AMGEN TO PRESENT NEW, POSITIVE CLINICAL AND REAL-WORLD DATA ACROSS INFLAMMATION PORTFOLIO AT EADV 2022

August 30, 2022

New Positive Data From Phase 3 SPROUT Trial, Studying Otezla (apremilast) in Children Ages 6-17 With Moderate to Severe Plaque Psoriasis

Positive Results From the Phase 3 DISCREET Study, Investigating Clinical Efficacy and Safety of Otezla in Patients With Moderate to Severe Genital Psoriasis

New Rocatinlimab Phase 2 Analyses Highlight Emerging Clinical Profile in Moderate to Severe Atopic Dermatitis

THOUSAND OAKS, Calif., Aug. 30, 2022 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced that clinical and real-world data from across its inflammation portfolio, including both established treatments and pipeline assets, will be presented at the 31st European Academy of Dermatology and Venereology (EADV), taking place in Milan, Italy, Sept. 7-10, 2022.

Presentations will cover a range of clinical data for Otezla® (apremilast), including positive, 16-week results from the Phase 3 SPROUT study in children ages 6-17 with moderate to severe plaque psoriasis. Successful 16-week results from the Phase 3 DISCREET study, assessing the efficacy and safety of Otezla® (apremilast), in patients with moderate to severe genital psoriasis will also be presented. Furthermore, there will be data presented on the role of Otezla in patients with plaque psoriasis featuring special area skin involvement or persistent itch, incorporating data and analyses from the EMBRACE and ADVANCE studies.

Other research highlights being presented from Amgen's portfolio include a late-breaking post-hoc analysis from the rocatinlimab (AMG 451/KHK4083) Phase 2b study with a focus on patients with moderate to severe head and neck atopic dermatitis and a biomarker analysis of blood and tissue samples in subjects treated with rocatinlimab. Finally, a new analysis of the multinational UPLIFT survey on the impact of psoriasis involvement in special locations on quality of life will be presented.

"The research that will be presented at EADV reinforces the strength of Amgen's inflammation portfolio and our continued support for patients living with autoimmune skin diseases like plaque psoriasis and moderate to severe atopic dermatitis. We remain committed to delivering novel therapies which address pressing treatment gaps that continue to exist for patients," said David M. Reese, M.D., executive vice president of Research and Development at Amgen.

Key Abstracts and Presentation Times:

Otezla Abstracts

- **Efficacy and Safety of Apremilast in Pediatric Patients with Moderate to Severe Plaque Psoriasis: 16-Week Results From a Phase 3, Randomized, Double-Blind, Placebo-Controlled Study**
  - Abstract #3459, #D1T01.3 Late Breaking Oral Presentation, Sept. 8, 2022 from 3:15-3:30pm CEST
- **Efficacy and Safety of Apremilast in Patients With Genital Psoriasis: Results From the Phase 3 Randomized, Placebo-Controlled, Double-Blind DISCREET Study**
  - Abstract #1673, #P1559 E-Poster, Sept. 7, 2022 from 7am CEST
- **Impact of Apremilast on Quality of Life in Psoriasis Patients From ADVANCE With Special Area Skin Involvement or Persistent Itch**
  - Abstract #2730, #P1620 E-Poster, Sept. 7, 2022 from 7am CEST
- **Effect of Apremilast on Quality of Life and Psoriasis in Special Areas: 16-Week Subgroup Analysis From EMBRACE**
  - Abstract #63, #P1422 E-Poster, Sept. 7, 2022 from 7am CEST
- **Efficacy and Safety of Apremilast Over 52 Weeks in Patients With Psoriasis in Special Areas and Impaired Quality of Life: Results From EMBRACE**
  - Abstract #2758, #P1624 E-Poster, Sept. 7, 2022 from 7am CEST
- **Efficacy of Apremilast in Patients With Moderate to Severe Scalp Psoriasis and Prior Conventional Systemic Therapy and/or Phototherapy**
  - Abstract #1786, #P1582 E-Poster, Sept. 7, 2022 from 7am CEST
- **Apremilast Adherence in Psoriasis and Psoriatic Arthritis Patients in the Telehealth Setting versus the In-person Setting During the COVID-19 Pandemic**
  - Abstract #992, #P1504 E-Poster, Sept. 7, 2022 from 7am CEST
- **The Needs of Psoriasis Patients and Benefits of Apremilast in French Clinical Practice**
  - Abstract #72, #P1423 E-Poster, Sept. 7, 2022 from 7am CEST
- **Impact of Special Area Psoriasis Involvement on Quality of Life: Analysis of the Multinational UPLIFT Survey**
  - Abstract #2971, #P1630 E-Poster, Sept. 7, 2022 from 7am CEST
- **Real-World Observation on Patient-Physician Agreement on Body Locations Affected by Psoriasis**
  - Abstract #1083, #P1514 E-Poster, Sept. 7, 2022 from 7am CEST

