AMGEN TO PRESENT INNOVATIVE RHEUMATOLOGY RESEARCH AT EULAR 2024

June 12, 2024

Data Highlight Positive Outcomes in Uncontrolled Gout With KRYSTEXXA® and Progress in Addressing Sjögren's Disease

THOUSAND OAKS, Calif., June 12, 2024 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced the presentation of data across its diverse portfolio and pipeline at the European Alliance of Associations for Rheumatology's (EULAR) 2024 Congress, June 12-15 in Vienna. The 27 abstracts from Amgen-sponsored and partner-led studies demonstrate Amgen's commitment to improving the lives of patients living with inflammatory and rheumatic disease through the development of novel medicines.

Key presentations include the first findings showing dazodalibep improved major biomarkers in Sjögren's disease, as well as data on treatment outcomes for uncontrolled gout based on a post-hoc analysis of the MIRROR trial for KRYSTEXXA® (pegloticase) with methotrexate.

"We are deeply committed to advancing patient care through continuous innovation and rigorous science. The data presented at EULAR 2024 further demonstrate our efforts to address complex diseases," said Jay Bradner, M.D., executive vice president, Research and Development, and chief scientific officer at Amgen. "By advancing scientific research, we are not only enhancing our understanding of these conditions, but also paving the way for more effective treatments that have the potential to significantly improve patient outcomes."

Additional presentations include new long-term data from the FOREMOST study of Otezla® (apremilast) in early oligoarticular psoriatic arthritis, as well as a post-hoc analysis of TAVNEOS® (avacopan) versus prednisone taper in patients with severe active MPA/GPA and active ear, nose or throat manifestations.

For more information on the Amgen abstracts, see below.

Abstracts and Presentation Times:

Amgen-Sponsored Abstracts

Dazodalibep

- **CD40L blockade with dazodalibep significantly improves disease activity, swollen and tender joint counts, while reducing multiple T- and B-cell biomarkers in the MIDORA phase 2 study of patients with moderate-to-severe active rheumatoid arthritis**
  Abstract #AB0746, Rheumatoid Arthritis (Publication only)
- **Dazodalibep (anti-CD40L) effectively reduces multiple proteins associated with B-, T, and dendritic cell biomarkers in Sjögren's disease: Corroboration of immunophenotyping findings from the ALISS phase 2 study**
  Abstract #OP0058, Clinical Abstract Sessions: New Targets and New Treatments in Sjön's Disease (Oral Abstract Presentations), Wednesday, June 12 from 5:00 to 5:10 p.m. CDT

Sjögren's Disease

- **Global burden of Sjögren's disease (SjD): Findings from a systematic literature review (SLR) of humanistic and clinical outcomes**
  Abstract #AB0815, Sjögren`s syndrome (Publication Only)

KRYSTEXXA® (pegloticase)

- **Achievement of "gout remission" during intensive urate-lowering over 52 weeks of pegloticase therapy**
  Abstract #POS0239, Clinical Poster Tours: Gout treatment in 2024 (Poster Tours), Friday, June 14 at 9:30 a.m. CDT
- **Influence of acute gout flare and serum urate lowering on biomarkers of systemic inflammation**
  Abstract #AB0114, Crystal related disorders (Publication Only)
- **Patient-reported quality of life in uncontrolled gout and changes with intensive urate-lowering: Comparison of tophaceous and non-tophaceous patients**
  Abstract #AB0112, Crystal related disorders (Publication Only)
- **Pre-infusion glucocorticoid reduction/elimination in patients with uncontrolled gout treated with pegloticase and methotrexate: Experience of one community rheumatology practice**
  Abstract #POS0936, Crystal related disorders (Poster View), Friday, June 14 at 9:30 a.m. CDT

Uncontrolled Gout

- **Cardiovascular disease, chronic kidney disease, pain, and psychological issues in patients with controlled vs. uncontrolled gout: A retrospective claims-based cohort analysis**
  Abstract #POS0569, Crystal related disorders (Poster View), Wednesday, June 12 at 3:30 p.m. CDT
- **The concept of gout remission as viewed by rheumatologists, nephrologists, and primary care physicians**

Abstract #POS0269, Clinical Poster Tours: Gout treatment in 2024 (Poster Tours), Friday, June 14 at 9:30 a.m. CDT

