### IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ILLINOIS EASTERN DIVISION

IN RE: TEPEZZA MARKETING, SALES PRACTICES, AND PRODUCTS LIABILITY LITIGATION

No. 1:23-cv-03568 MDL No. 3079

This Document Relates to All Cases

Judge Thomas M. Durkin

Chief Magistrate Judge M. David Weisman

# HORIZON THERAPEUTICS USA, INC.'S MEMORANDUM REGARDING INITIAL BELLWETHER TRIAL CASE SELECTION

# TABLE OF CONTENTS

BACK	KGROU	ND		2	
RECO	MMEN	IDATIO	ONS	3	
I.	Representativeness Methodology				
	A.	Data Analyzed for Purposes of Assessing Representativeness			
	B.	Representative Factors		5	
		1.	Timing of Infusions.	5	
		2.	Prescriber's Knowledge and Views About Tepezza®	6	
		3.	Full Course of Infusions.	7	
		4.	Benefits from Tepezza®	8	
		5.	Nature and Severity of Alleged Injury	9	
		6.	Plaintiff's Gender	10	
		7.	Plaintiff's Age	11	
II.	Summaries of the Eleven Remaining Initial Bellwether Discovery Cases				
	A.	Horizon's Proposed Initial Bellwether Trial Cases			
		1.	Gloria Pledger (Case No. 1:22-CV-06562) (Random selection)	11	
		2.	Amarilis Polanco (Case No. 1:23-CV-02503) (Horizon selection)	14	
		3.	Consuelo Egger (Case No. 1:23-CV-15306) (PLC selection)	16	
		4.	Geri Kanesta-Rychner (Case No. 1:23-CV-03575) (PLC selection)	18	
	B.	Less Representative Cases for Consideration if Necessary			
		1.	Sara Perkett (Case No. 1:23-CV-15994) (Horizon selection)	21	
		2.	Sara Meilleur (Case No. 1:23-CV-15501) (Horizon selection)	23	
		3.	Peter Chryssos (Case No. 1:23-CV-03033) (PLC selection)	26	
	C.	Nonrepresentative Outlier Cases That Should Be Excluded from Consideration 29			
		1.	Rebecka Meyers (Case No. 1:23-CV-03585) (PLC selection)	29	

## Case: 1:23-cv-03568 Document #: 291 Filed: 01/17/25 Page 3 of 43 PageID #:8831

2.	Joseph Ford (Case No. 1:23-CV-02703) (Random selection)	32
3.	Richard Stern (Case No. 1:23-CV-02659) (Random selection)	. 34
4.	Brooke Bounds (Case No. 1:23-CV-06423) (Random selection)	37
CONCLUSION		4(

The goal of the bellwether process is to advance to trial cases that are "representative of the entire class of plaintiffs" to serve as a "roadmap to help resolve the remainder of the cases." Hr'g Tr. 18:2-8 (Mar. 20, 2024) (ECF No. 134) (J. Durkin). With that goal in mind, Horizon Therapeutics USA, Inc. ("Horizon") selected seven objective criteria to identify representative cases in this MDL: (1) the timing of plaintiff's Tepezza® infusions; (2) whether plaintiff's prescriber's knowledge about Tepezza® at the time of prescription was typical among prescribers; (3) whether plaintiff completed a full course of eight Tepezza® infusions; (4) the benefits plaintiff received from Tepezza® treatment; (5) the severity and type of hearing impairment experienced by plaintiff allegedly due to Tepezza®; (6) plaintiff's gender; and (7) plaintiff's age. Based on analysis of available data across MDL cases, Horizon determined the most representative plaintiff is a female, over the age of 50, who started a full course of Tepezza® within nine months of August 2021, received benefits from Tepezza<sup>®</sup>, and experienced mild to moderate sensorineural hearing loss and tinnitus allegedly caused by Tepezza<sup>®</sup>. Further, she will have been prescribed Tepezza<sup>®</sup> by a physician whose knowledge and views about Tepezza®, including its benefits and risks, were typical among prescribers at the time.

Applying this analysis to the Initial Bellwether Discovery Cases, pursuant to Case Management Order No. 3 (ECF No. 69) ("CMO No. 3"), Horizon has identified the **Pledger**, **Polanco**, **Egger**, **and Kanesta-Rychner** cases as most representative, and recommends they proceed as the Initial Bellwether Trial Cases. Horizon additionally addresses the representativeness, or lack thereof, of the remaining seven Initial Bellwether Discovery Cases.<sup>2</sup> Of

<sup>&</sup>lt;sup>1</sup> A summary table outlining the representative data points for the Initial Bellwether Discovery Cases is attached as Exhibit A, Appendix 1, Initial Bellwether Discovery Case Selection Representativeness Factors).

<sup>&</sup>lt;sup>2</sup> CMO No. 3, Section V dictates that the individual plaintiff summaries shall not exceed three pages. The Parties agreed that the memoranda shall not exceed 40 pages to allow for an introduction.

those cases, Horizon urges the Court to conclude that *Meyers*, *Ford*, *Stern*, and *Bounds* are not representative and to exclude them from consideration for a bellwether trial.

### BACKGROUND

The claims in this MDL are brought by Thyroid Eye Disease ("TED") patients alleging Horizon failed to warn of permanent hearing loss and/or tinnitus associated with the use of Tepezza®, a biologic medication "which treats thyroid eye disease." *See* Transfer Order (ECF No. 1). TED is an incapacitating autoimmune disorder characterized by inflammation in the muscles and tissues surrounding the eye, leading to symptoms of proptosis (bulging eyes), diplopia (double vision), eyelid retraction, eye pain, eye redness and swelling, among others. Approved by the Food and Drug Administration ("FDA") in January 2020, Tepezza® is the first and only FDA-approved medication specifically indicated for TED.<sup>3</sup>

Pursuant to CMO No. 3, which governs the bellwether selection process for discovery and trial, an initial pool of 69 bellwether-eligible cases was identified, from which the parties each selected four cases "representative of the body of then-filed cases as a whole," and randomly selected four additional cases, for a total of 12 "Initial Bellwether Discovery Cases." *See* CMO No. 3 § III(F). The parties have engaged in extensive "core" fact discovery in these 12 cases. On October 28, 2024, the Court granted Horizon's motion to dismiss the *Merriweather* case, leaving eleven Initial Bellwether Discovery Cases. Mem. Op. and Order (ECF No. 246). Now, with the

<sup>&</sup>lt;sup>3</sup> See First. Am. Compl. ("FAC") ¶ 42, Chryssos v. Horizon, No. 1:23-cv-03033 (N.D. III. Feb. 29, 2024) (ECF No. 12).

<sup>&</sup>lt;sup>4</sup> The parties selected their four cases based upon a review of each plaintiff's Plaintiff Profile Form ("PPF") and medical records collected pursuant to CMO No. 3.

