AMGEN TO PRESENT DATA AT ACR 2023 ACROSS EXPANDED RHEUMATOLOGY PIPELINE AND PORTFOLIO

November 1, 2023

Breadth of Research Reflects Amgen's Commitment to Rheumatology

Data Include Sjögren's Syndrome, Uncontrolled Gout, Severe Active ANCA-Associated Vasculitis and Psoriatic Arthritis

THOUSAND OAKS, Calif., Nov. 1, 2023 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced the presentation of new scientific and clinical research across its expanded rheumatology pipeline and portfolio, following the recent acquisition of Horizon Therapeutics. More than 20 abstracts will be presented during the American College of Rheumatology (ACR) Convergence 2023, taking place Nov. 10-15, in San Diego.

"The data at ACR will illustrate our continued growth in rheumatology as we advance unique treatment approaches across a broader range of diseases," said David M. Reese, M.D., executive vice president of Research and Development at Amgen. "Drawing on our decades of experience in inflammation, we're looking forward to advancing new treatment areas like Sjögren's syndrome and uncontrolled gout."

At ACR, new results will be presented from the Phase 2 study of dazodalibep, an investigational therapy for Sjögren's. Other research highlights include new TAVNEOS® (avacopan) data from the Phase 3 ADVOCATE study evaluating diffuse alveolar hemorrhage (DAH) in patients with severe active ANCA-associated vasculitis (GPA/MPA), as well as an oral presentation on Otezla® (apremilast) in FOREMOST, the first placebo-controlled study designed to specifically assess people with early oligoarticular psoriatic arthritis. Additionally, new real-world data showing a significant uptake in the use of KRYSTEXXA® (pegloticase) with methotrexate or other immunomodulators by clinicians following the U.S. labeling update, will be delivered at the meeting.

Abstracts and Presentation Times:

Amgen Sponsored Abstracts

AMJEVITA® (adalimumab-atto)

- **Pharmacokinetic and Safety Similarity of High- and Low-Concentration Formulations of Adalimumab Biosimilar ABP 501**
  Abstract #2161, Poster Session C: RA – Treatments Poster III, Tuesday, Nov. 14 from 9-11am PST

Enbrel® (etanercept)

- **Outcomes in Patients With Rheumatoid Arthritis Initiating Therapy With Etanercept, Adalimumab, or Janus Kinase Inhibitors**
  Abstract #0441, Poster Session A: RA – Treatments Poster I, Sunday, Nov. 12 from 9-11am PST

KRYSTEXXA® (pegloticase)

- **Treatment-Emergent Major Adverse Cardiovascular and Thromboembolic Events Were Infrequent During Pegloticase Therapy: Pooled Clinical Trial Findings**
  Abstract #0236, Poster Session A: Metabolic & Crystal Arthropathies – Basic & Clinical Science Poster I, Sunday, Nov. 12 from 9-11am PST
- **Oral Urate-Lowering Therapy Use and Efficacy Following Pegloticase Treatment: Findings from a Rheumatology Network Database**
  Abstract #0237, Poster Session A: Metabolic & Crystal Arthropathies – Basic & Clinical Science Poster I, Sunday, Nov. 12 from 9-11am PST
- **Incidence and Prevalence of Cardiovascular and Metabolic Diseases Following Gout Diagnosis in the United Kingdom Using the THIN Database**
  Abstract #0239, Poster Session A: Metabolic & Crystal Arthropathies – Basic & Clinical Science Poster I, Sunday, Nov. 12 from 9-11am PST
- **Venous Thromboembolism in Patients with Gout in the US**
  Abstract #0242, Poster Session A: Metabolic & Crystal Arthropathies – Basic & Clinical Science Poster I, Sunday, Nov. 12 from 9-11am PST
- **Finding Lost-to-Care Gout Patients in a Large Community Rheumatology Network: Patient Re-engagement Initiative with Metrics (PRIME)**
  Abstract #1102, Poster Session B: Metabolic & Crystal Arthropathies – Basic & Clinical Science Poster II, Monday, Nov. 13 from 9-11am PST
- **Evaluation of Outcomes Following Discontinuation of Pegloticase Therapy**
  Abstract #1103, Poster Session B: Metabolic & Crystal Arthropathies – Basic & Clinical Science Poster II, Monday, Nov. 13