Rocatinlimab (AMG 451/KHK4083) Abstracts

- **KHK4083/AMG 451 (rocatinlimab), an anti-OX40 monoclonal antibody, provides durable transcriptomic improvement in skin with atopic dermatitis patients**
  - Abstract #3533, #D2T01.3, Late Breaking Oral Presentation, Sept. 9, 2022 from 5:15-5:30pm CEST
- **Rocatinlimab demonstrates improvements in head and neck atopic dermatitis in patients with moderate-severe disease in a phase 2 trial**
  - Abstract #3587, #D1T01.3, Late Breaking Oral Presentation, Sept. 8, 2022 from 4:15-4:30pm CEST

TEZSPIRE® (tezepelumab-ekko) Abstracts

- **Safety and Efficacy of Tezepelumab in Moderate-to-Severe Atopic Dermatitis: Results of a Phase 2b Randomized, Double-Blind, Placebo-Controlled Trial**
  - Abstract #48, #P0196 E-Poster, Sept. 7, 2022 from 7am CEST

ABP 654

- **Pharmacokinetics of ABP 654, a proposed biosimilar to ustekinumab reference product**
  - Abstract #2405, #P0495 E-Poster, Sept. 7, 2022 from 7am CEST

Abstracts can be found on the EADV website.

About SPROUT

SPROUT (PPS0-003) a phase 3, multi-center, randomized, double-blind, placebo-controlled study to assess the efficacy and safety of Otezla® (apremilast) in pediatric patients from 6 through 17 years of age with moderate to severe plaque psoriasis (defined as BSA involvement of ≥ 10, PASI score of ≥ 12, sPGA score of ≥ 3). A total of 245 patients were randomized 2:1 to receive Otezla 20 mg (patients 20kg to 50 kg) twice daily or Otezla 30 mg (patients ≥ 50 kg) twice daily or placebo for the first 16 weeks. All patients then received Otezla during an open-label extension phase through week 52.

The primary endpoint was the percentage of patients with sPGA response [defined as a sPGA score of clear (0) or almost clear (1) with greater than or equal to 2-point reduction from baseline] at week 16.

About DISCREET

DISCREET (PSOR-025) is a Phase 3, multicenter, randomized, placebo-controlled, double-blind study evaluating the efficacy and safety of Otezla® (apremilast), in patients with moderate to severe genital psoriasis (defined as modified sPGA-G score ≥ 3). Patients also had moderate to severe plaque psoriasis (sPGA score ≥ 3) with BSA involvement ≥ 1% in a non-genital area and had an inadequate response or intolerance to topical therapy for psoriasis affecting the genital area. The study randomized 289 patients 1:1 to receive Otezla 30 mg twice daily or placebo for the first 16 weeks. Following the 16-week placebo-controlled, double-blind phase of the trial, patients continued or switched to Otezla during the extension phase of the study and were treated through week 32.