<sup>&</sup>lt;sup>5</sup> The random selection group was selected by Google's random generator. See CMO No. 3 § III(C)

<sup>&</sup>lt;sup>6</sup> On January 13, 2025, the Court dismissed the Initial Bellwether Discovery plaintiffs' design defect claims. *See* Mem. Op. & Order at 16-23 (ECF No. 288). The Court also dismissed in part the fraudulent misrepresentation claims brought by plaintiffs Chryssos, Egger, Meyers, and Stern, as well as plaintiff Ford's fraud claim in full. *See id.* at 24-30.

benefit of core fact discovery and the parties' bellwether trial selection briefing, the Court will select four of the remaining eleven cases to proceed through supplemental fact discovery, expert discovery, dispositive motions, and toward trial. CMO No. 3 § VII.<sup>7</sup>

### RECOMMENDATIONS

Horizon recommends the following cases to proceed toward trial as most representative of the entire class of plaintiffs in this MDL, in the following order:

- (1) Gloria Pledger (Case No. 1:22-CV-06562);
- (2) Amarilis Polanco (Case No. 1:23-CV-02503);
- (3) Consuelo Egger (Case No. 1:23-CV-15306); and
- (4) Geri Kanesta-Rychner (Case No. 1:23-CV-03575).

As detailed below, all four cases meet objective criteria for representativeness, involve core facts typical of all cases in this MDL, and do not involve non-representative, case-specific ancillary facts that would distract from the key issues in this MDL. Horizon's four recommended cases include one case randomly selected for Initial Bellwether Discovery (*Pledger*), one case initially selected by Horizon (*Polanco*), and two cases initially selected by the PLC (*Egger* and *Kanesta-Rychner*). Horizon suggests that *Pledger* proceed to trial first because it satisfies all seven representative factors and presents more cross-cutting issues than other cases, all of which will best aid the Court and the parties in assessing the entire MDL inventory.

In the event the Court selects a case outside the four recommended by Horizon, the Court should consider cases that, while less representative than Horizon's proposed Initial Bellwether Trial Cases, are not significant outliers. These less representative cases are:

<sup>&</sup>lt;sup>7</sup> This Section, starting on page 6, is inadvertently referred to as Section V in CMO No. 3.

<sup>&</sup>lt;sup>8</sup> Horizon has not consented to a *Lexecon* waiver in *Kanesta-Rychner*, which was filed in the U.S. District Court for the Western District of Washington (Tacoma). *See* CMO No. 3 § IV.

- (1) Sara Perkett (Case No. 1:23-CV-15994);
- (2) Sara Meilleur (Case No. 1:23-CV-15501); and
- (3) Peter Chryssos (Case No. 1:23-CV-03033).

The remaining four cases are significant outliers in this MDL that should not be considered for bellwether trials. Each of these cases fails to meet the majority of representative factors and involves outlier ancillary facts that would not help resolve issues common to all cases in the MDL:

- (1) Rebecka Meyers (Case No. 1:23-CV-03585);
- (2) Joseph Ford (Case No. 1:23-CV-02703);
- (3) Richard Stern (Case No. 1:23-CV-02659); and
- (4) Brooke Bounds (Case No. 1:23-CV-06423).

As shown below, *Meyers, Ford, Stern*, and *Bounds* have numerous distinguishing features making them outliers that should be removed from consideration for bellwether trial selection.

### I. Representativeness Methodology

### A. Data Analyzed for Purposes of Assessing Representativeness

To determine which cases are representative, Horizon considered information and data from four sources: (1) the 12 Initial Bellwether Discovery Cases; (2) PPFs and medical records of the remaining bellwether-eligible plaintiffs; (3) PPFs of the remaining plaintiffs in this MDL who, to date, have submitted one<sup>9</sup>; and (4) data regarding the background population of TED patients in the United States.<sup>10</sup> The 12 Initial Bellwether Discovery Cases have the most data points available,

<sup>&</sup>lt;sup>9</sup> As of the date of this filing, 213 cases have been filed, of which 205 have been served on Horizon, and 201 have provided Horizon with a PPF. While three of these 213 cases have been dismissed, they remain included for purposes of the information and data considered.

<sup>&</sup>lt;sup>10</sup> The data and characteristics regarding the background population of TED patients in the United States exists in published scientific literature cited throughout the briefing.

including completed PPFs and Plaintiff Fact Sheets ("PFSs"),<sup>11</sup> substantial medical records, and physician and plaintiff depositions conducted during core fact discovery,<sup>12</sup> but the entire MDL inventory was useful in generating data to evaluate representativeness.<sup>13</sup>

For each of the Initial Bellwether Discovery Cases, Horizon categorized the data from these sources into seven "representative factors," described in detail in Section I.B. below. In Section II, Horizon applies these representative factors to each of the remaining eleven Initial Bellwether Discovery Cases.

### **B.** Representative Factors

The below objective criteria, based on representative trends or key case characteristics among the MDL plaintiffs, are critical to identifying representative bellwether trial cases.<sup>14</sup> Each of the seven factors outlined below provides a touchstone for the representative analysis.

### 1. Timing of Infusions

While the first page of Tepezza®'s FDA-approved label always warned about hearing impairment as a potential adverse effect, this MDL—like any pharmaceutical failure-to-warn case—takes place against a backdrop of an evolving medical understanding regarding the alleged injury of "severe and permanent hearing impairment and/or tinnitus." *See, e.g., Chryssos* FAC ¶

 $<sup>^{11}</sup>$  Only the 12 Initial Bellwether Discovery plaintiffs were required to complete PFSs, which provide more fulsome data. See CMO No. 3  $\S$  VI.B.

<sup>&</sup>lt;sup>12</sup> Horizon deposed 11 plaintiffs and 38 treating physicians in the Initial Bellwether Discovery Cases, including 12 physicians who prescribed Tepezza<sup>®</sup>. *See* CMO No. 3 § VI.D. The plaintiff in *Merriweather* was not deposed because that case was dismissed before her scheduled deposition.

<sup>&</sup>lt;sup>13</sup> While Horizon engaged in extensive collection of medical records for the 69 cases eligible for selection as Initial Bellwether Discovery Cases and utilized that data in assessing representativeness, information on the 57 cases not selected as Initial Bellwether Discovery Cases remains limited to PPFs and medical more limited records. PPF deficiency review and medical records collection for non-bellwether-eligible cases, which continue to be filed, is ongoing.

<sup>&</sup>lt;sup>14</sup> See Alexandra D. Lahav, *Bellwether Trials*, 76 GEO. WASH. L. REV. 576, 606 (2008) (representative factors provide for "obvious and objective means for determining the parameters of the group that will be subject to extrapolation").

12. Plaintiffs' theory of liability in this MDL depends on what Horizon knew at the time each plaintiff received his or her Tepezza® infusions. Given the median date for the first infusion of Tepezza® among the bellwether-eligible cases is August 23, 2021, 15 a plaintiff receiving Tepezza® infusions substantially before or after that date would not be representative. Horizon proposes Initial Bellwether Trial Cases where the first Tepezza® infusions were within 9 months of the median date for the bellwether-eligible plaintiffs; two plaintiffs had their first infusions before the median and two after. 16 The following plaintiffs had first infusion dates outside that range: Bounds (December 2022; 16.1 months after), Meyers (April 2020; 16 months earlier), Meilleur (July 2022; 10.9 months after), and Chryssos (June 2022; 10.1 months after).

