UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION
OFFICE OF ADMINISTRATIVE LAW JUDGES

In the Matter of AMGEN INC., a corporation, and HORIZON THERAPEUTICS PLC, a corporation.	Docket No. 9414

ANSWER AND DEFENSES OF RESPONDENTS AMGEN INC. AND HORIZON THERAPEUTICS PLC

Pursuant to Rule 3.12 of the Federal Trade Commission's ("FTC") Rules of Practice for Adjudicative Proceedings, Respondents Amgen Inc. ("Amgen") and Horizon Therapeutics plc ("Horizon") (together "Respondents") hereby answer the Complaint (the "Complaint") filed by the FTC in relation to Amgen's proposed acquisition of Horizon as follows:

PRELIMINARY STATEMENT

Amgen is a U.S.-based biotechnology company whose mission is to discover, develop and deliver first-in-class and best-in-class medicines to patients around the globe suffering from serious illnesses. In December 2022, Amgen announced its agreement to acquire Horizon, an Ireland-based biotechnology company focused on developing medicines to treat patients suffering from rare, autoimmune and severe inflammatory diseases, for approximately $27.8 billion (the "Transaction"). The Transaction will extend Amgen's ability to treat the

world's most devastating illnesses, benefitting patients in the United States and around the globe with the application of cutting-edge scientific innovation.

Horizon's medicines treat serious rare diseases. The FTC's claims focus on two of those medicines: TEPEZZA®, the first and only FDA-approved treatment for thyroid eye disease ("TED"), and KRYSTEXXA®, the first and only FDA-approved treatment for chronic refractory gout ("CRG"). TED and CRG are debilitating illnesses, as are other illnesses that Horizon's medicines are indicated to treat. Notably, the FTC does not allege that Amgen's medicines compete with *any* of Horizon's medicines, including TEPEZZA® or KRYSTEXXA®.

As an independent business, Horizon does not have the resources Amgen has to bring its medicines to all of the patients around the world who badly need them. The Transaction gives Horizon the capabilities, expertise, and global scale it needs to do that. Amgen and Horizon expect that, together, they can utilize Amgen's industry-leading research and development and manufacturing capabilities, strong provider relationships, extensive global presence and decades of experience to make Horizon's medicines accessible to many more patients, more quickly than Horizon could on its own, not only in the United States but around the world.

Against that background, the FTC's attempt to prevent this procompetitive merger is as misguided as it is unprecedented. The FTC has never challenged a merger between pharmaceutical companies based on allegations that did not include a horizontal product overlap or claims of potential head-to-head competition between the merging parties. The Complaint does not allege any such concerns—and there are none. Given the lack of any material competition between Amgen and Horizon, the Transaction should have been cleared months ago under well-established precedent, and Amgen, Horizon and their patients should already be

realizing the Transaction's significant benefits. Instead, the FTC has delayed the Transaction for months, and now asks this Court to scuttle it. It does so based on a novel and highly speculative "cross-benefit" and "cross-market" bundling theory that has no legal or factual support. And it does so despite Amgen committing to the FTC, before the agency filed its Complaint in this Court (and before the FTC filed its initial Complaint in federal court), that it would not bundle its products with TEPEZZA® or KRYSTEXXA®—the very conduct about which Plaintiffs allege concern.

Putting to one side that Amgen would have neither motive nor ability to engage in that conduct, Amgen also made clear that it would be willing to formalize that commitment in a binding consent order. Amgen continues to stand ready to enter into such a binding commitment, which would fully resolve the FTC's hypothesized concerns of Amgen bundling its products with TEPEZZA® or KRYSTEXXA®, avoid further delay in delivering the patient benefits from the Transaction, and avoid further waste of administrative resources.

To obtain the extraordinary relief it seeks, the FTC must show that, "notwithstanding the merger's [] procompetitive effects, [it] has met its burden of proof of establishing" that the merger of Amgen and Horizon, "at this time and in this remarkably dynamic industry, [] is likely to substantially lessen competition in the manner it predicts." *United States v. AT&T*, 310 F. Supp. 3d 161, 194 (D.D.C. 2018). The FTC cannot meet its burden based on presumptions, which apply only in merger cases involving actual horizontal overlaps. *See United States v. AT&T*, 916 F.3d 1029, 1032 (D.C. Cir. 2019). The FTC "cannot use a short cut to establish a presumption of anticompetitive effect"; it must make a "fact-specific" showing that the proposed merger is anticompetitive. *Id.* Further, where a respondent has made a commitment, prior to the filing of the complaint, that fully addresses the alleged

concerns—as Amgen did here—the Court must take that commitment into account in determining the merits of the FTC's claims that the transaction is likely to substantially lessen competition. *See, e.g.*, *AT&T Inc.*, 310 F. Supp. 3d at 241 n.51. The FTC's Complaint fails to make the required showing.

In particular, the FTC's allegations are far too speculative to support a showing of probable and imminent harm to competition. TEPEZZA® and KRYSTEXXA® currently are the only FDA-approved treatments for their respective diseases. The FTC's case is based on its assertion that, in the event a TED or CRG rival emerged, Amgen would respond to such a future rival by giving pharmacy benefit managers ("PBMs") rebates on Amgen products (such as Enbrel®) to "ensure" favorable formulary placement for TEPEZZA® or KRYSTEXXA® and thereby exclude that rival. Even setting aside Amgen's commitment that it will not do that, in the real world there are many reasons why Amgen would not have an incentive or the ability to engage in that type of conduct. First, TEPEZZA® and KRYSTEXXA® both are primarily reimbursed through medical benefit plans, rather than pharmacy benefit plans. In the medical benefit context, bundled discounting is rare. And cross-benefit bundling, *i.e.*, bundling between medical benefit products like Horizon's TEPEZZA® and KRYSTEXXA® and pharmacy benefit products like Amgen's Enbrel®, is even rarer—if it is ever done at all—due to a number of logistical, economic, legal and regulatory barriers. Indeed, Amgen does not have *any* contracts that bundle a pharmacy benefit product with a medical product today, and has no plans to try to pursue such a bundle in the future, including with any Horizon product.

