ANALYSIS OF AGREEMENT CONTAINING CONSENT ORDER TO AID PUBLIC COMMENT

In the Matter of Amgen Inc. and Horizon Therapeutics plc,
Docket No. DO9414

INTRODUCTION

The Federal Trade Commission ("Commission") has accepted, subject to final approval, an Agreement Containing Consent Order ("Consent Agreement") from Amgen Inc. ("Amgen") and Horizon Therapeutics plc ("Horizon") to remedy the anticompetitive effects resulting from Amgen's proposed acquisition of Horizon (the "Acquisition"). Amgen is one of the world's largest biopharmaceutical companies and Horizon currently enjoys a monopoly on the medicines that treat thyroid eye disease ("TED") and chronic refractory gout ("CRG"). The Commission alleged in its Complaint that the Acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, by enabling Amgen to leverage its portfolio of blockbuster drugs to foreclose actual or potential rivals to Horizon's top-selling medications, thereby substantially lessening competition in the markets for the sale of FDA-approved drugs to treat TED and CRG and tending to create a monopoly in those same markets.

The Consent Agreement, which contains the proposed Decision and Order ("Order" or "D&O") will remedy the alleged violations by preserving the competition that would otherwise be eliminated by the Acquisition. Specifically, under the terms of the proposed Order, Amgen is prohibited from leveraging its drug portfolio to foreclose or disadvantage competitors to Tepezza or Krystexxa for 15 years from the date of the issuance of the proposed Order. To protect robust future competition in the TED and CRG markets, including due to acquisitions by Amgen that may or may not be reportable under the Hart-Scott-Rodino ("HSR") Premerger Notification Act, the proposed Order requires Amgen to obtain the Commission's prior approval for the acquisition of any product or business interest involved in: (1) the manufacture or sale of any drug indicated to treat TED or CRG, or (2) the pre-commercial development of any drug in development for TED or CRG that has completed an FDA Phase II or Phase III clinical trial until December 31, 2032.

The Consent Agreement with the proposed Order has been placed on the public record for thirty days for receipt of comments from interested persons. Comments received during this period will become part of the public record. After thirty days, the Commission will review the D&O as well as any comments received, and decide whether it should withdraw, modify, or make final the D&O.

THE PARTIES AND TRANSACTION

Amgen is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware with its principal executive offices located at One Amgen Center Drive, Thousand Oaks, California. Amgen is a biotechnology company that develops, manufactures, and delivers human therapeutics. In 2022, Amgen had global product sales of about $24.8 billion (and total revenues of about $26.3 billion). The United States is Amgen's

largest market, representing approximately 72% of its sales. Amgen's current product portfolio includes 27 approved drugs, nine of which generated 2022 sales in excess of $1 billion.

Horizon is a public limited company organized, existing, and doing business under and by virtue of the laws of Ireland with its principal executive offices located at 70 St. Stephen's Green, Dublin 2, D02 E2X4, Ireland. Horizon is a global biotechnology company focused on the discovery, development, and commercialization of medicines that treat rare, autoimmune, and severe inflammatory diseases. Horizon markets and distributes eleven drug products in the United States through its wholly owned subsidiary, Horizon Therapeutics USA, Inc. Horizon's U.S. headquarters is in Deerfield, Illinois. The company's two leading marketed drugs are Tepezza for the treatment of TED and Krystexxa for the treatment of CRG. The two drugs accounted for approximately 74% of Horizon's approximately $3.6 billion in net sales in 2022, with Tepezza generating $1.96 billion and Krystexxa netting $716 million.

Pursuant to an agreement, dated December 11, 2022, Amgen agreed to acquire all of the issued and ordinary share capital of Horizon through a newly formed, wholly owned subsidiary of Amgen for $116.50 per share in cash. The total value of the Acquisition is approximately $28 billion.