### 2. <u>Prescriber's Knowledge and Views About Tepezza®</u>

The prescribing physician's testimony will be central to any bellwether trial in this litigation. These physicians will provide the context for the jury's assessment of the potential risks and benefits of Tepezza® and otherwise play the critical role of the learned intermediary. A representative case will involve a prescriber with a typical understanding and knowledge about

<sup>&</sup>lt;sup>15</sup> See App. 5, Plaintiffs Eligible As Initial Bellwether Discovery Cases (Ex. A). Horizon relies on the median date among the bellwether-eligible cases rather than all MDL plaintiffs because Horizon cannot confirm infusion dates without the infusion records, which are not yet available for many of the non-bellwether-eligible cases. Prior medical record review for the bellwether-eligible cases revealed that infusion dates listed in complaints and PPFs can be inaccurate. For context, however, the median first Tepezza<sup>®</sup> infusion date among the Initial Bellwether Discovery Cases is March 31, 2022. See App. 1 (Ex. A). Plaintiffs Egger, Kanesta-Rychner, and Perkett all received their first Tepezza<sup>®</sup> infusion within one month of that date. The median first Tepezza<sup>®</sup> infusion date among all plaintiffs from whom PPFs have been received is January 25, 2022. See App. 6, Total Case Inventory (Ex. A).

<sup>&</sup>lt;sup>16</sup> The following are the differences between the first infusion dates of Horizon's proposed Initial Bellwether Trial Cases and the median date for bellwether-eligible plaintiffs: Pledger: 1.3 months before; Polanco: 3.4 months before; Egger: 7.3 months after; Kanesta-Rychner: 8.2 months after.

<sup>&</sup>lt;sup>17</sup> Under the learned intermediary doctrine, a failure-to-warn claim concerning a prescription medication cannot succeed when a physician prescribed plaintiff with an awareness of the risk that plaintiff alleges the defendant did not properly disclose. *See Brooks v. Merck & Co.*, 443 F. Supp. 2d 994, 999 (S.D. Ill. 2006) (applying Illinois law).

Tepezza<sup>®</sup>. Prescribing physicians in all 12 Initial Bellwether Discovery Cases testified to an awareness of the potential for hearing impairment when he or she prescribed Tepezza<sup>®</sup> to the plaintiff. Prescribers also consistently testified that Tepezza<sup>®</sup> effectively treats TED, which previously had limited, if any, effective treatment options. To help assess the representativeness of a prescriber's knowledge and views about Tepezza<sup>®</sup>, counsel for Horizon developed a composite Tepezza<sup>®</sup> prescriber knowledge score based on how they testified regarding nine key issues, with one point assigned for each positive response. Pee App. 2, Prescriber Knowledge (Ex. A). The median score is 8/9. See App. 1 (Ex. A). The only prescribing physicians who scored 6/9 or lower are those for plaintiffs Ford (3/9), Meyers (6/9), and Stern (6/9). Id. Cases with an atypical prescriber will not further the parties' understanding of the overall case inventory.

### 3. Full Course of Infusions

The dosing regimen approved by the FDA and included on the FDA-approved label from Tepezza®'s launch through present is eight infusions spaced three weeks apart.<sup>20</sup> The substantial majority of bellwether-eligible plaintiffs (72%) received all eight infusions. Cases presenting an

<sup>&</sup>lt;sup>18</sup> Prescribing physicians also required plaintiffs, prior to starting treatment, to sign Tepezza<sup>®</sup> Patient Enrollment Forms that referenced the potential for hearing impairment. *See e.g.*, Plaintiff Kanesta-Rychner Exhibits (Ex. F), Tepezza<sup>®</sup> Patient Enrollment Form, 565542.003-Allenmore Ambulatory Infusion Suite pgs. 1892-1893 (Feb. 17, 2022).

<sup>&</sup>lt;sup>19</sup> These issues are whether the prescribers testified that: (1) Tepezza<sup>®</sup> treats the root cause of TED; (2) Tepezza<sup>®</sup> changed the treatment paradigm for TED; (3) Tepezza<sup>®</sup> is currently the standard of care treatment for TED; (4) Tepezza<sup>®</sup> was the best treatment option when they prescribed to plaintiffs; (5) prescriber was aware of the risk of permanent and severe hearing impairment with Tepezza<sup>®</sup> at time of prescription; (6) prescriber discussed the possibility of hearing impairment with plaintiff; (7) prescriber monitored plaintiff's hearing while on Tepezza<sup>®</sup>; (8) a warning on the label regarding permanent and severe hearing impairment would not have changed prescriber's decision to prescribe Tepezza<sup>®</sup> to plaintiff; and (9) prescriber still prescribes Tepezza<sup>®</sup> through present.

<sup>&</sup>lt;sup>20</sup> See Drug Label for Tepezza<sup>®</sup>, U.S Food & Drug Admin. (Jan. 2020), <a href="https://www.accessdata.fda.gov/drugsatfda\_docs/label/2020/761143s000lbl.pdf">https://www.accessdata.fda.gov/drugsatfda\_docs/label/2020/761143s000lbl.pdf</a>; Drug Label for Tepezza<sup>®</sup>, U.S Food & Drug Admin. (July 2023), <a href="https://www.accessdata.fda.gov/drugsatfda">https://www.accessdata.fda.gov/drugsatfda</a> docs/label/2023/761143s023lbl.pdf.

incomplete course of Tepezza<sup>®</sup> would not allow the jury to fully assess the benefits of the FDA-approved treatment regimen, and the facts and circumstances surrounding the stopping of treatment may distract from the issues central to the MDL. Plaintiffs Ford, Meyers, and Chryssos are non-representative because they did not complete a full course of Tepezza<sup>®</sup>.

### 4. Benefits from Tepezza<sup>®</sup>

When making a prescribing decision, a doctor must weigh the potential risks of a medication against its potential benefits. *See, e.g., Robinson v. Ortho-McNeil Pharm., Inc.*, 533 F. Supp. 2d 838, 841 (S.D. Ill. 2008) (prescribing physicians are tasked with "weighing the benefits of any medication against its potential dangers") (quoting *Kirk v. Michael Reese Hosp. & Med. Ctr.*, 513 N.E.2d 387, 392 (Ill. 1987)). Depositions revealed that Tepezza® provided most Initial Bellwether Discovery plaintiffs with substantial and lasting benefits for their TED symptoms. To help assess the representativeness of a plaintiff's Tepezza® benefits, counsel for Horizon developed a composite benefits score based on prescriber testimony and medical records of the Initial Bellwether Discovery plaintiffs, with one point assigned for each factor, for a total of four points. *Prepara Benefits* (App. 3) (Ex. A). A plaintiff who did not obtain representative benefits from Tepezza® would present the jury with nonrepresentative facts when evaluating the potential risks versus benefits of using Tepezza®. The average and most common Tepezza® benefits score is 3/4. *See* App. 1 (Ex. A). The only plaintiffs who scored lower than 3/4 are Bounds (2/4), Ford (1/4), and Stern (1/4). *Id.* 

These Tepezza® benefits factors are: (1) prescriber testimony and medical records evidencing an improvement in TED symptoms; (2) prescriber testimony and medical records evidencing lasting TED benefits through present; (3) plaintiff did not require any TED surgical procedures post-Tepezza®; and (4) plaintiff did not require any corticosteroid treatment post-Tepezza®.