Even setting aside the genuine distinctions between pharmacy and medical benefit products, the real-world dynamics of treating rare diseases present another significant barrier. In the context of medicines like TEPEZZA® and KRYSTEXXA®, indicated to relieve suffering

from serious rare diseases for which treatment options are limited and differentiated, and where treatment decisions can have life-altering consequences, patients and physicians often have strong treatment preferences and would be highly likely to resist any attempt to restrict access to a preferred treatment. For such treatments, clinical utility and patient and provider preferences drive utilization, not discounting for formulary positioning. Particularly as applied to rare diseases, the FTC's hypothesized bundling theory—that Amgen could foreclose rare disease competitors through bundled rebates—is a square peg in a round hole.

In the Complaint, the FTC does not meaningfully address the real-world factors that refute its incentive and ability theory. The Complaint is utterly silent as to the actual dynamics of rare disease treatment. When addressing the barriers that exist to bundling across medical benefit and pharmacy benefit products, the FTC relies on inaccurate generalizations and speculation. The FTC asserts that vertical integration among insurance plans and PBMs has eroded the distinctions between the two types of benefits. But in the real world, there are many plans and PBMs that are not vertically integrated, and a majority of covered patients get a medical benefit from one firm and a pharmacy benefit from another. And the FTC ignores the many other real world regulatory and structural impediments to such bundles, including that rebates involving medical benefit products generally erode profitability because of how medical benefit products are reimbursed.

The FTC claims that the barriers may not apply because a subcutaneous version of TEPEZZA®, today in early stages of development by Horizon, *may* be successful. And if it is, it *may* be approved by the FDA for patient self-administration (which is in addition to approval for subcutaneous use and can be limited to physician-administration by the FDA). And if it is, it *may* be covered as a pharmacy benefit product for *some* patients at *some point* in the future (and

even then, the Plaintiffs' theory would further require that the future TEPEZZA® competitor *also* obtain approval for a comparable self-administered offering, which is even more speculative). There are a number of factual inaccuracies in those assertions—and the assertions say nothing about KRYSTEXXA®. But even setting those aside, such speculation about possibilities that may or may not come to pass years in the future are not enough to block a merger under the Clayton Act. And even *if* those events came to pass, and even *if* the FTC in the future had concerns about such events, the FTC has an entire division focused on investigating and challenging anticompetitive conduct when it believes a company has engaged in it.

On top of the FTC's conjecture regarding a subcutaneous version of TEPEZZA®, its case goes on to pile more speculation on speculation. The FTC repeatedly alleges that there are no rivals to TEPEZZA® or KRYSTEXXA® today, and thus acknowledges there is no existing incentive to engage in the hypothesized bundling. The FTC speculates that, while not present today, rivals to Horizon's TEPEZZA® and KRYSTEXXA® products may emerge in the future and threaten Horizon's position as a supplier of treatments for TED and CRG. Never mind that the handful of pipeline products identified in the Complaint are in early stages of development and must overcome several clinical development and regulatory hurdles to get to market; or that, if any do, the timing and impact of their entry is highly uncertain. The Complaint also ignores that these pipeline products are all differentiated from TEPEZZA® and KRYSTEXXA® and provides no basis for predicting that any would ever threaten Amgen's sales in a way that would support the FTC's theory. As the FTC tells it, entry may happen at some point, or it may not, and that is enough. That is wrong, and insufficient reason to block this Transaction.

On top of that, the FTC speculates that, if and when any such entry occurs, though years away at best, the competitive conditions for the Amgen medicines the FTC claims would

be used in the bundle, such as Enbrel®, will not have changed—that is, the alleged coercive power that the FTC claims Amgen now has and could theoretically exert to gain favorable formulary placement for KRYSTEXXA® and TEPEZZA® will not have eroded. Put to one side that this unsupported claim is at odds with widely reported commercial realities faced by Amgen's products;[1] or that, even today, Enbrel®, with shares below 20% in any conceivable market, faces significant competition and declining sales; or that the other Amgen products cited in the Complaint face similar, or even more, competitive markets, which are also growing more competitive by the day. The notion that PBMs are vulnerable to economic coercion by Amgen when negotiating for coverage of medicines like Enbrel® is also implausible given the reality that PBMs hold the leverage in such negotiations, a reality the FTC acknowledges in other contexts.[2] But commercial realities are of no moment to the FTC's speculation-fueled case here. Brushing facts aside, the FTC bases its entire theory on the contention that Amgen's products, though they plainly have no coercive power even today, may somehow have coercive power years from now. Again, that is not a proper basis for a merger challenge.

The Complaint makes several additional baseless assumptions. It assumes without support that Amgen would earn greater profits by excluding putative future rivals of TEPEZZA® or KRYSTEXXA® than it would lose from giving discounts on medicines like Enbrel®. This wholly unfounded proposition ignores that Amgen has many, and far more plausible, ways to compete against any future TED and CRG competitors that do not involve

[1] *See, e.g.*, David Wainer, *Elizabeth Warren and the FTC are the Least of Amgen's Problems*, WALL ST. J., Mar. 24, 2023, https://www.wsj.com/articles/elizabeth-warren-and-the-ftc-are-the-least-of-amgens-problems-889163a6.

[2] *See, e.g.*, Fed. Trade Comm'n, Press Release, *FTC Launches Inquiry Into Prescription Drug Middlemen Industry* (June 7, 2022), *available at* https://www.ftc.gov/news-events/news/press-releases/2022/06/ftc-launches-inquiry-prescription-drug-middlemen-industry.

bundling, such as lowering the price for TEPEZZA® and KRYSTEXXA®, offering non-bundled discounts on TEPEZZA® or KRYSTEXXA® alone, or competing with non-price tools such as differentiating medical evidence about safety and efficacy. The Complaint also baselessly assumes that the theoretically targeted rivals of TEPEZZA® and KRYSTEXXA® would not be able to offer competitive inducements in favor of their own treatments. And it assumes that enough payors would respond to the hypothesized bundling by excluding the theoretically targeted rival from enough formularies to deprive it of competitive scale and harm competition. All of those assumptions are wholly unfounded.