- **Treatment patterns and quality of life in patients with controlled and uncontrolled gout**
  Abstract #POS0940, Crystal related disorders *(Poster View),* Friday, June 14 at 9:30 a.m. CDT

Otezla® (apremilast)

- **Apremilast reduces axial inflammation in patients with psoriatic arthritis as assessed by CANDEN MRI scoring: Results from the phase 4 MOSAIC study**
  Abstract #POS0982, Psoriatic arthritis (Poster View), Friday, June 14 at 9:30 a.m. CDT
- **Apremilast reduces inflammation as measured by MRI, clinical outcomes, and patient-reported outcomes in patients with psoriatic arthritis: Results from the phase 4 MOSAIC study**
  Abstract #POS0968, Psoriatic arthritis (Poster View), Friday, June 14 at 9:30 a.m. CDT
- **Apremilast treatment in early oligoarticular psoriatic arthritis (PsA) improves clinical and patient-reported outcomes for up to 48 weeks – Data from the FOREMOST study**
  Abstract #POS0976, Psoriatic arthritis (Poster View), Friday, June 14 at 9:30 a.m. CDT
- **Apremilast for psoriatic arthritis in the Netherlands: Real-world data from the REWARD study**
  Abstract #AB0453, Psoriatic arthritis (Publication Only)
- **The use of disease activity thresholds for the Psoriatic Arthritis Impact of Disease (PsAID-12) questionnaire to assess patient perceptions of disease burden in patients with early oligoarticular psoriatic arthritis treated with apremilast in the FOREMOST study**
  Abstract #AB0473, Psoriatic arthritis (Publication Only)

Prolia® (denosumab)

- **Comparative effectiveness of denosumab versus bisphosphonates among treatment-experienced postmenopausal women with osteoporosis in the U.S. Medicare program**
  Abstract #POS0089, Clinical Poster Tours: Treatment Options in Metabolic bone diseases and Osteoporosis (Poster Tours), Thursday, June 13 at 9:54 a.m. CDT
- **Comparative effectiveness of denosumab versus zoledronic acid among postmenopausal women with osteoporosis in the U.S. Medicare program**
  Abstract #POS0583, Other diseases (Poster View), Thursday, June 13 at 9:30 a.m. CDT
- **Risk of fragility fracture after long-term discontinuation of osteoporosis treatment in post-menopausal osteoporosis women in France: A population-based study conducted on the nationwide claim database (SNDS)**
  Abstract #OP0035, Clinical Abstract Sessions: Risk factors and treatment in osteoporosis (Oral Abstract Presentations), Wednesday, June 12 at 4:50 p.m. CDT

TAVNEOS® (avacopan)

- **Avacopan versus prednisone taper in patients with ANCA-associated vasculitis and ear, nose, or throat involvement**
  Abstract #OP0174, Clinical Abstract Sessions: Vasculitis across different vessel sizes (Oral Abstract Presentations), Thursday, June 13 at 11:20 a.m. CDT
- **Data from the ADVOCATE trial on 28 patients with ANCA-associated vasculitis who received avacopan without concomitant glucocorticoid use in the first 29 days**
  Abstract #POS0246, Clinical Poster Tours: Miscellaneous in Vasculitis (Poster Tours), Friday, June 14 at 9:36 a.m. CDT

UPLIZNA® (inebilizumab-cdon)

- **Burden of glucocorticoid use and associated toxicities in commercially insured adults with IgG4-related disease**
  Abstract #POS0357, Clinical Poster Tours: IgG4 Related Disease (Poster Tours), Friday, June 14 at 2:45 p.m. CDT
- **Insights into the design and study population of MITIGATE: The first multinational randomized controlled clinical trial in IgG4-related disease (IgG4-RD), evaluating the efficacy and safety of inebilizumab**
  Abstract #POS0347, Clinical Poster Tours: IgG4 Related Disease (Poster Tours), Friday, June 14 at 2:45 p.m. CDT

Partner-Led Abstracts

Sjögren's Disease

- **The use of natural language processing to characterize disease burden: Sexual distress in Sjögren's disease**
  Abstract #AB0793, Sjön`s syndrome (Publication Only)
- **Using social media listening to characterize the flare lexicon in patients with Sjögren's disease**
  Abstract #AB0794, Sjön`s syndrome (Publication Only)

TAVNEOS® (avacopan)