### 5. Nature and Severity of Alleged Injury

A bellwether trial plaintiff with atypical hearing impairment increases the risk of an inflated (and non-representative) damages award. Medical records and PPFs show that more than 90% of the bellwether-eligible plaintiffs have sensorineural hearing loss with a pure-tone average ("PTA") ranging from slight to moderately severe hearing loss, and the median plaintiff having mild hearing loss. <sup>22</sup> See App. 4, Plaintiff Audiogram Data (Ex. A). Only 3.5% bellwether-eligible plaintiffs have less hearing loss (*i.e.*, "normal" hearing), and only 3.5% have more hearing loss (*i.e.*, "severe" or "profound"). *Id.* PTA is a type of audiometry that provides an average of a plaintiff's hearing across multiple frequencies, but hearing specialists in the Initial Bellwether Discovery Cases often characterized plaintiffs' hearing based only upon the frequency with the worst level of hearing loss. Measured by the worst frequency in either ear,

See App. 1 (Ex. A). A large majority of plaintiffs—78% of the 69 bellwether-eligible plaintiffs and 80% of all plaintiffs—also report some other form of hearing impairment, mostly tinnitus. See App. 4 (Ex. A). Additionally, 71% of the bellwether-eligible plaintiffs and 75% of the Initial Bellwether Discovery Cases do not utilize

<sup>&</sup>lt;sup>22</sup> PTA is a method commonly used in epidemiological studies, whereby a patient's hearing threshold at four frequencies (500, 1000, 2000, and 4000 Hz) are averaged to assess a patient's overall hearing. George Gates & Howard Hoffman, *What the Numbers Mean: An Epidemiological Perspective on Hearing*, Nat'l Inst. on Deafness and Other Comme'n Disorders, <a href="https://www.nidcd.nih.gov/health/statistics/what-numbers-mean-epidemiological-perspective-hearing">https://www.nidcd.nih.gov/health/statistics/what-numbers-mean-epidemiological-perspective-hearing</a> (Sept. 13, 2011). Medical records show that 17% of bellwether-eligible plaintiffs have no audiometric testing record to determine the severity or extent of their hearing impairment after finishing their Tepezza® infusions, so Horizon has excluded them from the calculations. Horizon characterizes the degree of plaintiffs' hearing loss using a common, recognized scale: normal hearing (-10 to 15 dB); slight hearing loss (16 to 25 dB); mild hearing loss (26 to 40 dB); moderate hearing loss (41 to 55 dB); moderately severe hearing loss (56 to 70 dB); severe hearing loss (71 to 90 dB); and profound hearing loss (greater than 90 dB). *See Degree of Hearing Loss*, Am. Speech-Language-Hearing Ass'n, https://www.asha.org/public/hearing/degree-of-hearing-loss/ (last visited Jan. 13, 2025) (citing J.G. Clark, Uses and abuses of hearing loss classification, 23 ASHA 493 (1981)).

hearing aids for their alleged hearing impairment. *Id*.

Given that most alleged injuries involve slight to mild hearing impairment, the representative impact on plaintiffs, including any economic damages, is likely *de minimis*. For example, out of the 12 Initial Bellwether Discovery Cases, six plaintiffs still work, while five plaintiffs retired before starting Tepezza® and only one plaintiff—Meyers—retired after Tepezza®, alleging her hearing impairment was the primary factor leading to her retirement. *See* App. 5 (Ex. A). Meyers is also the only Initial Bellwether Discovery plaintiff seeking to recover lost wages.

Bellwether cases involving plaintiffs who have mild to moderately severe sensorineural hearing loss and tinnitus, and plaintiffs who do not bring a lost wages claim would be most useful in valuing the remaining inventory of claims.

### 6. Plaintiff's Gender

The prevalence and severity of a patient's TED is significantly influenced by the patient's gender. Women have a five-times higher incidence of TED than men.<sup>23</sup> Women similarly comprise a large majority—72%—of the 69 bellwether-eligible plaintiffs. *See* App. 5 (Ex. A). Men tend to develop more severe TED than women and develop it at a later point in life.<sup>24</sup> Because TED's prevalence and severity are gender-dependent, a female plaintiff is most representative. As men, plaintiffs Ford, Stern, and Chryssos are not the most representative plaintiffs.

<sup>&</sup>lt;sup>23</sup> Colm McAlinden, *An Overview of Thyroid Eye Disease*, 1 Eye and Vision 9, 1 (2014) ("The incidence of TED is 16 per 100,000 females and 2.9 per 100,000 males....").

<sup>&</sup>lt;sup>24</sup> See id.; Kavoussi et al., The Relationship Between Sex and Symmetry in Thyroid Eye Disease, Clinical Ophthalmology 1295, 1297 (2014) ("Although TED is more frequent in women, the female-to-male ratio is reversed at 1:4 in severe disease."); see also Plaintiff Peter Chryssos Exhibits (Ex. H), Dr. Schloss Dep. 74:8-11 (Oct. 28, 2024) (prescriber testifying to disease severity in men).

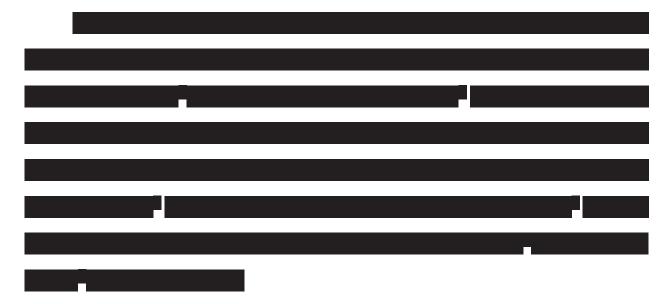
### 7. Plaintiff's Age

Age is the strongest risk factor for hearing impairment,<sup>25</sup> and TED is typically diagnosed in a patient's fifties.<sup>26</sup> 93% of all MDL plaintiffs are over the age of 50.<sup>27</sup> See App. 6 (Ex. A). Selecting an outlier plaintiff under the age of 50 is not representative and would not assist in evaluating other MDL cases. Ms. Bounds is one of thirteen plaintiffs (6%) in the MDL under age 50—and the second youngest overall—and should be excluded on that basis (among numerous others). *Id*.