The primary endpoint was the proportion of patients who achieve modified sPGA-G response at week 16 (defined as modified sPGA-G score of clear (0) or almost clear (1) with at least a 2-point reduction from baseline at Week 16).

About ADVANCE

ADVANCE (NCT03721172) is a Phase 3, multicenter, randomized, placebo-controlled, double-blind study evaluating the efficacy and safety of Otezla® (apremilast), in patients with mild to moderate plaque psoriasis (defined as BSA involvement of 2% to 15%, Psoriasis Area and Severity Index (PASI) score of 2 to 15, sPGA score of 2 to 3). In this study, 595 patients were randomized 1:1 to receive Otezla (n=297) 30 mg twice daily or placebo (n=298) for the first 16 weeks. All patients then received Otezla during an open-label extension phase through week 32.

The primary endpoint was the percentage of patients with sPGA response [defined as a sPGA score of clear (0) or almost clear (1) with a >2 point reduction from baseline] at week 16.

About EMBRACE

EMBRACE (NCT03774875) is a phase 4, multicenter, randomized, placebo-controlled, double-blind study evaluating the efficacy and safety of Otezla® (apremilast), over 52 Weeks in patients with plaque psoriasis not controlled by topicals. A total of 277 patients, who had psoriasis in one or more 1 special areas, a Psoriasis Area and Severity Index (PASI) score between 3 and 10 and Dermatology Life Quality Index (DLQI) score above 10, were randomized (2:1) to receive Otezla or placebo from Weeks 0 to 16, after which all patients continued with Otezla or were switched from placebo to Otezla until Week 52.

The primary endpoint was DLQI response (4-point reduction or more) at Week 16. Secondary endpoints included DLQI score, Itch Numeric Rating Scale, skin discomfort/pain visual analog scale, affected body surface area, and Patient Benefit Index response (score 1 or more). Safety analyses included all patients treated with Otezla at any time.

About the UPLIFT Survey

In 2020, Amgen conducted the global Understanding Psoriatic Disease Leveraging Insights for Treatment (UPLIFT) survey exploring the evolution of attitudes and behaviors of 3,806 people living with psoriasis and psoriatic arthritis, 473 dermatologists and 450 rheumatologists in eight countries in North America, Europe and Asia. The survey was conducted in 2020 and was overseen by an academic steering committee of thought leaders in dermatology and rheumatology. The survey builds upon findings from the 2012 Multinational Assessment of Psoriasis and Psoriatic Arthritis (MAPP) survey, a first-of-its-kind study conducted by Celgene that looked in-depth at the effect of psoriasis and psoriatic arthritis on people living with these conditions.

About APPRECIATE

APPRECIATE (NCT02740218) is a multinational, observational, retrospective, cross-sectional study in patients treated for psoriasis with Otezla, conducted across seven countries (Austria, Germany, Ireland, Spain, Sweden, Switzerland, and UK) from May 2016 to October 2019. The aim of this post-hoc analysis was to explore the agreement of patients and physicians on specific body locations affected by psoriasis (genital, non-genital inverse, palmoplantar, scalp) by comparing data collected by from both adult patients and their dermatologists.

About REALIZE

REALIZE (NCT03757013) is a longitudinal multicenter observational study assessing adult patients from French clinical practice with moderate to severe chronic plaque psoriasis, that had been prescribed Otezla according to the French label up to four weeks previously. Data were collected at 0, 6 and 12 months of follow-up, including patient and disease characteristics, patient benefit index questionnaire (PBI; range 0 [no patient-relevant benefit] to 4 [maximum patient-relevant benefit]), nine-item Treatment Satisfaction Questionnaire for Medication (TSQM-9; range 0-100), Dermatology Life quality Index (DLQI; range 0 to 30) and adverse events (AEs).