- **Safety and effectiveness of avacopan beyond 52 weeks: Experience to date in the Early Access Program (EAP)**
  Abstract #POS0865, Vasculitis, small and medium size vessels (Poster View), Thursday, June 13 at 2:45 p.m. CDT
- **Design of AVACOSTAR: A real-world study of avacopan in ANCA-associated vasculitis (AAV)**
  Abstract #AB1241, Vasculitis, small and medium size vessels (Publication Only)

Uncontrolled Gout

- **Osteoporosis in patients with gout in the United States**
  Abstract #POS0563, Crystal related disorders (Poster View), Wednesday, June 12 at 3:30 p.m. CDT

About KRYSTEXXA® (pegloticase)

KRYSTEXXA® (pegloticase) is the first and only biologic approved by the FDA to treat adults living with uncontrolled gout, a painful and debilitating inflammatory condition with which people continue to have abnormally high levels of uric acid and symptoms despite the use of conventional therapies.

In 2022, the FDA approved expanding labeling to include co-administration with the immunomodulator methotrexate, based on results from the MIRROR randomized controlled trial, which showed significant improvements in efficacy and safety, including a reduction in infusion reactions.

About Uncontrolled Gout

Gout is a chronic, progressive inflammatory form of arthritis that is caused by high urate levels in the body. Tiny needle-like crystals can form and build up almost anywhere in the body. Patients with uncontrolled gout continue to have high levels of uric acid and ongoing symptoms of gout despite the use of oral urate-lowering therapies. Uncontrolled gout is a chronic, systemic disease, and if not addressed can have significant clinical consequences.

KRYSTEXXA U.S. Indication

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.

Limitations of Use: KRYSTEXXA is not recommended for the treatment of asymptomatic hyperuricemia.

KRYSTEXXA U.S. Important Safety Information

WARNING: ANAPHYLAXIS AND INFUSION REACTIONS, G6PD DEFICIENCY ASSOCIATED HEMOLYSIS AND METHEMOGLOBINEMIA

- **Anaphylaxis and infusion reactions have been reported to occur during and after administration of KRYSTEXXA.**
- **Anaphylaxis may occur with any infusion, including a first infusion and generally manifests within 2 hours of the infusion. Delayed hypersensitivity reactions have also been reported.**
- **KRYSTEXXA should be administered in healthcare settings and by healthcare providers prepared to manage anaphylaxis and infusion reactions.**
- **Patients should be premedicated with antihistamines and corticosteroids and closely monitored for anaphylaxis for an appropriate period after administration of KRYSTEXXA.**
- **Serum uric acid levels should be monitored prior to each infusion and treatment discontinued if levels increase to above 6 mg/dL, particularly when 2 consecutive levels above 6 mg/dL are observed.**
- **Patients at risk for glucose-6-phosphate dehydrogenase (G6PD) deficiency should be screened prior to starting KRYSTEXXA. Hemolysis and methemoglobinemia have been reported with KRYSTEXXA in patients with G6PD deficiency. KRYSTEXXA is contraindicated in patients with G6PD deficiency.**

CONTRAINDICATIONS

- In patients with G6PD deficiency.
- In patients with history of serious hypersensitivity reactions, including anaphylaxis, to KRYSTEXXA or any of its components.

WARNINGS AND PRECAUTIONS

Gout Flares: An increase in gout flares is frequently observed upon initiation of anti-hyperuricemic therapy, including KRYSTEXXA. Gout flare prophylaxis with a non-steroidal anti-inflammatory drug (NSAID) or colchicine is recommended starting at least 1 week before initiation of KRYSTEXXA therapy and lasting at least 6 months, unless medically contraindicated or not tolerated.

Congestive Heart Failure: KRYSTEXXA has not been formally studied in patients with congestive heart failure, but some patients in the pre-marketing placebo-controlled clinical trials experienced exacerbation. Caution should be exercised in patients who have congestive heart failure and patients should be closely monitored following infusion.

ADVERSE REACTIONS

The most commonly reported adverse reactions (≥5%) are:

- **KRYSTEXXA co-administration with methotrexate trial:** gout flares, arthralgia, COVID-19, nausea and fatigue;

KRYSTEXXA alone: gout flares, arthralgia, COVID-19, nausea, fatigue, infusion reactions, pain in extremity, hypertension and vomiting.