For all its speculation, the Complaint revealingly does not identify a *single* document produced by Amgen (or Horizon) suggesting any plan to engage in the conduct alleged by the FTC. Rather, the documents tell a consistent story that Amgen's plan is to increase sales of TEPEZZA® by expanding its availability in international geographies and for patients suffering from chronic TED symptoms (as opposed to acute). Instead, the Complaint implausibly alleges that Amgen spent $28 billion to buy Horizon and somehow did not create even a single document describing its supposed "real" plan to bundle its products with Horizon's medicines. Particularly considering that bundling is often procompetitive and not inherently anticompetitive, it is implausible that an acquiror in Amgen's position would not reduce to writing such a strategy if it was at all contemplated. There is a reason for the total lack of documentary support for the FTC's claims—the FTC's bundling allegations are simply made up.

The FTC attempts, but fails, to compensate for the total lack of documentary support by pointing to unproven (and easily disproved) allegations made by a rival pharmaceutical company in a separate case that has nothing to do with Horizon's products; and the FTC even tries to rely upon a motion to dismiss ruling which the court in that case itself

observed followed from its inability to consider extrinsic evidence (such as the actual Amgen contracts at issue and other facts not pleaded in the complaint). That case, and that decision, plainly have no relevance to this case, and the FTC does not even allege that that bundle in that case is actually anticompetitive. That the FTC must resort to citing unproven allegations of an Amgen rival only further underscores the weakness of its claims.

Even if the FTC were able to show that, at some point in the future post-merger, Amgen was likely to offer bundled discounts for favorable formulary placement of Horizon medicines (and it cannot), that would not automatically mean that the Transaction is likely to substantially lessen competition. The law recognizes that "[b]undled discounts are pervasive, and examples abound" across the economy, and that bundles "generally benefit buyers because the discounts allow the buyer to get more for less." *Cascade Health Sol. v. PeaceHealth*, 515 F.3d 884, 894-95 (9th Cir. 2008). Indeed, "cutting prices in order to increase business often is the very essence of competition." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 594 (1986). For that reason, it is well understood that bundled discounting is often procompetitive and can harm competition in only limited circumstances. *E.g.*, *Collins Inkjet Corp. v. Eastman Kodak Co.*, 781 F.3d 264 (6th Cir. 2015) (bundled discount anticompetitive only where it is significant enough to take the competitive product below cost such that an equally efficient competitor will be unable to compensate buyers for the foregone discount). There is no basis to assume that the bundled discounts about which the FTC speculates—which will not come about in any event for all the reasons explained—would be the rare form of competition-reducing price cutting.

As noted, if (hypothetically) Amgen ever engaged in activity unlawful under the antitrust laws, the FTC could of course file suit at that time. Both the Sherman Act and Section 5

of the FTC Act supply a cause of action to the FTC to enjoin anticompetitive conduct such as bundling that substantially harms competition in a relevant market. There is simply no good reason, and no legal basis under Section 7 of the Clayton Act, to prevent the consummation of a highly complementary Transaction, and to forestall the benefits it will deliver to patients in need, when the alleged conduct not only is entirely unfounded, but also addressable under the antitrust laws if, hypothetically, it ever occurred in the future. For all of these reasons, the FTC's challenge lacks any factual or legal support.

Respondents provide their specific responses to the FTC's allegations below.

RESPONSES TO THE SPECIFIC ALLEGATIONS OF THE COMPLAINT

Except to the extent specifically stated herein, Respondents deny each and every allegation contained in the Complaint, including all allegations contained in headings or otherwise not contained in one of the Complaint's numbered paragraphs.

The preamble to the Complaint characterizes this action and asserts legal conclusions to which no response is required; to the extent that a response is deemed necessary, Respondents state that the FTC has issued a Complaint regarding the Transaction and in all other respects denies the allegations in the first paragraph of the preamble to the Complaint.

Respondents respond to the numbered paragraphs of the Complaint as follows:

NATURE OF THE CASE

1. Respondents deny the allegations in paragraph 1, except admit that Amgen proposes to acquire Horizon pursuant to an agreement dated December 11, 2022, and that Horizon has certain medicines indicated for the treatment of thyroid eye disease ("TED") and chronic gout in adult patients refractory to conventional therapy ("CRG").

2. Respondents deny the allegations in paragraph 2, including, for Horizon, on the basis that it is without knowledge or information sufficient to form a belief about Amgen's alleged prior acquisitions, except (a) Amgen admits that in 2002 Amgen acquired each share of Immunex common stock for a fixed ratio of 0.44 shares of Amgen common stock and cash of $4.50; (b) Amgen admits that in 2019 it acquired Otezla for $13.4 billion in cash, or approximately $11.2 billion net of anticipated future cash tax benefits as part of a divestiture that the FTC sanctioned; (c) Respondents admit that Amgen proposes to acquire Horizon in a Transaction that values the entire issued and to be issued ordinary share capital of Horizon at approximately $27.8 billion on a fully diluted basis; and (d) Amgen admits it has a portfolio of marketed medicines and a pipeline of development programs relating to different therapeutic areas.

3. Respondents deny the allegations in paragraph 3, including, for Horizon, on the basis that it is without knowledge or information sufficient to form a belief about allegations relating to Amgen's negotiations with PBMs and payers.

4. Respondents deny the allegations in paragraph 4, including, for Horizon, on the basis that it is without knowledge or information sufficient to form a belief about allegations relating to Amgen's alleged agreements, negotiations with PBMs and payers or product sales, except Amgen admits in 2022 Enbrel® generated $4.044 billion in global sales.

5. Respondents deny the allegations in paragraph 5, including, for Horizon, on the basis that it is without knowledge or information sufficient to form a belief about allegations relating to Amgen's alleged negotiations with payers, except admit that the United States District Court for the District of Delaware is presiding over a case captioned *Regeneron*

Pharms., Inc. v. Amgen Inc., 1:22-cv-00697-RHA-JHL (D. Del.) and refer to the filings in that case for their full and accurate contents.