THE RELEVANT PRODUCTS AND MARKET STRUCTURE

The Sale of FDA-Approved Drugs to Treat Thyroid Eye Disease

A relevant line of commerce in which to analyze the effects of the Acquisition is the sale of FDA-approved drugs to treat TED. TED is a serious, progressive, and vision-threatening rare autoimmune condition, with a potential patient population of over 60,000 in the United States. While TED often occurs in people living with hyperthyroidism or Graves' disease, it is a distinct disease that is caused by autoantibodies activating an IGF-1R-mediated signaling complex on cells within the retro-orbital space. This disease leads to a cascade of negative effects that may cause long-term, irreversible eye damage including proptosis (eye bulging), strabismus (misalignment of the eyes) and diplopia (double vision)—and in some cases can lead to blindness.

Horizon's Tepezza (teprotumumab-trbw), a fully human monoclonal antibody and a targeted inhibitor of the insulin-like growth factor-1 receptor, is the first and only drug approved by the FDA to treat TED. The FDA granted Tepezza an orphan drug designation in January 2020. Tepezza is administered to patients intravenously by a healthcare provider, typically in an outpatient infusion center or a doctor's office. The wholesale acquisition cost for a single vial of Tepezza is almost $15,000, and a full course of treatment of Tepezza can cost over $350,000.

As the only FDA-approved TED treatment, Tepezza currently faces no direct competition in the United States. However, Tepezza's monopoly in the TED market is threatened by potential entry in the coming years from rivals developing competing drugs. For example, Viridian Therapeutics, Inc. ("Viridian") is advancing multiple candidates through clinical programs for the treatment of patients with TED that could threaten Tepezza's monopoly. Viridian has initiated a Phase 3 clinical trial for its leading candidate, VRDN-001, in patients

with active TED. In addition to its program for intravenously administered VRDN-001, Viridian is developing subcutaneous products with the goal of providing a more conveniently administered therapy to patients with TED.

The Sale of FDA-approved Drugs to Treat Chronic Refractory Gout

A relevant line of commerce in which to analyze the effects of the Acquisition is the sale of FDA-approved drugs to treat CRG in adult patients. Gout is one of the most common forms of inflammatory arthritis and is associated with multiple comorbidities. CRG is severe chronic gout in adult patients that is refractory to conventional therapy. Of the 9.5 million gout sufferers in the United States, more than 100,000 patients may have CRG, which frequently causes crippling disabilities and significant joint damage.

Horizon's Krystexxa (pegloticase injection) is the first and only FDA-approved drug to treat CRG. The FDA granted Krystexxa an orphan drug designation in September 2010, and subsequently approved a supplemental Biologics License Application in July 2022, expanding the drug's labeling to include Krystexxa co-administered with methotrexate, an immunomodulatory therapy. Krystexxa is a PEGylated uric acid specific enzyme that is administered intravenously in an outpatient infusion center or doctor's office by healthcare providers. The annual wholesale acquisition cost of a course of treatment of Krystexxa is approximately $650,000.

As the only FDA-approved CRG treatment, Krystexxa currently faces no direct competition in the United States. However, Krystexxa's monopoly in the CRG market is threatened by potential entry in the coming years. For example, Selecta Biosciences ("Selecta") initiated a Phase 3 clinical program of a candidate, SEL-212, for the treatment of CRG. SEL-212 is a combination of Selecta's ImmTOR immune tolerance platform and a therapeutic uricase enzyme (pegadricase).

THE RELEVANT GEOGRAPHIC MARKET

The United States is the relevant geographic market in which to assess the competitive effects of the proposed Acquisition. FDA-approved drugs to treat TED and CRG are prescription pharmaceutical products and regulated by FDA. As such, products sold outside the United States, but not approved for sale in the United States, do not provide viable competitive alternatives for U.S. consumers.

COMPETITIVE EFFECTS OF THE ACQUISITION

Emerging competition to Tepezza and Krystexxa promises to generate a host of benefits for patients who suffer from TED and CRG, for doctors who prescribe treatments for the conditions, and for patients, employers, and health plans that ultimately pay for the medications. The Acquisition, however, would likely result in substantial competitive harm by foreclosing or disadvantaging such emerging competition and entrenching Tepezza's and Krystexxa's monopoly positions.