- **KRYSTEXXA pre-marketing placebo-controlled trials:** gout flares, infusion reactions, nausea, contusion or ecchymosis, nasopharyngitis, constipation, chest pain, anaphylaxis and vomiting.

Please see Full Prescribing Information, including Boxed Warning.

About Otezla® (apremilast)

Otezla® (apremilast) is an oral small-molecule inhibitor of phosphodiesterase 4 (PDE4) specific for cyclic adenosine monophosphate (cAMP). PDE4 inhibition results in increased intracellular cAMP levels, which is thought to indirectly modulate the production of inflammatory mediators. The specific mechanism(s) by which Otezla exerts its therapeutic action in patients is not well defined.

Since its initial FDA approval in 2014, Otezla has been prescribed to more than 840,000 patients worldwide.

About Psoriatic Arthritis

Psoriatic arthritis is a chronic, inflammatory form of arthritis, which can cause swelling, stiffness and pain in and around the joints that worsens over time and can decrease physical function. It is estimated that nearly 38 million people worldwide have psoriatic arthritis. Around a third of people living with psoriasis may go on to develop psoriatic arthritis. If left untreated, psoriatic arthritis can cause disability.

Otezla U.S. Indications

Otezla (apremilast) is indicated for the treatment of adult patients with plaque psoriasis who are candidates for phototherapy or systemic therapy.

Otezla is indicated for the treatment of adult patients with active psoriatic arthritis.

Otezla is indicated for the treatment of adult patients with oral ulcers associated with Behçet's Disease.

Otezla U.S. Important Safety Information

Contraindications

- Otezla is contraindicated in patients with a known hypersensitivity to apremilast or to any of the excipients in the formulation

Warnings and Precautions

- Hypersensitivity: Hypersensitivity reactions, including angioedema and anaphylaxis, have been reported during postmarketing surveillance. If signs or symptoms of serious hypersensitivity reactions occur, discontinue Otezla and institute appropriate therapy
- Diarrhea, Nausea, and Vomiting: Cases of severe diarrhea, nausea, and vomiting were associated with the use of Otezla. Most events occurred within the first few weeks of treatment. In some cases, patients were hospitalized. Patients 65 years of age or older and patients taking medications that can lead to volume depletion or hypotension may be at a higher risk of complications from severe diarrhea, nausea, or vomiting. Monitor patients who are more susceptible to complications of diarrhea or vomiting; advise patients to contact their healthcare provider. Consider Otezla dose reduction or suspension if patients develop severe diarrhea, nausea, or vomiting
- Depression: Carefully weigh the risks and benefits of treatment with Otezla for patients with a history of depression and/or suicidal thoughts/behavior, or in patients who develop such symptoms while on Otezla. Patients, caregivers, and families should be advised of the need to be alert for the emergence or worsening of depression, suicidal thoughts or other mood changes, and they should contact their healthcare provider if such changes occur
    - Plaque Psoriasis: Treatment with Otezla is associated with an increase in depression. During clinical trials in patients with moderate to severe plaque psoriasis, 1.3% (12/920) of patients reported depression compared to 0.4% (2/506) on placebo. Depression was reported as serious in 0.1% (1/1308) of patients exposed to Otezla, compared to none in placebo-treated patients (0/506). Suicidal behavior was observed in 0.1% (1/1308) of patients on Otezla, compared to 0.2% (1/506) on placebo. One patient treated with Otezla attempted suicide; one patient on placebo committed suicide
    - Psoriatic Arthritis: Treatment with Otezla is associated with an increase in depression. During clinical trials, 1.0% (10/998) reported depression or depressed mood compared to 0.8% (4/495) treated with placebo. Suicidal ideation and behavior was observed in 0.2% (3/1441) of patients on Otezla, compared to none in placebo-treated patients. Depression was reported as serious in 0.2% (3/1441) of patients exposed to Otezla, compared to none in placebo-treated patients (0/495). Two patients who received placebo committed suicide compared to none on Otezla
    - Behçet's Disease: Treatment with Otezla is associated with an increase in depression. During the clinical trial, 1% (1/104) reported depression or depressed mood compared to 1% (1/103) treated with placebo. No instances of suicidal ideation or behavior were reported in patients treated with Otezla or treated with placebo
- Weight Decrease: Monitor body weight regularly; evaluate unexplained or clinically significant weight loss, and consider discontinuation of Otezla
    - Plaque Psoriasis: Body weight loss of 5-10% occurred in 12% (96/784) of patients with moderate to severe plaque psoriasis treated with Otezla and in 5% (19/382) of patients treated with placebo. Body weight loss of ≥10%