6. Respondents deny the allegations in paragraph 6, including, for Horizon, on the basis that it is without knowledge or information sufficient to form a belief about Amgen's alleged expectations for TEPEZZA®'s growth, except admit that (a) TEPEZZA® is currently the only FDA-approved medicine that is indicated for the treatment of TED and KRYSTEXXA® is currently the only FDA-approved medicine that is indicated for the treatment of CRG; (b) TEPEZZA®'s net sales for 2022 were approximately $1.97 billion, or approximately 54% of Horizon's net sales, and KRYSTEXXA®'s net sales for 2022 were approximately $716 million, or approximately 19.7% of Horizon's net sales; and (c) TEPEZZA® has significant growth potential in key ex-U.S. markets, which complements Amgen's international growth strategy.

7. Respondents deny the allegations in paragraph 7, except admit that Horizon filed a 2022 SEC Form 10-K on March 1, 2023, and refer to that document for its full and accurate contents. To the extent any of the allegations in paragraph 7 purport to state a legal conclusion, no response is required as to such allegations.

8. Respondents deny the allegations in paragraph 8.

9. Respondents deny the allegations in paragraph 9, except (a) Amgen states that it is without knowledge or information sufficient to form a belief about what information is contained in internal, non-public Horizon documents; (b) Horizon states that it is without knowledge or information sufficient to form a belief about Amgen's beliefs; and (c) Horizon admits that certain Horizon employees produced an internal document and refers to that document for its full and accurate contents.

10. Respondents deny the allegations in paragraph 10. To the extent any of the allegations in paragraph 10 purport to state a legal conclusion, no response is required as to such allegations.

11. Respondents deny the allegations in paragraph 11. Respondents further state that they are without knowledge or information sufficient to form a belief about the alleged "management strategies" of the unnamed "entities" referenced therein. To the extent any of the allegations in paragraph 11 purport to state a legal conclusion, no response is required as to such allegations.

12. Respondents deny the allegations in paragraph 12, except (a) Amgen states that it is without knowledge or information sufficient to form a belief about what information is contained in internal, non-public Horizon documents; (b) Horizon states that it is without knowledge or information sufficient to form a belief about what information is contained in internal, non-public Amgen documents; (c) Horizon admits that certain Horizon employees produced an internal document and refers to that document for its full and accurate contents; and (d) Amgen admits that certain Amgen employees created an internal document and refers to that document for its full and accurate contents.

13. Respondents deny the allegations in paragraph 13, except admit that Horizon is currently in Phase 1 clinical trials for a subcutaneously administered version of TEPEZZA® that could potentially obtain FDA approval in the future, subject to significant remaining risk and uncertainty including the results of a Phase 3 clinical trial and FDA review. To the extent any of the allegations in paragraph 13 purport to state a legal conclusion, no response is required as to such allegations.

14. Respondents deny the allegations in paragraph 14. To the extent any of the allegations in paragraph 14 purport to state a legal conclusion, no response is required as to such allegations.

15. Respondents deny the allegations in paragraph 15. To the extent any of the allegations in paragraph 15 purport to state a legal conclusion, no response is required as to such allegations.

JURISDICTION

16. Respondents state that because the allegations in paragraph 16 purport to state a legal conclusion, no response is required as to such allegations. To the extent a response is required, Respondents deny the allegations in paragraph 16.

17. Respondents state that because the allegations in paragraph 17 purport to state a legal conclusion, no response is required as to such allegations. To the extent a response is required, Respondents deny the allegations in paragraph 17.

RESPONDENTS

18. Respondents admit the allegations in paragraph 18, insofar as the phrase "largest market" means the country in which Amgen makes the majority of its revenues, except Horizon states it is without knowledge or information sufficient to form a belief about the allegations in the last four sentences in paragraph 18 regarding Amgen's product sales and the focus of its research or development.

19. Respondents admit the allegations in paragraph 19, insofar as the word "leading" in the fourth sentence means medicines with the largest amount of net sales in 2022. To the extent the allegations in paragraph 19 repeat allegations contained in paragraph 6, Respondents incorporate their answer to paragraph 6.

THE ACQUISITION

20. Respondents admit the allegations in paragraph 20.

THE ALLEGED RELEVANT PRODUCT MARKETS

21. Respondents deny the allegations in paragraph 21. To the extent any of the allegations in paragraph 21 purport to state a legal conclusion, no response is required as to such allegations.

22. Respondents deny the allegations in paragraph 22, except admit that the quoted language is excerpted from Horizon's annual report for the fiscal year ended December 31, 2021, and refer to that report for its full and accurate contents. To the extent any of the allegations in paragraph 22 purport to state a legal conclusion, no response is required as to such allegations.

23. Respondents are without knowledge or information regarding the truth of the allegations concerning the annual incidence of TED in the United States, the potential patient population, or the population suffering from moderate-to-severe acute TED each year. To the extent the allegations in paragraph 23 are based on public sources, Respondents refer to those sources for their full and accurate content.

24. Respondents admit the allegations in paragraph 24.

25. Respondents deny the allegations in paragraph 25, except admit that (a) TEPEZZA® is the first and only medicine approved by the FDA to treat TED; (b) the Orphan Drug Act, Pub . L. No. 97-414 and the FDA regulations, 21 C.F.R. § 316, govern Orphan Drug designation and refer to the Orphan Drug Act, Pub . L. No. 97-414 and the FDA regulations, 21 C.F.R. § 316, for their contents; and (c) the FDA issued a press release dated January 21, 2020, and refer to the press release for its full and accurate contents.

26. Respondents deny the allegations in paragraph 26, and state that, to the extent the allegations in paragraph 26 purport to summarize any sources describing the efficacy, differentiating factors and benefits of TEPEZZA® vis-à-vis other options for the treatment of TED, Respondents refer to those sources for their full and accurate contents. To the extent any of the allegations in paragraph 26 purport to state a legal conclusion, no response is required as to such allegations.