Post-Acquisition, Amgen Would Possess the Ability and Incentive to Foreclose or Disadvantage Rivals to Tepezza or Krystexxa

Post-Acquisition, Amgen would have the ability and incentive to sustain and entrench its dominant positions in the markets for FDA-approved TED and CRG drugs by leveraging its portfolio of blockbuster drugs to foreclose or disadvantage future rivals in these markets.

Negotiations with PBMs and payers (i.e., health plans or plan sponsors) are crucial to Amgen, as these entities' formulary and utilization management decisions effectively determine which medications patients can access. Amgen often gives these entities substantial rebates in exchange for favorable formulary positions for its drugs. Drugs reimbursed through the pharmacy benefit are typically self-administered and dispensed through a retail or specialty pharmacy. Most of Amgen's blockbuster drugs, such as Enbrel, are covered under payers' pharmacy benefits. In contrast, drugs that are administered by a healthcare provider, such as Tepezza and Krystexxa, are typically reimbursed under payers' medical benefits. Payers typically rely on PBMs to negotiate their pharmacy benefit coverage and rebates, while medical benefit managers (often owned by the same PBMs) or health plans themselves generally negotiate their medical benefit policies and rebates.

With its broad and powerful drug portfolio, Amgen does not limit itself to single-product rebate agreements with PBMs and payers. For example, one tactic Amgen employs is providing cross-market bundles or bundled rebates. Through this strategy, Amgen provides greater rebates on one or more of its blockbuster products to secure favorable formulary placement for other medications in different product markets. Due to the enormous sales and consistent volume of Amgen's blockbuster drugs, which last year generated over $4 billion in global sales, even small enhancements to rebates can ensure payers accept such contracts. Therefore, Amgen post-Acquisition may have the ability to insulate Tepezza and Krystexxa from competitive threats through strategies that include conditioning rebates on one or more of its must-have blockbuster drugs in return for payer agreements to deny coverage to, or otherwise disfavor, potential or actual rivals to the two medications. That strategy would have the effect of raising rivals' barriers to entry and foreclosing them from effectively competing in the markets for the sale of FDA-approved drugs to treat TED and CRG.

A bundle of one of Amgen's blockbuster drugs such as Enbrel with Tepezza or Krystexxa would be both a cross-market bundle (i.e., a bundle involving drugs in different product markets) and a cross-benefit bundle (i.e., a bundle that includes drugs managed by a health plan's medical benefit with drugs managed by its pharmacy benefit). Although payers have historically siloed pharmacy and medical benefits from one another, the same payer determines coverage for drugs that are reimbursed through its beneficiaries' pharmacy and medical benefits and bears the cost of the drug regardless of whether it is reimbursed through the pharmacy or medical benefit. Additionally, each of the three largest PBMs, in part due to recent consolidation, is now vertically integrated with payers that manage patients' medical benefits: OptumRx/United Healthcare, CVS Caremark/Aetna, and Express Scripts/Cigna. Even non-vertically integrated PBMs are increasingly able to combine pharmacy and medical benefit capabilities that allow them to market cross-benefit management tools to their clients. These industry trends, which are altering a market structure that previously siloed pharmacy and medical benefits from one

another, would facilitate Amgen's ability to implement cross-benefit bundles that link its blockbuster pharmacy benefit drugs, like Enbrel, and medical benefit drugs acquired through the Acquisition, like Tepezza and Krystexxa.

Post-Acquisition, Amgen also will have the incentive to leverage its portfolio to bias decisions about drug coverage to protect the value of its newly acquired monopoly products. Multiple rivals are developing competitors to Tepezza and Krystexxa, threatening the massive profit pools generated by these drugs. Competitive entry would likely lead to competition on the merits, with payers leveraging drugs off one another to secure lower prices. Thus, the merged firm will have an incentive to leverage Amgen's blockbuster drugs to defend the monopoly share of the Tepezza and Krystexxa markets.