occurred in 2% (16/784) of patients treated with Otezla compared to 1% (3/382) of patients treated with placebo
    - Psoriatic Arthritis: Body weight loss of 5-10% was reported in 10% (49/497) of patients taking Otezla and in 3.3% (16/495) of patients taking placebo
    - Behçet's Disease: Body weight loss of >5% was reported in 4.9% (5/103) of patients taking Otezla and in 3.9% (4/102) of patients taking placebo
- Drug Interactions: Apremilast exposure was decreased when Otezla was co-administered with rifampin, a strong CYP450 enzyme inducer; loss of Otezla efficacy may occur. Concomitant use of Otezla with CYP450 enzyme inducers (e.g., rifampin, phenobarbital, carbamazepine, phenytoin) is not recommended

Adverse Reactions

- Plaque Psoriasis: The most common adverse reactions (≥ 5%) are diarrhea, nausea, upper respiratory tract infection, and headache, including tension headache. Overall, the safety profile of Otezla in patients with mild to moderate plaque psoriasis was consistent with the safety profile previously established in adult patients with moderate to severe plaque psoriasis
- Psoriatic Arthritis: The most common adverse reactions (≥ 5%) are diarrhea, nausea, and headache
- Behçet's Disease: The most common adverse reactions (≥ 10%) are diarrhea, nausea, headache, and upper respiratory tract infection.

Use in Specific Populations

- Otezla has not been studied in pregnant women. Advise pregnant women of the potential risk of fetal loss.

Please click here for Otezla® Full Prescribing Information.

About TAVNEOS® (avacopan)
TAVNEOS® (avacopan), approved by the FDA as an adjunctive treatment of severe active ANCA-associated vasculitis (GPA/MPA), is a first-in-class, orally administered small molecule that employs a novel, highly targeted mode of action. TAVNEOS blocks the complement 5a receptor (C5aR) from binding C5a, the pro-inflammatory complement system fragment. This is presumed to block C5a-mediated neutrophil activation and migration. The precise mechanism of TAVNEOS in ANCA-associated vasculitis (GPA/MPA) has not been definitively established.

About ANCA-Associated Vasculitis
ANCA-associated vasculitis is an umbrella term for a group of multi-system autoimmune diseases with small vessel inflammation. Inflamed vessels may rupture or become occluded giving rise to a broad array of clinical symptoms and signs related to a systemic inflammatory response which may result in profound impairment in the kidneys, lungs and other organs. Prior to the approval of TAVNEOS in severe active ANCA-associated vasculitis (GPA/MPA), the combination of immunosuppressants most often used for the treatment of ANCA-associated vasculitis (GPA/MPA) include cyclophosphamide or rituximab, combined with daily glucocorticoids (steroids) for prolonged periods, which can be associated with significant clinical consequences.

TAVNEOS U.S. Indication
TAVNEOS is indicated as an adjunctive treatment of adult patients with severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (granulomatosis with polyangiitis [GPA] and microscopic polyangiitis [MPA]) in combination with standard therapy including glucocorticoids. TAVNEOS does not eliminate glucocorticoid use.

TAVNEOS U.S. Important Safety Information

Contraindications

Serious hypersensitivity to avacopan or to any of the excipients.

Warning and Precautions

Hepatotoxicity: Serious cases of hepatic injury have been observed in patients taking TAVNEOS, including life-threatening events. Obtain liver test panel before initiating TAVNEOS, every 4 weeks after start of therapy for six months and as clinically indicated thereafter. Monitor patients closely for hepatic adverse reactions, and consider pausing or discontinuing treatment as clinically indicated (refer to section 5.1 of the Prescribing Information). TAVNEOS is not recommended for patients with active, untreated and/or uncontrolled chronic liver disease (e.g., chronic active hepatitis B, untreated hepatitis C, uncontrolled autoimmune hepatitis) and cirrhosis. Consider the risk and benefit before administering this drug to a patient with liver disease.

Serious Hypersensitivity Reactions: Cases of angioedema occurred in a clinical trial, including one serious event requiring hospitalization. Discontinue immediately if angioedema occurs and manage accordingly. TAVNEOS must not be re-administered unless another cause has been established.