### II. Summaries of the Eleven Remaining Initial Bellwether Discovery Cases

### A. Horizon's Proposed Initial Bellwether Trial Cases

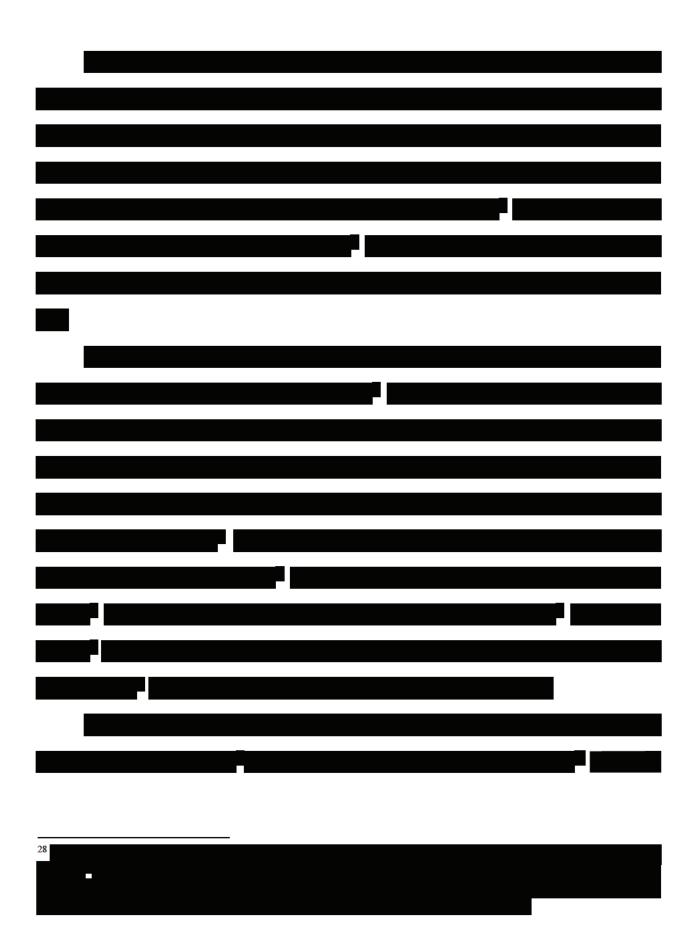


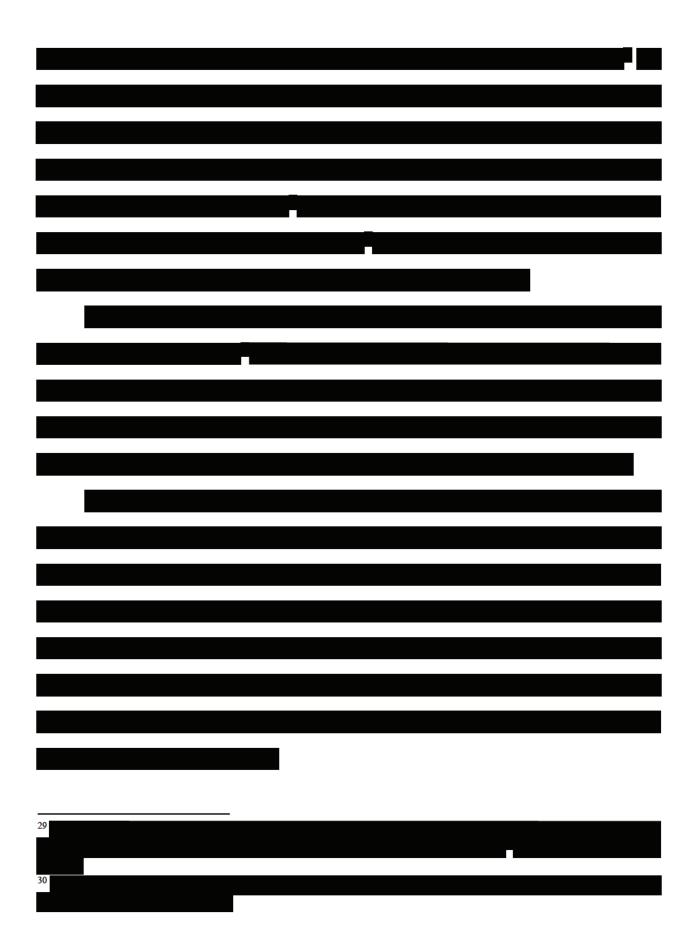


<sup>&</sup>lt;sup>25</sup> See Paul Mitchell et al., Five-Year Incidence and Progression of Hearing Impairment in an Older Population, 32 Ear and Hearing 251, 255-256 (Mar.-Apr. 2011).

<sup>&</sup>lt;sup>26</sup> Richard C. Allen, *In the US, gender, age, ethnicity, and other factors influence TED prevalence rates*, Am. Acad. of Ophthalmology (Sept. 26, 2023), <a href="https://www.aao.org/education/editors-choice/in-us-gender-age-ethnicity-other-factors-influence">https://www.aao.org/education/editors-choice/in-us-gender-age-ethnicity-other-factors-influence</a> (noting the age group with highest prevalence rate was 50 to 54 years old).

<sup>&</sup>lt;sup>27</sup> The average plaintiff age across all MDL cases and bellwether-eligible cases, respectively, is 64 and 65 years old.