About Psoriasis

Psoriasis is a serious, chronic inflammatory disease that causes raised, red, scaly patches to appear on the skin, typically affecting the outside of the elbows, knees or scalp, though it can appear on any location.[1] Approximately 125 million people worldwide have psoriasis, including around 14 million people in Europe and more than 8 million people in the United States.[2,3] About 80% of those patients have plaque psoriasis.[4]

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 700,000 patients worldwide.[5]

Otezla® (apremilast) 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® (apremilast) 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 reactions: 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 the full Prescribing Information for Otezla.

About Atopic Dermatitis
Atopic dermatitis is a chronic inflammatory disease that causes excessively dry, itchy skin that can be painful. Repeated scratching can cause the skin to thicken, harden or become vulnerable to infection. Atopic dermatitis is the most common form of eczema – affecting 1-3% of adults worldwide – and the prevalence is increasing. The disease typically manifests in childhood followed by other allergy symptoms.

About Rocatinlimab (AMG 451/KHK4083)
Rocatinlimab (AMG 451/KHK4083) is an investigational, potential first-in-class anti-OX40 monoclonal antibody that inhibits and reduces the number of OX40+ pathogenic T cells responsible for orchestrating the atopic dermatitis inflammatory response.

Amgen and Kyowa Kirin Collaboration
On June 1, 2021, Amgen and Kyowa Kirin entered into an agreement to jointly develop and commercialize AMG 451/KHK4083. Under the terms of the agreement, Amgen will lead the development, manufacturing, and commercialization for AMG 451/KHK4083 for all markets globally, except Japan, where Kyowa Kirin will retain all rights. If approved, the companies will co-promote the asset in the United States and Kyowa Kirin has opt-in rights to co-promote in certain other markets including Europe and Asia. The initial AMG 451/KHK4083 antibody was discovered in collaboration between Kyowa Kirin US Research and La Jolla Institute for Immunology.

About TEZSPIRE® (tezepelumab-ekko)
TEZSPIRE is a first-in-class human monoclonal antibody that works on the primary source of inflammation: the airway epithelium, which is the first point of contact for viruses, allergens, pollutants and other environmental insults. Specifically, TEZSPIRE targets and blocks TSLP, a key epithelial cytokine that sits at the top of multiple inflammatory cascades and initiates an overreactive immune response to allergic, eosinophilic and other types of airway inflammation associated with severe asthma.[6,7] TSLP is released in response to multiple triggers associated with asthma exacerbations, including allergens, viruses and other airborne particles.[6,7]

Expression of TSLP is increased in the airways of patients with asthma and has been correlated with disease severity.[6,8] Blocking TSLP may prevent the release of pro-inflammatory cytokines by immune cells, resulting in the prevention of asthma exacerbations and improved asthma control.[6,8] By working at the top of the cascade, TEZSPIRE helps stop inflammation at the source and has the potential to treat a broad population of severe asthma patients.[6,8]

TEZSPIRE is also in development for other potential indications including chronic obstructive pulmonary disease, chronic rhinosinusitis with nasal polyps, chronic spontaneous urticaria and eosinophilic esophagitis (EoE). In October 2021, tezepelumab was granted Orphan Drug Designation by the FDA for the treatment of EoE.

TEZSPIRE® (tezepelumab-ekko) U.S. Indication
TEZSPIRE is indicated for the add-on maintenance treatment of adult and pediatric patients aged 12 years and older with severe asthma.

TEZSPIRE is not indicated for the relief of acute bronchospasm or status asthmaticus.

TEZSPIRE® (tezepelumab-ekko) Important Safety Information
CONTRAINDICATIONS
Known hypersensitivity to tezepelumab-ekko or excipients.

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions

Hypersensitivity reactions (e.g., rash and allergic conjunctivitis) can occur following administration of TEZSPIRE. These reactions can occur within hours of administration, but in some instances have a delayed onset (i.e., days). In the event of a hypersensitivity reaction, initiate appropriate treatment as clinically indicated and then consider the benefits and risks for the individual patient to determine whether to continue or discontinue treatment with TEZSPIRE.

Acute Asthma Symptoms or Deteriorating Disease

TEZSPIRE should not be used to treat acute asthma symptoms, acute exacerbations, acute bronchospasm, or status asthmaticus.