Hepatitis B Virus (HBV) Reactivation: Hepatitis B reactivation, including life threatening hepatitis B, was observed in the clinical program. Screen patients for HBV. For patients with evidence of prior infection, consult with physicians with expertise in HBV and monitor during TAVNEOS therapy and for six months following. If patients develop HBV reactivation, immediately discontinue TAVNEOS and concomitant therapies associated with HBV reactivation, and consult with experts before resuming.

Serious Infections: Serious infections, including fatal infections, have been reported in patients receiving TAVNEOS. The most common serious infections reported in TAVNEOS group were pneumonia and urinary tract infections. Avoid use of TAVNEOS in patients with active, serious infection, including localized infections. Consider the risks and benefits before initiating TAVNEOS in patients with chronic infection, at increased risk of infection or who have been to places where certain infections are common.

Adverse Reactions

The most common adverse reactions (≥5% of patients and higher in the TAVNEOS group vs. prednisone group) were: nausea, headache, hypertension, diarrhea, vomiting, rash, fatigue, upper abdominal pain, dizziness, blood creatinine increased, and paresthesia.

Drug Interactions

Avoid coadministration of TAVNEOS with strong and moderate CYP3A4 enzyme inducers. Reduce TAVNEOS dose when co-administered with strong CYP3A4 enzyme inhibitors to 30 mg once daily. Monitor for adverse reactions and consider dose reduction of certain sensitive CYP3A4 substrates.

Please see Full Prescribing Information and Medication Guide.

About Amgen

Amgen discovers, develops, manufactures and delivers innovative medicines to help millions of patients in their fight against some of the world's toughest diseases. More than 40 years ago, Amgen helped to establish the biotechnology industry and remains on the cutting-edge of innovation, using technology and human genetic data to push beyond what's known today. Amgen is advancing a broad and deep pipeline that builds on its existing portfolio of medicines to treat cancer, heart disease, osteoporosis, inflammatory diseases and rare diseases.

In 2024, Amgen was named one of the "World's Most Innovative Companies" by Fast Company and one of "America's Best Large Employers" by Forbes, among other external recognitions. Amgen is one of the 30 companies that comprise the Dow Jones Industrial Average®, and it is also part of the Nasdaq-100 Index®, which includes the largest and most innovative non-financial companies listed on the Nasdaq Stock Market based on market capitalization.

For more information, visit Amgen.com and follow Amgen on X, LinkedIn, Instagram, TikTok, YouTube and Threads.

Amgen Forward-Looking Statements

This news release contains forward-looking statements that are based on the current expectations and beliefs of Amgen. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements, including any statements on the outcome, benefits and synergies of collaborations, or potential collaborations, with any other company (including BeiGene, Ltd. or Kyowa Kirin Co., Ltd.), the performance of Otezla® (apremilast) (including anticipated Otezla sales growth and the timing of non-GAAP EPS accretion), our acquisitions of Teneobio, Inc., ChemoCentryx, Inc., or Horizon Therapeutics plc (including the prospective performance and outlook of Horizon's business, performance and opportunities, any potential strategic benefits, synergies or opportunities expected as a result of such acquisition, and any projected impacts from the Horizon acquisition on our acquisition-related expenses going forward), as well as estimates of revenues, operating margins, capital expenditures, cash, other financial metrics, expected legal, arbitration, political, regulatory or clinical results or practices, customer and prescriber patterns or practices, reimbursement activities and outcomes, effects of pandemics or other widespread health problems on our business, outcomes, progress, and other such estimates and results. Forward-looking statements involve significant risks and uncertainties, including those discussed below and more fully described in the Securities and Exchange Commission reports filed by Amgen, including our most recent annual report on Form 10-K and any subsequent periodic reports on Form 10-Q and current reports on Form 8-K. Unless otherwise noted, Amgen is providing this information as of the date of this news release and does not undertake any obligation to update any forward-looking statements contained in this document as a result of new information, future events or otherwise.