27. Respondents deny the allegations in paragraph 27, except admit that TEPEZZA® has achieved sales growth since the introduction of TEPEZZA®, and state that, to the extent the allegations of the first sentence in paragraph 27 purport to summarize any public sources describing the efficacy, differentiating factors and benefits of TEPEZZA® vis-à-vis other options for the treatment of TED, Respondents refer to those sources for their full and accurate contents. To the extent any of the allegations in paragraph 27 purport to state a legal conclusion, no response is required as to such allegations.

28. Respondents deny the allegations in paragraph 28. Respondents further state that they are without knowledge or information sufficient to form a belief regarding the allegations as to what unnamed "other firms" purportedly identify or recognize. To the extent any of the allegations in paragraph 28 purport to state a legal conclusion, no response is required as to such allegations.

29. Respondents deny the allegations in paragraph 29. To the extent any of the allegations in paragraph 29 purport to state a legal conclusion, no response is required as to such allegations.

30. Respondents deny the allegations in paragraph 30, except admit that KRYSTEXXA® (pegloticase) is indicated for the treatment of chronic gout in adult patients who

have failed to normalize serum uric acid and whose signs and symptoms are inadequately controlled with xanthine oxidase inhibitors at the maximum medically appropriate dose or for whom these drugs are contraindicated. To the extent any of the allegations in paragraph 30 purport to state a legal conclusion, no response is required as to such allegations.

31. Respondents are without knowledge or information regarding the truth of the allegations in Paragraph 31. To the extent the allegations in paragraph 31 are based on public sources, Respondents refer to those sources for their full and accurate content.

32. Respondents deny the allegations in paragraph 32 on the basis that they provide an incomplete description of KRYSTEXXA® and how it is administered, except admit that KRYSTEXXA® is marketed by Horizon and is the only FDA-approved medicine that is indicated for the treatment of CRG.

33. Respondents deny the allegations in paragraph 33, except admit that (a) there are no other FDA-approved medicines to treat CRG available today; (b) Horizon's Orphan Drug marketing exclusivity for KRYSTEXXA® expired in 2017; (c) KRYSTEXXA®'s composition of matter patent expires in the year stated in the allegation in paragraph 33; (d) in July 2022, the FDA approved the supplemental Biologics License Application, expanding the KRYSTEXXA®'s labeling to include KRYSTEXXA® co-administered with methotrexate, an immunomodulatory therapy; (e) the co-administration of KRYSTEXXA® with methotrexate is expected to help to reduce the development of anti-drug antibodies that can limit the efficacy of the medicine; (f) by reducing the development of drug resistance, KRYSTEXXA® with methotrexate is expected to help CRG patients achieve greater recovery than KRYSTEXXA® alone; and (g) in clinical studies, patients receiving the combination medicine experienced fewer infusion reactions. Respondents state that to the extent paragraph 33 purports to state

information from medical literature or the results of clinical studies, Respondents refer to such literature or studies for their full and accurate contents.

34. Respondents deny the allegations in paragraph 34, except admit that KRYSTEXXA® has a different mechanism of action (MOA) from XOIs and uricosurics and differs in safety and efficiency in treating certain patients. Respondents state that to the extent paragraph 34 purports to state information from medical literature or the results of clinical studies, Respondents refer to such literature or studies for their full and accurate contents.

35. Respondents deny the allegations in paragraph 35, except admit that KRYSTEXXA® is currently the only FDA-approved medicine that is indicated for the treatment of CRG. To the extent any of the allegations in paragraph 35 purport to state a legal conclusion, no response is required as to such allegations.

36. Respondents deny the allegations in paragraph 36, except (a) Amgen states that it is without knowledge or information sufficient to form a belief about what information is contained in internal, non-public Horizon documents and (b) Horizon admits that certain Horizon employees created an internal document and refers to that document for its full and accurate contents. Respondents further state that they are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding what other industry participants supposedly consider as the relevant market for KRYSTEXXA®.

37. Respondents deny the allegations in paragraph 37. To the extent any of the allegations in paragraph 37 purport to state a legal conclusion, no response is required as to such allegations.

38. Respondents deny the allegations in paragraph 38. To the extent any of the allegations in paragraph 38 purport to state a legal conclusion, no response is required as to such allegations.

THE ALLEGED RELEVANT GEOGRAPHIC MARKET

39. Respondents deny the allegations in paragraph 39, except admit that the FDA regulates drug products in the United States and that companies must obtain FDA approval before marketing a drug product in the United States. To the extent any of the allegations in paragraph 39 purport to state a legal conclusion, no response is required as to such allegations.

40. Respondents deny the allegations in paragraph 40, except admit that the FDA approval process for branded drugs such as those to treat TED and CRG can be lengthy. To the extent any of the allegations in paragraph 40 purport to state a legal conclusion, no response is required as to such allegations.

41. Respondents deny the allegations in paragraph 41. To the extent any of the allegations in paragraph 41 purport to state a legal conclusion, no response is required as to such allegations.

THE ALLEGED MARKET STRUCTURE

42. Respondents deny the allegations in paragraph 42, except admit that TEPEZZA® is the only FDA-approved medication for the treatment of TED.

43. Respondents deny the allegations in paragraph 43, except admit that (a) TEPEZZA® is administered by a healthcare provider as an intravenous infusion, typically in an outpatient infusion center or a doctor's office; (b) Horizon is researching and developing a potential subcutaneous injector version of TEPEZZA®, which is currently in Phase 1 clinical trials and for which the prospects and timing for launch are uncertain; and (c) Horizon is working

with Xeris Pharmaceuticals, Inc., to potentially develop a subcutaneous version of TEPEZZA®, which is currently in early stages of development and for which the prospects and timing for approval and launch are uncertain.

44. Respondents deny the allegations in paragraph 44, except (a) Amgen states that it is without knowledge or information sufficient to form a belief about what information is contained in internal, non-public Horizon documents and (b) Horizon admits that certain Horizon employees created the document referenced in paragraph 44 and refers to the document for its full and accurate contents.