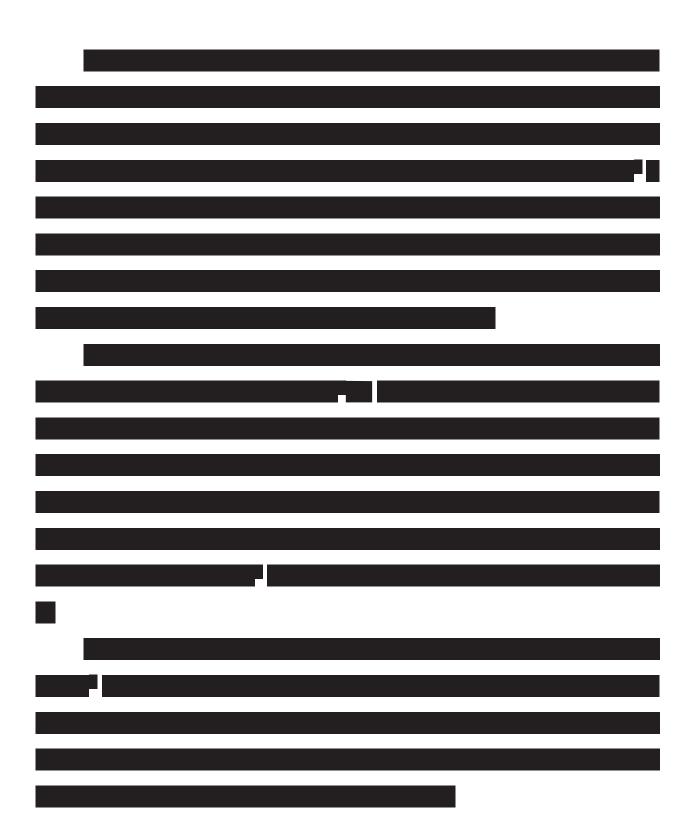


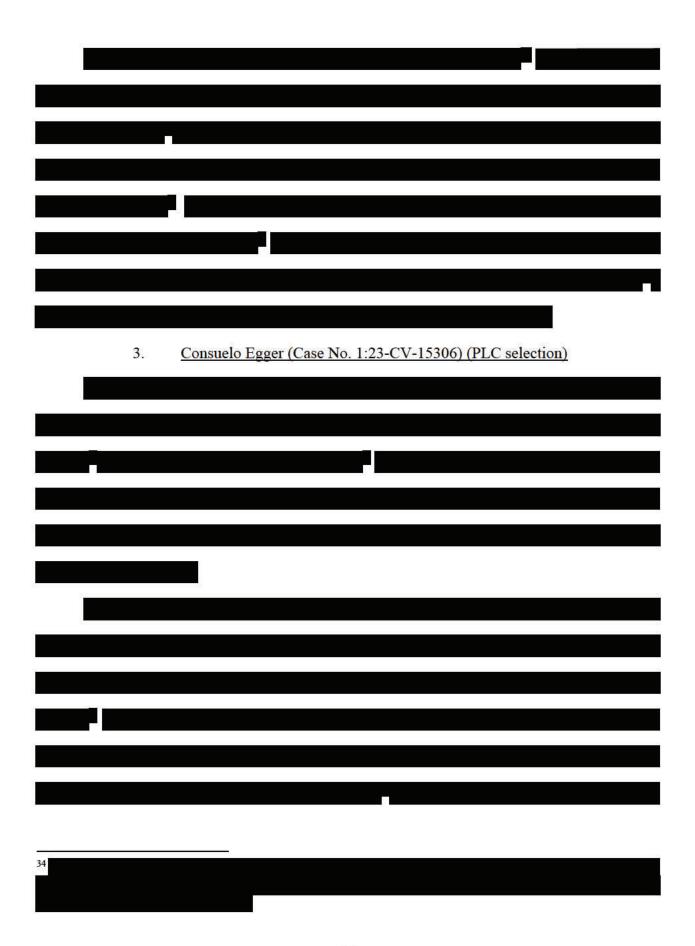




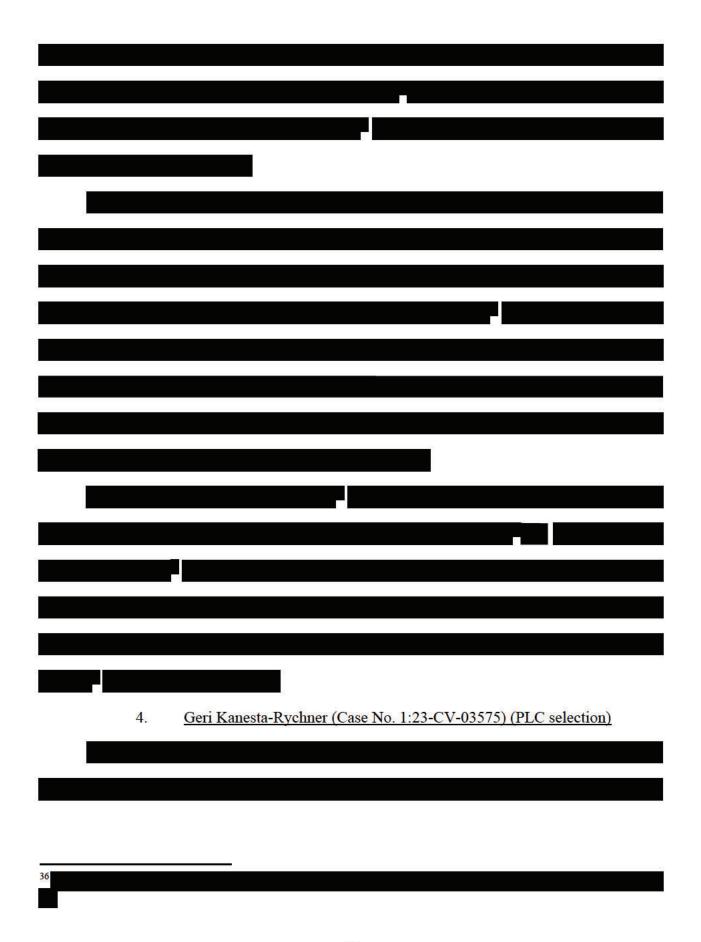


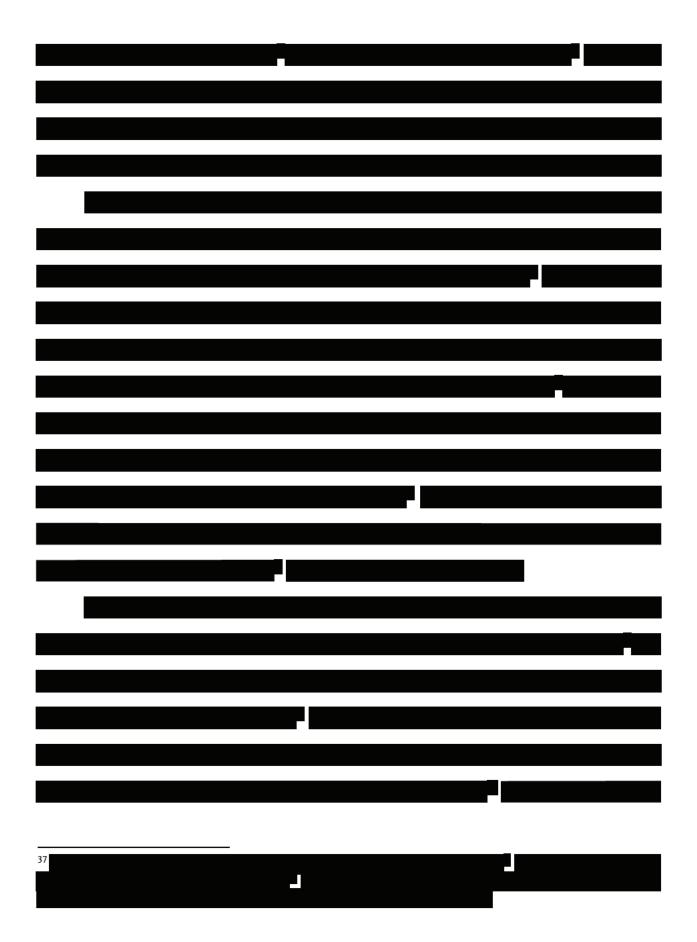








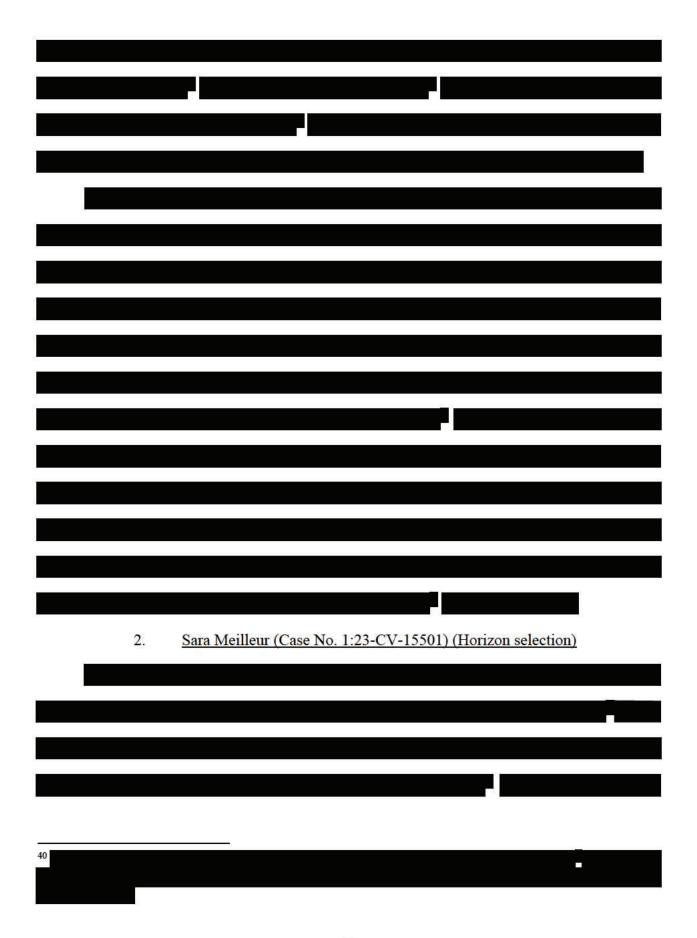




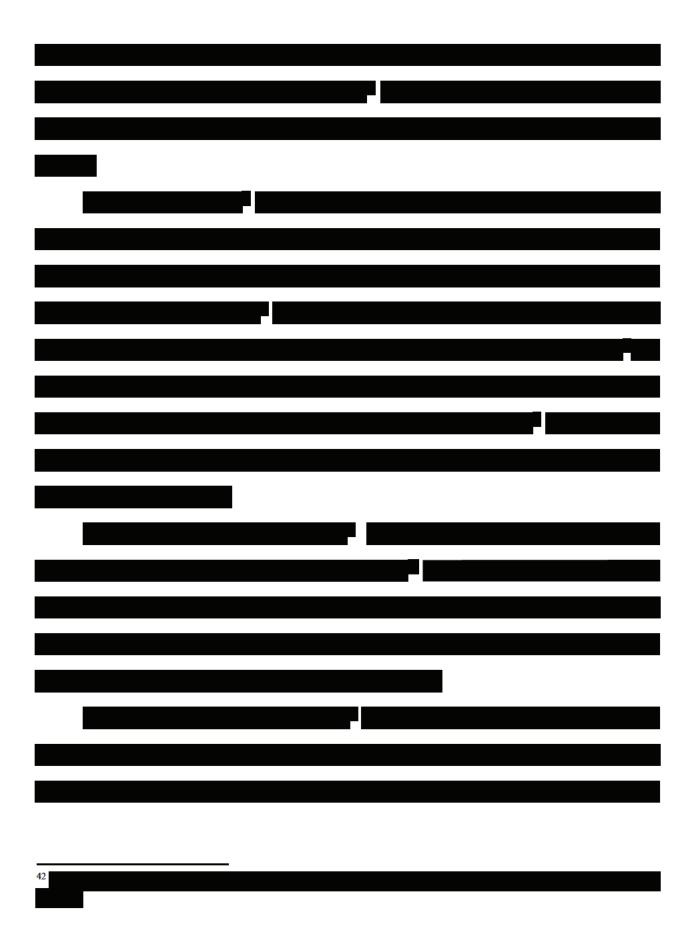


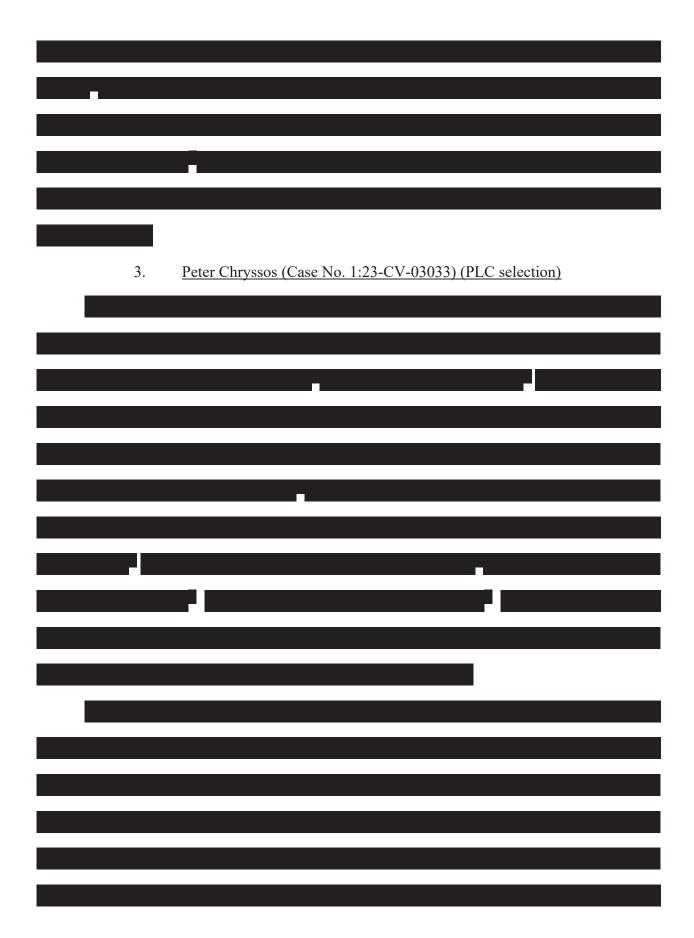
В.	Less Representative Cases for Consideration if Necessary
Б.	
	1. <u>Sara Perkett (Case No. 1:23-CV-15994) (Horizon selection)</u>