No forward-looking statement can be guaranteed and actual results may differ materially from those we project. Discovery or identification of new product candidates or development of new indications for existing products cannot be guaranteed and movement from concept to product is uncertain; consequently, there can be no guarantee that any particular product candidate or development of a new indication for an existing product will be successful and become a commercial product. Further, preclinical results do not guarantee safe and effective performance of product candidates in humans. The complexity of the human body cannot be perfectly, or sometimes, even adequately modeled by computer or cell culture systems or animal models. The length of time that it takes for us to complete clinical trials and obtain regulatory approval for product marketing has in the past varied and we expect similar variability in the future. Even when clinical trials are successful, regulatory authorities may question the sufficiency for approval of the trial endpoints we have selected. We develop product candidates internally and through licensing collaborations, partnerships and joint ventures. Product candidates that are derived from relationships may be subject to disputes between the parties or may prove to be not as effective or as safe as we may have believed at the time of entering into such relationship. Also, we or others could identify safety, side effects or manufacturing problems with our products, including our devices, after they are on the market.

Our results may be affected by our ability to successfully market both new and existing products domestically and internationally, clinical and regulatory developments involving current and future products, sales growth of recently launched products, competition from other products including biosimilars, difficulties or delays in manufacturing our products and global economic conditions. In addition, sales of our products are affected by pricing pressure, political and public scrutiny and reimbursement policies imposed by third-party payers, including governments, private insurance plans and managed care providers and may be affected by regulatory, clinical and guideline developments and domestic and international trends toward managed care and healthcare cost containment. Furthermore, our research, testing, pricing, marketing and other operations are subject to extensive regulation by domestic and foreign government regulatory authorities. Our business may be impacted by government investigations, litigation and product liability claims. In addition, our business may be impacted by the adoption of new tax legislation or exposure to additional tax liabilities. If we fail to meet the compliance obligations in the corporate integrity agreement between us and the U.S. government, we could become subject to significant sanctions. Further, while we routinely obtain patents for our products and technology, the protection offered by our patents and patent applications may be challenged, invalidated or circumvented by our competitors, or we may fail to prevail in present and future intellectual property litigation. We perform a substantial amount of our commercial manufacturing activities at a few key facilities, including in Puerto Rico, and also depend on third parties for a portion of our manufacturing activities, and limits on supply may constrain sales of certain of our current products and product candidate development. An outbreak of disease or similar public health threat, such as COVID-19, and the public and governmental effort to mitigate against the spread of such disease, could have a significant adverse effect on the supply of materials for our manufacturing activities, the distribution of our products, the commercialization of our product candidates, and our clinical trial operations, and any such events may have a material adverse effect on our product development, product sales, business and results of operations. We rely on collaborations with third parties for the development of some of our product candidates and for the commercialization and sales of some of our commercial products. In addition, we compete with other companies with respect to many of our marketed products as well as for the discovery and development of new products. Further,

some raw materials, medical devices and component parts for our products are supplied by sole third-party suppliers. Certain of our distributors, customers and payers have substantial purchasing leverage in their dealings with us. The discovery of significant problems with a product similar to one of our products that implicate an entire class of products could have a material adverse effect on sales of the affected products and on our business and results of operations. Our efforts to collaborate with or acquire other companies, products or technology, and to integrate the operations of companies or to support the products or technology we have acquired, may not be successful. There can be no guarantee that we will be able to realize any of the strategic benefits, synergies or opportunities arising from the Horizon acquisition, and such benefits, synergies or opportunities may take longer to realize than expected. We may not be able to successfully integrate Horizon, and such integration may take longer, be more difficult or cost more than expected. A breakdown, cyberattack or information security breach of our information technology systems could compromise the confidentiality, integrity and availability of our systems and our data. Our stock price is volatile and may be affected by a number of events. Our business and operations may be negatively affected by the failure, or perceived failure, of achieving our environmental, social and governance objectives. The effects of global climate change and related natural disasters could negatively affect our business and operations. Global economic conditions may magnify certain risks that affect our business. Our business performance could affect or limit the ability of our Board of Directors to declare a dividend or our ability to pay a dividend or repurchase our common stock. We may not be able to access the capital and credit markets on terms that are favorable to us, or at all.

The scientific information discussed in this news release related to our product candidates is preliminary and investigative. Such product candidates are not approved by the U.S. Food and Drug Administration, and no conclusions can or should be drawn regarding the safety or effectiveness of the product candidates. Further, any scientific information discussed in this news release relating to new indications for our products is preliminary and investigative and is not part of the labeling approved by the U.S. Food and Drug Administration for the products. The products are not approved for the investigational use(s) discussed in this news release, and no conclusions can or should be drawn regarding the safety or effectiveness of the products for these uses.

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