from 9-11am PST

- **Predictors of Pegloticase Urate-lowering Response in the Presence and Absence of Methotrexate Co-therapy**
  Abstract #1107, Poster Session B: Metabolic & Crystal Arthropathies – Basic & Clinical Science Poster II, Monday, Nov. 13 from 9-11am PST
- **Minimal Clinically Important Difference (MCID) of Quality of Life Assessments in Patients with Uncontrolled Gout**
  Abstract #1108, Poster Session B: Metabolic & Crystal Arthropathies – Basic & Clinical Science Poster II, Monday, Nov. 13 from 9-11am PST
- **Real-world Trends in the Use of Immunomodulation as Co-Therapy to Pegloticase: Claims-Based Findings Since 2016**
  Abstract #1123, Poster Session B: Metabolic & Crystal Arthropathies – Basic & Clinical Science Poster II, Monday, Nov. 13 from 9-11am PST
- **Human Cardiovascular Disease Model Provides Transcriptomic Evidence of Cardiovascular Risk Associated With Febuxostat**
  Abstract #1145, Poster Session B: Miscellaneous Rheumatic & Inflammatory Diseases Poster II, Monday, Nov. 13 from 9-11am PST
- **Understanding Community Perspectives on Disease Management: A Social Media Analysis of Gout Care Strategies**
  Abstract #1204, Poster Session B: Patient Outcomes, Preferences, & Attitudes Poster II, Monday, Nov. 13 from 9-11am PST

Otezla® (apremilast)

- **16-Week Results from FOREMOST, a Placebo-Controlled Study Involving Oligoarticular Psoriatic Arthritis Treated With Apremilast**
  Abstract #1691, Oral Abstract Session: Spondyloarthritis Including Psoriatic Arthritis – Treatment II: PsA, Monday Nov. 13 from 5-5:10pm PST
- **Apremilast Reduces Inflammation as Measured by MRI of the Hand in Patients With Psoriatic Arthritis: Primary Results from the Phase 4 MOSAIC Study**
  Abstract #1690, Oral Abstract Session: Spondyloarthritis Including Psoriatic Arthritis – Treatment II: PsA**,** Monday Nov. 13 from 4:45-4:55pm PST
- **The Burden of Oligoarticular Psoriatic Arthritis in the United States**
  Abstract #0966, Poster Session B: Epidemiology & Public Health Poster II**,** Monday Nov. 13 from 9-11am PST
- **Efficacy of Apremilast on Peripheral and Axial Inflammation in Patients With Psoriatic Arthritis Based on Whole-Body Magnetic Resonance Imaging**
  Abstract #1041, Poster Session B: Imaging of Rheumatic Diseases Poster I**,** Monday Nov. 13 from 9-11am PST
- **Effect of Apremilast Treatment on the Domains of MDA-Joints in Patients With Early Oligoarticular Psoriatic Arthritis: 16-Week Results From FOREMOST**
  Abstract #1413, Poster Session B: Spondyloarthritis Including Psoriatic Arthritis – Treatment Poster II: SpA, Monday Nov. 13 from 9-11am PST
- **Effects of Apremilast on Changes in Cardiometabolic Parameters by Diabetes and Obesity Status in Patients with Psoriatic Arthritis**
  Abstract #1414, Poster Session B: Spondyloarthritis Including Psoriatic Arthritis – Treatment Poster II: SpA, Monday Nov. 13 from 9-11am PST

Prolia® (denosumab)

