps that there should be a warning to those patients. I think if you're unlucky enough to have both thyroid eye disease and inflammatory bowel disease, I suspect that there would be a variety of responses.

Patients with inflammatory bowel disease are also miserable when their disease is active, and they might decide to -- again, when you're at the lower threshold of active for your thyroid eye disease, but at the higher threshold of activity

EXHIBIT 4

Table of Plaintiffs' Treatment Dates

Exhibit 4 - IN RE: TEPEZZA MARKETING, SALES PRACTICES, AND PRODUCTS LIABILITY LITIGATION MDL No. 3079

PLAINTIFFS' TREATMENT DATES

Caption	State of Residence	Pending Jurisdiction	Dates of TEPEZZA® Use
Donna Walker v. Horizon Therapeutics USA, Inc. Case No. 1:22-cv-06375	Arizona	N.D. Ill.	June 2020 through November 2020
Angela Simpson v. Horizon Therapeutics USA, Inc. Case No. 4:23-cv-00055	Georgia	M.D. Ga.	June 2020 through December 2020
Dan Weibel v. Horizon Therapeutics USA, Inc. Case No. 1:22-cv-04518	Arizona	N.D. Ill.	June 2020 through September 2020
Cynthia Williams v. Horizon Therapeutics USA, Inc. Case No. 1:22-cv-06838	Virginia	N.D. Ill.	November 2020 through June 2021
John Ingram v. Horizon Therapeutics USA, Inc. Case No. 1:22-cv-06836	Virginia	N.D. Ill.	December 2020 through August 2021
Karen Scott v. Horizon Therapeutics USA, Inc. Case No. 1:23-cv-00803	Alabama	N.D. Ill.	April 2021 through September 2021
John Fisher v. Horizon Therapeutics USA, Inc. Case No. 1:23-cv-00805	Pennsylvania	N.D. Ill.	April 2021 through September 2021
Lisa Nethery v. Horizon Therapeutics USA, Inc. Case No. 1:22-cv-05005	North Carolina	N.D. Ill.	June 2021 through July 2021
Gloria Pledger v. Horizon Therapeutics USA, Inc. Case No. 1:22-cv-06562	Maryland	N.D. Ill.	June 2021 through December 2021
Andrea Leeds v. Horizon Therapeutics USA, Inc. Case No. 1:22-cv-06837	New York	N.D. Ill.	July 2021 through October 2021
Rachel Snyder v. Horizon Therapeutics USA, Inc. Case No. 1:22-cv-06747	Kentucky	N.D. Ill.	July 2021 through December 2021

Exhibit 4 - IN RE: TEPEZZA MARKETING, SALES PRACTICES, AND PRODUCTS LIABILITY LITIGATION MDL No. 3079

PLAINTIFFS' TREATMENT DATES

Caption	State of Residence	Pending Jurisdiction	Dates of TEPEZZA® Use
Deborah Welch Klostermann v. Horizon Therapeutics USA, Inc. Case No. 1:23-cv-02160	Pennsylvania	N.D. Ill.	July 2021 through December 2021
Kimberly Exton v. Horizon Therapeutics USA, Inc. Case No. 6:23-cv-00282	New York	N.D.N.Y.	August 2021 through February 2022
Norma Diaz v. Horizon Therapeutics USA, Inc. Case No. 1:23-cv-00896	California	N.D. Ill.	November 2021 through April 2022
Lenda Krone v. Horizon Therapeutics USA, Inc. Case No. 1:23-cv-00069	Georgia	N.D. Ill.	January 2022 through June 2022
Kimberly Perez v. Horizon Therapeutics USA, Inc. Case No. 1:22-cv-06718	California	N.D. Ill.	April 2022 through June 2022
Karen Lucci v. Horizon Therapeutics USA, Inc. Case No. 1:22-cv-07351	Pennsylvania	N.D. Ill.	April 2022 through September 2022
Geri Kanesta-Rychner v. Horizon Therapeutics USA, Inc. Case No. 3:23-cv-05221	Washington	W.D.Wash.	April 2022 through September 2022
Margaret Lukowski v. Horizon Therapeutics USA, Inc. Case No. 5:23-cv-01159	California	N.D.Cal.	August 2022 through October 2022

BEFORE THE UNITED STATES JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

IN RE: TEPEZZA MARKETING, SALES PRACTICES, AND PRODUCTS LIABILITY LITIGATION	**MDL No. 3079**

PROOF OF SERVICE

Pursuant to Rule 4.1(a) of the Rules of Procedure for the United States panel on Multidistrict Litigation, I hereby certify that on April 14, 2023, the foregoing Response in Opposition to Plaintiff's Motion for Transfer and Coordination or Consolidation was electronically filed with the Clerk of Court using the CM/ECF filing system, which will provide service on all counsel of record.

/s/ Eric A. Riegner

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