П	



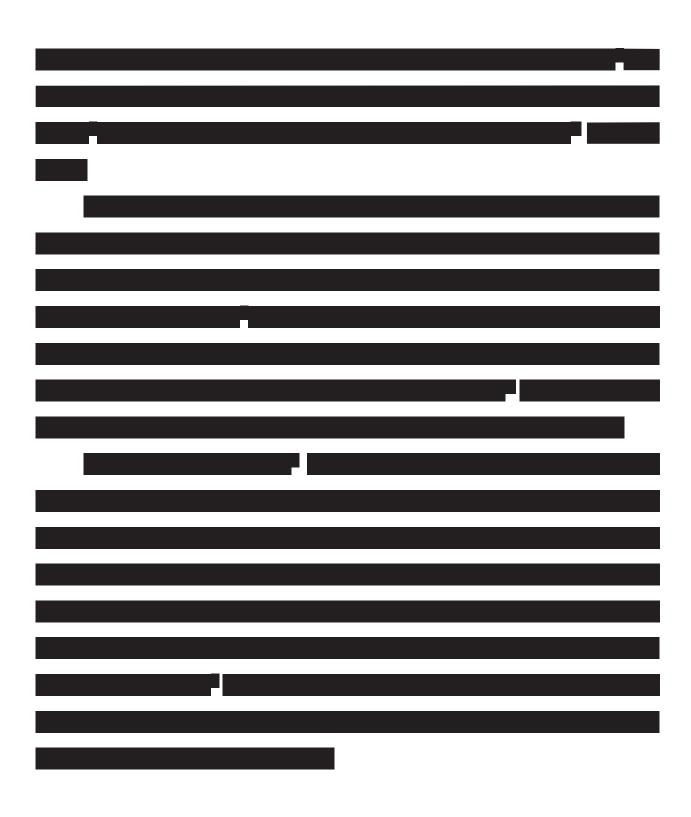












<sup>46 47</sup> 

# C. Nonrepresentative Outlier Cases That Should Be Excluded from Consideration

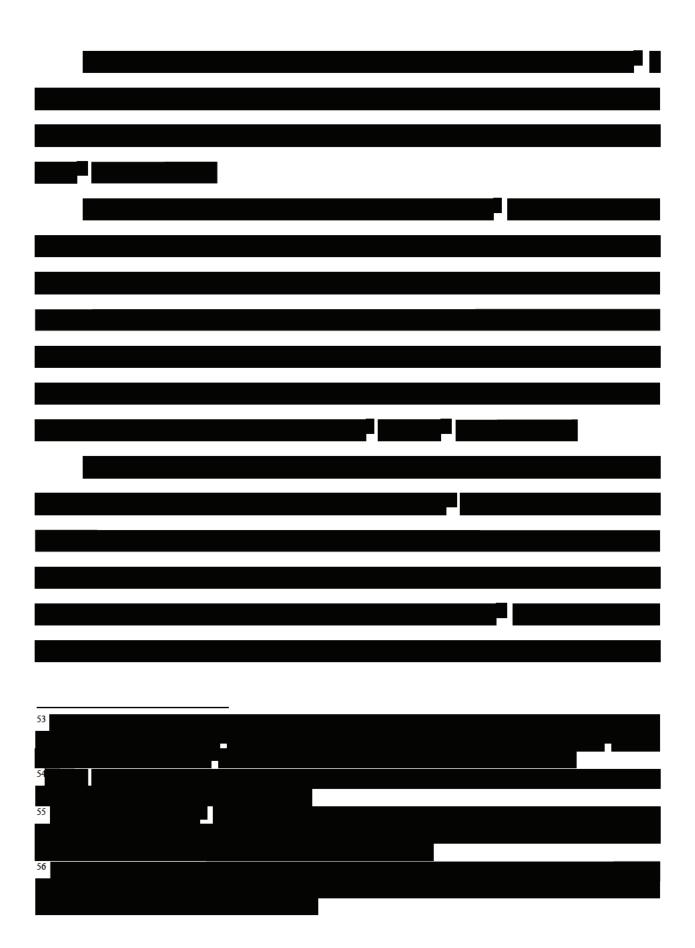
For the reasons discussed below, Horizon submits that the following four cases would not facilitate the goal of trying representative cases, and thus should be excluded from consideration as Initial Bellwether Trial Cases.