The Acquisition Would Entrench Tepezza's and Krystexxa's Monopolies

The Acquisition would entrench and extend Tepezza's and Krystexxa's monopolies in the TED and CRG markets by substituting Amgen, with its broad and powerful portfolio of blockbuster drugs, for Horizon with its smaller portfolio, thus raising entry barriers and dissuading smaller firms from aggressively competing. Currently, Horizon has only three prominent on-market drugs focused on small patient populations with rare diseases. The merged firm, however, would have Amgen's large portfolio of blockbuster drugs and ability to contract for cross-benefit bundles to secure preferential formulary placement, which Tepezza's and Krystexxa's impending competitors lack. Any potential competitor to Tepezza or Krystexxa would need a similar portfolio of highly utilized and rebated blockbuster drugs to compete effectively for payer coverage in the TED and CRG markets. As a result, the Acquisition could deter future entry and deprive patients, doctors, and payers of the benefits of competition and access to new treatments for two rare diseases.

THE PROPOSED ORDER

The proposed Order eliminates the competitive concerns raised by the proposed Acquisition by prohibiting the combined company from leveraging Amgen's drug portfolio to foreclose or disadvantage competitors to Tepezza or Krystexxa for 15 years from the date of the issuance of the D&O.

Pursuant to the proposed Order, post-Acquisition Amgen will be prohibited from directly, indirectly, explicitly, or implicitly conditioning any product rebate on, or any contract terms related to, any Amgen product in exchange for the purchase, coverage, placement, or positioning, individually or in any combination, of Krystexxa or Tepezza. The proposed Order defines rebates broadly to cover any concession or dollar amount provided by Amgen including, rebates, administrative fees, volume discounts, patient conversion payments, market share-related payments, formulary placement fees, disease management program payments, promotional allowances, portal fees, data fees, and specialty pharmacy discounts.

Pursuant to the proposed Order, post-Acquisition Amgen also will be prohibited from directly, indirectly, explicitly, or implicitly conditioning any product rebate on, or any contract terms related to, any Amgen product in exchange for the exclusion, detriment, or disadvantage,

individually or in any combination, of any competitor to Tepezza or Krystexxa. This prohibition applies to both drugs and biologics, as well as biosimilars and other drugs that are therapeutic equivalents, which share an FDA indication with Tepezza or Krystexxa, as well as products which are used as off-label treatments for TED or CRG.

In the event that Amgen believes that a federal, state, or local statute, rule, or regulation requires Amgen to enter into a contract which would be prohibited by the proposed Order, Amgen is required to provide 30-days prior notice to the Commission before entering into such a contract.

Additionally, because of the concentrated nature of the relevant markets, as well as the possibility of future acquisitions by Amgen in these markets, the proposed Order includes a prior approval for the acquisition of any product or business interest involved in: (1) the manufacture or sale of any drug indicated to treat TED or CRG, or (2) the pre-commercial development of any drug in development for TED or CRG that has completed an FDA Phase II or Phase III clinical trial. This provision is effective until December 31, 2032.

To ensure compliance with the proposed Order, the Commission will appoint a monitor to observe and report on Amgen's compliance. Among other obligations, the proposed Order requires Amgen to submit to the monitor all contracts with payers related to the purchase, coverage, placement, or positioning of Tepezza or Krystexxa in the United States and to maintain any documents related to any offers, negotiations, disputes, or enforcement for such contracts. Additionally, Amgen is required to submit regular reports to the Commission to enable the Commission to determine independently whether Amgen is complying with the proposed Order.

The purpose of the proposed Order is, among other things, to address the theories of harm to competition alleged by the Commission in its Complaint, in this matter, and in the Commission's Joint Federal Court Complaint for Temporary Restraining Order and Preliminary Injunction filed with the states of California, Illinois, Minnesota, New York, Washington and Wisconsin ("Interested States") in the United States District Court, Northern District of Illinois, June 22, 2023, Case # 1:23-cv-03053, by formalizing Amgen's commitment not to engage in the leveraging or conditioning of Amgen's drug products with Tepezza or Krystexxa, as described above. The Interested States will be receiving certain information from Amgen and the monitor as those states have had a strong interest in the resolution of the federal court complaint, have contributed significantly to the investigation of Amgen's potential anticompetitive transaction with Horizon, and will be kept apprised of Amgen's ongoing compliance with the proposed Order.

The purpose of this analysis is to facilitate public comment on the Consent Agreement and proposed Order, and it is not intended to constitute an official interpretation of the proposed Order or to modify its terms in any way.