Abrupt Reduction of Corticosteroid Dosage

Do not discontinue systemic or inhaled corticosteroids abruptly upon initiation of therapy with TEZSPIRE. Reductions in corticosteroid dose, if appropriate, should be gradual and performed under the direct supervision of a physician. Reduction in corticosteroid dose may be associated with systemic withdrawal symptoms and/or unmask conditions previously suppressed by systemic corticosteroid therapy.

Parasitic (Helminth) Infection

It is unknown if TEZSPIRE will influence a patient's response against helminth infections. Treat patients with pre-existing helminth infections before initiating therapy with TEZSPIRE. If patients become infected while receiving TEZSPIRE and do not respond to anti-helminth treatment, discontinue TEZSPIRE until infection resolves.

Live Attenuated Vaccines

The concomitant use of TEZSPIRE and live attenuated vaccines has not been evaluated. The use of live attenuated vaccines should be avoided in patients receiving TEZSPIRE.

ADVERSE REACTIONS

The most common adverse reactions (incidence ≥3%) are pharyngitis, arthralgia, and back pain.

USE IN SPECIFIC POPULATIONS

There are no available data on TEZSPIRE use in pregnant women to evaluate for any drug-associated risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes. Placental transfer of monoclonal antibodies such as Tezepelumab-ekko is greater during the third trimester of pregnancy; therefore, potential effects on a fetus are likely to be greater during the third trimester of pregnancy.

Please see the TEZSPIRE full Prescribing Information.

You may report side effects related to AstraZeneca products by clicking here.

About ABP 654

ABP 654 is being developed as a biosimilar candidate to STELARA® (ustekinumab), an approved human interleukin-12 and interleukin-23 antagonist indicated for the treatment of moderate to severe plaque psoriasis in adults and pediatric patients (6 years or older) who are candidates for phototherapy or systemic therapy, active psoriatic arthritis in adults and pediatric patients (6 years or older), as well as for adult patients with moderately to severely active Crohn's disease and moderately to severely active ulcerative colitis. ABP 654 has the same pharmaceutical form, dosage strength, route of administration and dosing regimen as United States-licensed and European Union (EU)-approved ustekinumab.

About Amgen

Amgen is committed to unlocking the potential of biology for patients suffering from serious illnesses by discovering, developing, manufacturing and delivering innovative human therapeutics. This approach begins by using tools like advanced human genetics to unravel the complexities of disease and understand the fundamentals of human biology.

Amgen focuses on areas of high unmet medical need and leverages its expertise to strive for solutions that improve health outcomes and dramatically improve people's lives. A biotechnology pioneer since 1980, Amgen has grown to be one of the world's leading independent biotechnology companies, has reached millions of patients around the world and is developing a pipeline of medicines with breakaway potential.

Amgen is one of the 30 companies that comprise the Dow Jones Industrial Average and is also part of the Nasdaq-100 index. In 2021, Amgen was named one of the 25 World's Best Workplaces™ by Fortune and Great Place to Work™ and one of the 100 most sustainable companies in the world by Barron's.

For more information, visit www.amgen.com and follow us on www.twitter.com/amgen.

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., Kyowa Kirin Co., Ltd., or any collaboration to manufacture therapeutic antibodies against COVID-19), the performance of Otezla® (apremilast) (including anticipated Otezla sales growth and the timing of non-GAAP EPS accretion), the Five Prime Therapeutics, Inc. acquisition, the Teneobio, Inc. acquisition, or the recently announced proposed acquisition of ChemoCentryx, Inc., 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 such as the ongoing COVID-19 pandemic on our business, 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. A breakdown, cyberattack or information security breach 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.

CONTACT: Amgen, Thousand Oaks
Michael Strapazon, 805-313-5553 (Media)
Jessica Akopyan, 805-447-0974 (Media)
Arvind Sood, 805-447-1060 (Investors)

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