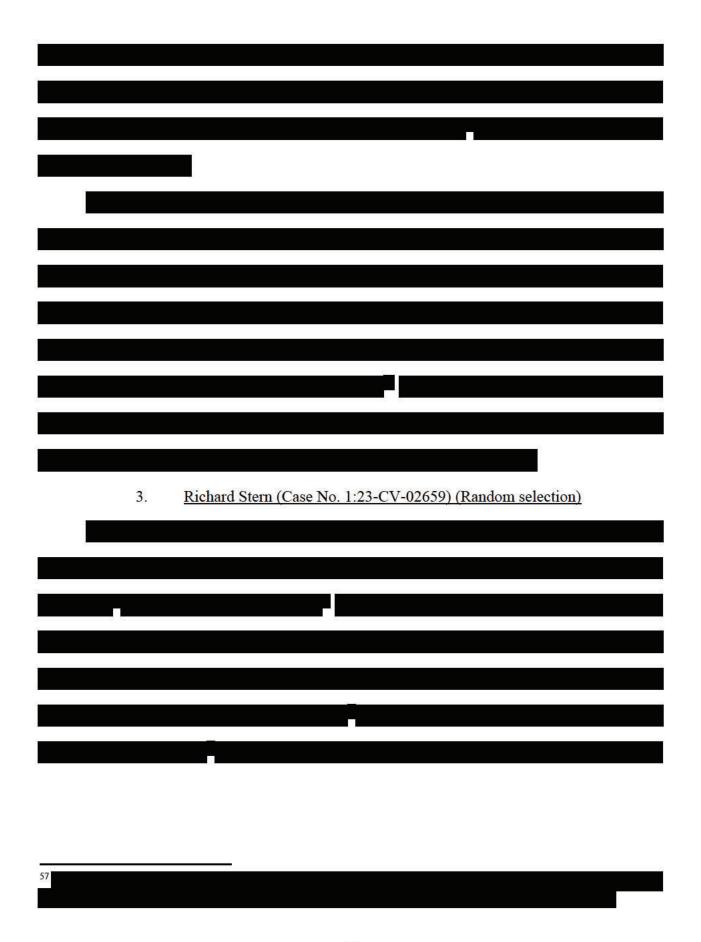
# Rebecka Meyers (Case No. 1:23-CV-03585) (PLC selection) 1.





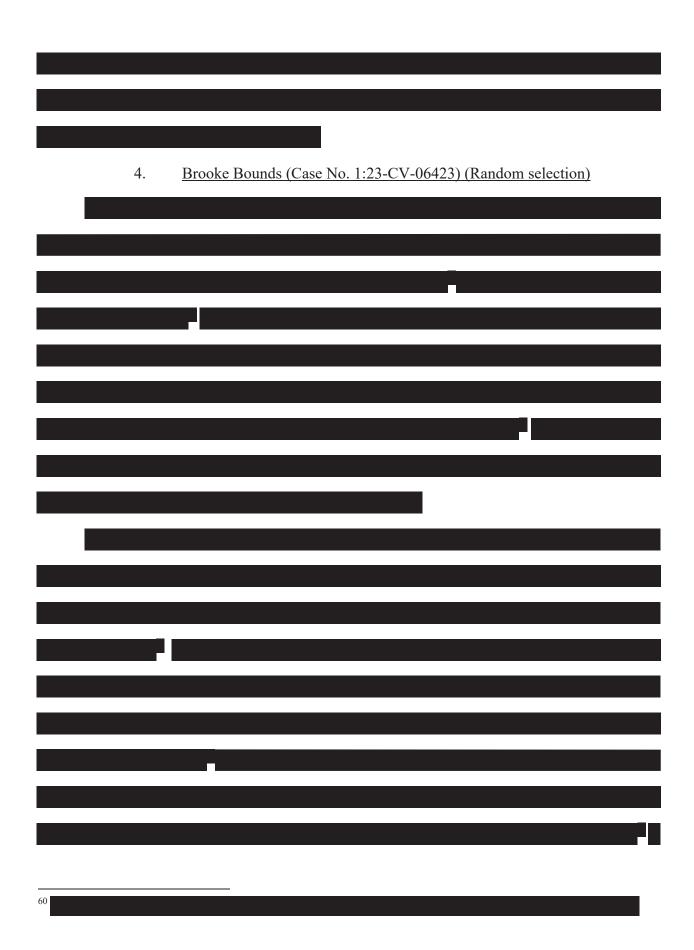
















#### **CONCLUSION**

For the foregoing reasons, Horizon respectfully suggests that the Court select the cases of Gloria Pledger (Case No. 1:22-CV-06562); Amarilis Polanco (Case No. 1:23-CV-02503); Consuelo Egger (Case No. 1:23-CV-15306); and Geri Kanesta-Rychner (Case No. 1:23-CV-03575) as Initial Bellwether Trial Cases, with the Pledger case proceeding as the first trial. Horizon urges the Court to conclude that the Meyers (Case No. 1:23-CV-03585), Ford (Case No. 1:23-CV-02703), Stern (Case No. 1:23-CV-02659), and Bounds (Case No. 1:23-CV-06423) cases are not representative and exclude them from the Bellwether Trial Cases. In the event the Court does not select each of the four cases recommended by Horizon, it should select the Perkett case (Case No. 1:23-CV-15994).

Dated: January 17, 2025 Respectfully Submitted,

#### /s/ Robert E. Johnston

Robert E. Johnston, Esq.
Kathryn S. Jensen, Esq.
Grant W. Hollingsworth, Esq.
HOLLINGSWORTHLLP
1350 I Street, N.W.
Washington, DC 20005
(202) 898-5800
rjohnston@hollingsworthllp.com
kjensen@hollingsworthllp.com
ghollingsworth@hollingsworthllp.com

#### /s/ Daniel W. McGrath

Daniel W. McGrath HINSHAW & CULBERTSON LLP 151 N. Franklin Street, Suite 2500 Chicago, Illinois 60606 (312) 704-3000 dmcgrath@hinshawlaw.com

Counsel for Horizon Therapeutics USA, Inc.

# Exhibit A

# Exhibit B

### **Exhibit C**

### Exhibit D

### Exhibit E

### Exhibit F

### Exhibit G

# Exhibit H

# Exhibit I

### Exhibit J

### Exhibit K

### Exhibit L