45. Respondents deny the allegations in paragraph 45, except, to the extent they purport to summarize information in public sources, Respondents refer to those materials for their true and accurate contents; further, to the extent any of the allegations in paragraph 45 purport to state a legal conclusion, no response is required as to such allegations. Amgen further states that it is without knowledge or information sufficient to form a belief about what information is contained in internal, non-public Horizon documents. Horizon furthers admits that certain Horizon employees produced the document referenced in paragraphs 44 and 45 and refers to that document for its full and accurate contents.

46. Respondents deny the allegations in paragraph 46, which depicts an Amgen document, not a Horizon document, except (a) Horizon states that it is without knowledge or information sufficient to form a belief about what information is contained in internal, non-public Amgen documents, and (b) Amgen admits that certain Amgen employees produced the document referenced in paragraph 46 and refers to that document for its full and accurate contents.

47. Respondents deny the allegations in paragraph 47, except to the extent they purport to summarize information in public sources, Respondents refer to those materials for their true and accurate contents. Respondents further state that they are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding Viridian's ongoing development or projections for FDA approval of VRDN-002 and VRDN-003.

48. Respondents deny the allegations in paragraph 48, except admit based on public sources that (a) Immunovant is a publicly traded, clinical-state biopharmaceutical company focused on treating autoimmune diseases and (b) Batoclimab is Immunovant's investigational compound and is a novel, fully human, monoclonal antibody targeting the neonatal Fc receptor (FcRn). Respondents further state that they are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding Immunovant's expectations or projections. To the extent any of the allegations in paragraph 48 purport to state a legal conclusion, no response is required as to such allegations.

49. Respondents deny the allegations in paragraph 49, except admit that Horizon's KRYSTEXXA® is the only FDA-approved medication that is indicated for the treatment of CRG. To the extent any of the allegations in paragraph 49 purport to state a legal conclusion, no response is required as to those allegations.

50. Respondents deny the allegations in paragraph 50, except to the extent they purport to summarize information in public or other sources, Respondents refer to those materials for their true and accurate contents. To the extent any of the allegations in paragraph 50 purport to state a legal conclusion, no response is required as to those allegations.

ALLEGED ANTICOMPETITIVE EFFECTS

51. Respondents deny the allegations in paragraph 51. To the extent the allegations in paragraph 51 purport to state a legal conclusion, no response is required as to those allegations.

52. Respondents deny the allegations in paragraph 52, including, for Horizon, on the basis that it is without knowledge or information sufficient to form a belief about allegations relating to Amgen's product sales and research and development pipeline, except Amgen admits that its product portfolio includes nine medicines that have generated more than $1 billion in annual net sales in 2022: Enbrel® ($4.1 billion), Prolia® ($3.6 billion), Otezla® ($2.3 billion), Xgeva® ($2.0 billion), Aranesp® ($1.4 billion), Nplate® ($1.3 billion), Repatha® ($1.3 billion), Kyprolis® ($1.2 billion), and Neulasta® ($1.1 billion). To the extent the allegations in paragraph 52 purport to state a legal conclusion, no response is required as to those allegations.

53. Respondents deny the allegations in paragraph 53, including, for Horizon, on the basis that it is without knowledge or information sufficient to form a belief about allegations relating to Amgen's product utilization, pricing practices or product sales, except admit that Enbrel® is a medicine indicated to treat rheumatoid arthritis, psoriatic arthritis, moderate to severe plaque psoriasis, ankylosing spondylitis, and moderate to severe juvenile idiopathic arthritis. To the extent the allegations in paragraph 53 purport to summarize Amgen documents or public sources, Respondents refer to those materials for their full and accurate contents.

54. Respondents deny the allegations in paragraph 54, including, for Horizon, on the basis that it is without knowledge or information sufficient to form a belief about allegations relating to internal, non-public Amgen documents, except that to the extent the

allegations in paragraph 54 purport to summarize Amgen documents or public sources, Respondents refer to those documents and materials for their full and accurate contents. To the extent the allegations in paragraph 54 purport to state a legal conclusion, no response is required as to those allegations.

55. Respondents deny the allegations in paragraph 55, including, for Horizon, on the basis that it is without knowledge or information sufficient to form a belief about allegations relating to Amgen's alleged PBM contracts. To the extent the allegations in paragraph 55 purport to state a legal conclusion, no response is required as to those allegations.

56. Respondents deny the allegations in paragraph 56, including, for Horizon, on the basis that it is without knowledge or information sufficient to form a belief about allegations relating to Amgen's alleged PBM contracts, except admit that the United States District Court for the District of Delaware is presiding over a case captioned *Regeneron Pharms., Inc. v. Amgen Inc.*, 1:22-cv-00697-RHA-JHL (D. Del.) and refer to the filings in that case for their full and accurate contents.

57. Respondents deny the allegations in paragraph 57. To the extent the allegations in paragraph 57 purport to state a legal conclusion, no response is required as to those allegations. Respondents further state that they are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding what "multiple payers" purportedly "agreed" to.

58. Respondents deny the allegations in paragraph 58, except (a) Horizon states that it is without knowledge or information sufficient to form a belief about what information is contained in internal, non-public Amgen documents, and (b) Amgen admits that certain Amgen employees created a document titled "Summary Observations" and refers to that

document for its full and accurate contents. To the extent the allegations in paragraph 58 purport to state a legal conclusion, no response is required as to those allegations. To the extent the allegations in paragraph 58 repeat allegations contained in paragraph 6, Respondents incorporate their answer to paragraph 6.

59. Respondents deny the allegations in paragraph 59, except (a) Horizon states that it is without knowledge or information sufficient to form a belief about what information is contained in internal, non-public Amgen documents, and (b) Amgen admits that certain Amgen employees produced a document as part of Amgen's evaluation of the Transaction, refers to that document for its full and accurate contents, and notes that none of Amgen's valuation analyses/models suggest any plan or intent to bundle Amgen products with Horizon products regardless of whether entry may or may not occur in the future. To the extent the allegations in paragraph 59 purport to state a legal conclusion, no response is required as to those allegations.

60. Respondents deny the allegations in paragraph 60, except (a) Horizon states that it is without knowledge or information sufficient to form a belief about what information is contained in internal, non-public Amgen documents, and (b) Amgen admits that Amgen's SVP of Finance emailed Amgen's EVP and CFO and refers to that email for its full and accurate contents. To the extent the allegations in paragraph 60 purport to state a legal conclusion, no response is required as to those allegations.

61. Respondents deny the allegations in paragraph 61. To the extent the allegations in paragraph 61 purport to state a legal conclusion, no response is required as to those allegations.

62. Respondents deny the allegations in paragraph 62, including because Respondents are without knowledge or information sufficient to form a belief about the activities of unnamed third parties, except admit in general that (a) PBMs negotiate pharmacy benefit coverage and rebates for payers; (b) medical benefit managers or health plans generally negotiate their medical benefit policies and rebates; (c) drugs reimbursed through pharmacy benefits are typically self-administered and dispensed through a retail or specialty pharmacy; and (d) drugs reimbursed through medical benefits are typically administered by a healthcare provider.

63. Respondents deny the allegations in paragraph 63, except state that, upon information and belief, OptumRx and United Healthcare are owned (directly or indirectly) by the same ultimate parent entity; CVS Caremark and Aetna are owned (directly or indirectly) by the same ultimate parent entity; and Express Scripts and Cigna are owned (directly or indirectly) by the same ultimate parent entity. To the extent the allegations in paragraph 63 purport to state a legal conclusion, no response is required as to those allegations.

64. Respondents deny the allegations in paragraph 64, except (a) Amgen states that it is without knowledge or information sufficient to form a belief about what information is contained in internal, non-public Horizon documents, and (b) Horizon admits that the quoted language is partially excerpted from documents created by Horizon employee(s) and refers to those documents for their full and accurate contents. To the extent the allegations in paragraph 64 purport to state a legal conclusion, no response is required as to those allegations.

65. Respondents deny the allegations in paragraph 65, except (a) Amgen states that it is without knowledge or information sufficient to form a belief about what information is contained in internal, non-public Horizon documents, and (b) Horizon admits that the quoted language is a partial excerpt from a document created by Horizon employee(s) and

refers to that document for its full and accurate contents. To the extent the allegations in paragraph 65 purport to state a legal conclusion, no response is required as to those allegations.

66. Respondents deny the allegations in paragraph 66. To the extent the allegations in paragraph 66 purport to state a legal conclusion, no response is required as to those allegations.

ALLEGED LACK OF COUNTERVAILING FACTORS

67. Respondents deny the allegations in paragraph 67, except admit that for TED and CRG therapies, drug development times and FDA approval requirements are lengthy such that future entry is inherently speculative. To the extent the allegations in paragraph 67 purport to state a legal conclusion, no response is required as to those allegations.

68. Respondents are without knowledge or information sufficient to form a belief regarding the truth of the allegations in paragraph 68, including because it uses terms such as "entry" and "suitable" that are not defined and because its source(s) is not identified. To the extent the allegations in paragraph 68 purport to summarize information from public sources, Respondents refer to those materials for their full and accurate contents.

69. Respondents are without knowledge or information sufficient to form a belief regarding the truth of the allegations in paragraph 69, including because it uses terms such as "entrant" that are not defined and because there are no identified source(s) for the allegations. To the extent the allegations in paragraph 69 purport to summarize information from public sources, Respondents refer to those materials for their full and accurate contents.

70. Respondents deny the allegations in paragraph 70. To the extent the allegations in paragraph 70 purport to state a legal conclusion, no response is required as to those allegations.

71. Respondents deny the allegations in paragraph 71. To the extent the allegations in paragraph 71 purport to state a legal conclusion, no response is required as to those allegations.

72. Respondents deny the allegations in paragraph 72, except admit that Horizon has biologic reference product exclusivity in the United States covering TEPEZZA® until the year stated in the allegation. To the extent the allegations in paragraph 72 purport to state a legal conclusion, no response is required as to those allegations.

73. Respondents deny the allegations in paragraph 73. To the extent paragraph 73 purports to summarize any document created by Horizon employee(s), (a) Amgen states that it is without knowledge or information sufficient to form a belief about what information is contained in internal, non-public Horizon documents, and (b) Horizon refers to such document for its full and accurate contents.

74. Respondents are without knowledge or information sufficient to form a belief regarding the truth of the allegation in paragraph 74 that no manufacturers are currently developing a KRYSTEXXA® biosimilar.

75. Respondents deny the allegations in paragraph 75. To the extent the allegations in paragraph 75 purport to state a legal conclusion, no response is required as to those allegations.

ALLEGED VIOLATIONS

COUNT I – ALLEGED ILLEGAL AGREEMENT

76. The answers to the allegations in paragraphs 1 through 75 above are incorporated by reference.

77. Respondents deny the allegations in paragraph 77. To the extent the allegations in paragraph 77 purport to state a legal conclusion, no response is required as to those allegations.

COUNT II – ALLEGED ILLEGAL ACQUISITION

78. The answers to the allegations in paragraphs 1 through 75 above are incorporated by reference.

79. Respondents deny the allegations in paragraph 79. To the extent the allegations in paragraph 79 purport to state a legal conclusion, no response is required as to those allegations.

DEFENSES

Respondents assert the following defenses, without assuming the burden of proof on such defenses that would otherwise rest with the FTC.

1. The Complaint fails to state a claim on which relief can be granted.

2. The combination of Respondents' businesses will be procompetitive. The merger will result in substantial merger-specific efficiencies, cost synergies and other procompetitive effects that will directly benefit consumers. These benefits greatly outweigh any and all alleged anticompetitive effects.

3. The FTC's claims are too speculative to support any claim on which relief can be granted.

4. Amgen's commitment not to bundle Amgen products with TEPEZZA® or KRYSTEXXA® fully addresses and prevents the alleged anticompetitive effects.

5. The FTC has failed to define appropriate relevant markets.

6. The FTC has failed to sufficiently allege market power with respect to any relevant products or services.

7. The FTC's claims reflect improper selective enforcement of the antitrust laws.

8. The FTC's claims are barred in whole or in part by failure to show any plausible harm to consumers or consumer welfare or any plausible anticompetitive effect.

9. The FTC fails to allege a time frame for the alleged anticompetitive effects.

10. The Complaint does not allege a proper basis for relief pursuant to the Federal Trade Commission Act or the Clayton Act.

11. The relief that the FTC seeks is inconsistent with the public interest, the equities favor consummation of the Transaction and alternative remedies are available to the Commission.

12. The FTC's requested remedy is impermissibly overbroad. Even if there were merit to the FTC's case (and there is not), the appropriate remedy would not be to enjoin the Transaction, but instead simply—and at most—to enter an order limiting the bundling of certain Amgen products with either TEPEZZA® or KRYSTEXXA® in certain circumstances.

13. The FTC seeks relief through an administrative process that runs afoul of the U.S. Constitution. The process:

a. violates Article I of the Constitution, which provides that "[a]ll legislative Powers herein granted shall be vested in a Congress of the United States," U.S. Const. art. I, § 1, in that (i) Congress delegated to the FTC the power to decide whether to bring antitrust enforcement actions in administrative proceedings rather than in an Article III court and (ii)

Congress did not provide the FTC with an intelligible principle by which to exercise that power, giving it total, unguided discretion to decide whether to bring an antitrust enforcement action in an administrative proceeding rather than in an Article III court;

b. violates Article II of the Constitution and its separation of powers principles because (i) the FTC's Commissioners and Administrative Law Judges can only be removed for cause, (ii) the FTC bears no resemblance to the "quasi-legislative or quasi-judicial" body whose for-cause removal provisions were upheld in now-inapposite Supreme Court precedent, (iii) rather, the FTC today operates primarily as an enforcement agency (*e.g.*, by regularly bringing suit in administrative proceedings and federal court for injunctive and monetary relief, including relief to stop the consummation of transactions that could improve the lives of numerous patients in the United States and globally), *see, e.g.*, Daniel A. Crane, *Debunking Humphrey's Executor*, 83 Geo. Wash. L. Rev. 1835, 1859-68 (2015), and therefore (iv) the for-cause removal restriction impermissibly restricts the President's removal powers;

c. violates Article III of the Constitution by adjudicating private rights before a non-Article III body without meaningful review of the FTC's factual findings by an Article III court;

d. violates Respondents' right to Due Process under the Fifth Amendment by depriving Respondents of their right to adjudication before a neutral arbiter—specifically, the combining investigative, prosecutorial and adjudicative functions violates due process where "the probability of actual bias on the part of the judge or decision-maker is too high to be constitutionally tolerable," *Withrow v. Larkin*, 421 U.S. 35, 47, 58 (1975), as is the case here considering the FTC Commissioners vote out the complaint, direct its prosecution and pass judgment on its merits, relying on evidence that would not be admissible in an Article III court,

and in a proceeding where the FTC reportedly has not lost in 25 years, "reveal[ing] just how tilted this game is," *Axon Enter., Inc. v. FTC*, 143 S. Ct. 890, 917 (2023) (Gorsuch, J., concurring);

e. violates Respondents' right to Equal Protection under the Fifth Amendment, in that the FTC and the Department of Justice ("DOJ") arbitrarily decide between them which agency will review a transaction through a black box "clearance" process, and as a result of that arbitrary decision, the Transaction was reviewed by the FTC, which has the ability to judge its merits through an in-house proceeding that lacks the protections of an Article III court (such as the ability to rely on evidence not admissible under the Federal Rules of Evidence, and where the same decision-makers initiate, prosecute and decide the merits of the case), whereas if the DOJ reviewed the Transaction and decided to challenge it, such challenge could *only* be brought in an Article III court for final adjudication of the merits of the challenge; and

f. violates Respondents' right to a jury trial under the Seventh Amendment, in that the FTC review process includes no right for a regulated respondent to receive a trial by jury, while the Seventh Amendment applies whenever a respondent's private rights are at issue, which are historically understood to include property rights, and where the FTC seeks to directly regulate Respondents' rights to use their property, including Respondents' ability to engage in a private commercial transaction and the possibility of future civil penalties, *see* 15 U.S.C. § 45(l).

Respondents reserve the right to assert any other available defenses.

NOTICE

Respondents state that the Notice of the Complaint is a restatement of the rules of the FTC to which no response is required. To the extent a response is required, Respondents deny the allegations in the Notice of the Complaint except state that the FTC has provided notice of a hearing date on October 25, 2023.

NOTICE OF CONTEMPLATED RELIEF

Respondents state that the Notice of Contemplated Relief is a restatement of the rules of the FTC to which no response is required. To the extent a response is required, Respondents deny the allegations in the Notice of Contemplated Relief.

Respondents respectfully request that the Court: (i) deny the FTC's requested relief; (ii) dismiss the Complaint in its entirety with prejudice; (iii) award to Respondents their costs of suit, including expert fees and reasonable attorneys' fees, as may be allowed by law; and (iv) award to Respondents such other and further relief as the Court deems just and appropriate.

Dated: July 7, 2023

New York, New York

Respectfully submitted,

/s/ David R. Marriott

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CERTIFICATE OF SERVICE

I hereby certify that on July 7, 2023, I filed the foregoing document electronically using the FTC's E-Filing System, which will send notification of such filing to:

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The Honorable D. Michael Chappell
Administrative Law Judge
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I also certify that I caused the foregoing document to be served via email to:

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July 7, 2023

/s/ Jesse M. Weiss
Jesse M. Weiss

CERTIFICATE FOR ELECTRONIC FILING

I certify that the electronic copy sent to the Secretary of the Commission is a true and correct copy of the paper original and that I possess a paper original of the signed document that is available for review by the parties and the adjudicator.

July 7, 2023

/s/ Jesse M. Weiss
Jesse M. Weiss