- **Current Trends in the Risk of Subsequent Fracture After Initial Fracture, and Post-Fracture Treatment Among Commercially Insured Postmenopausal Women in the United States**
  Abstract #2528, Oral Abstract Session: Osteoporosis & Metabolic Bone Disease – Basic & Clinical Science, Tuesday, Nov. 14 from 4:15-4:25pm PST
- **Comparative Effectiveness of Denosumab versus Zoledronic Acid Among Postmenopausal Women with Osteoporosis in the U.S. Medicare Program**
  Abstract #2529, Oral Abstract Session: Osteoporosis & Metabolic Bone Disease – Basic & Clinical Science, Tuesday, Nov. 14 from 4:30-4:40pm PST
- **Comparative Effectiveness of Denosumab versus Alendronate among Postmenopausal Women with Osteoporosis in the U.S. Medicare Program**
  Abstract #2008, Poster Session C: Osteoporosis & Metabolic Bone Disease – Basic & Clinical Science Poster, Tuesday, Nov. 14 from 9-11am PST

TAVNEOS® (avacopan)

- **Change in Albuminuria in Patients with ANCA-Associated Vasculitis Treated with Avacopan**
  Abstract #0857, Oral Abstract Session: Vasculitis – ANCA-Associated I, Sunday, Nov. 12 from 5-5:15pm PST
- **Remission, Glucocorticoid Toxicity, Health-Related Quality of Life, and Safety Outcomes in Patients with Renal Involvement in the Phase 3 Trial of Avacopan for the Treatment of ANCA-Associated Vasculitis**
  Abstract #0683, Poster Session A: Vasculitis – ANCA-Associated Poster I: Treatment Outcomes, Sunday, Nov. 12 from 9-11am PST
- **Report on Twelve Patients with Diffuse Alveolar Hemorrhage in the Phase 3 Trial of Avacopan for the Treatment of ANCA-Associated Vasculitis**
  Abstract #0684, Poster Session A: Vasculitis – ANCA-Associated Poster I: Treatment Outcomes, Sunday, Nov. 12 from 9-11am PST
- **Efficacy and Safety of Avacopan in Patients Receiving Rituximab in a Phase 3 Trial**
  Abstract #0685, Poster Session A: Vasculitis – ANCA-Associated Poster I: Treatment Outcomes, Sunday, Nov. 12 from 9-11am PST
- **Safety and Efficacy of Avacopan in Patients 65 Years and Older with ANCA-Associated Vasculitis**
  Abstract #0686, Poster Session A: Vasculitis – ANCA-Associated Poster I: Treatment Outcomes, Sunday, Nov. 12 from 9-11am PST
- **A Real-World Descriptive Study of Renal Outcomes Among Patients with ANCA-Associated Vasculitis Initiating Remission Induction Therapy**
  Abstract #2379, Poster Session C: Vasculitis – ANCA-Associated Poster III: Biomarkers & Renal Outcomes, Tuesday, Nov. 14 from 9-11am PST

AMG 570 (rozibafusp alfa)

- **A Conceptual Framework to Characterize the Indirect Burden of Systemic Lupus Erythematosus (SLE): Findings from Qualitative Patient Interviews**
  Abstract #0171, Poster Session A: Health Services Research Poster I, Sunday, Nov. 12 from 9-11am PST

Dazodalibep

- **Dazodalibep, a CD40L Antagonist, in Subjects with Sjögren's Having Moderate-to-Severe Systemic Disease Activity: Full Crossover Results from a Phase 2, Randomized, Double-Blind, Placebo-Controlled, Proof of Concept Study**
  Abstract #1636, Oral Abstract Session: Sjögren's Syndrome – Basic & Clinical Science, Monday, Nov. 13 from 2-3:30pm PST
- **Dazodalibep, a CD40L Antagonist, in a Phase 2, Randomized, Double-Blind, Placebo-Controlled, Crossover Trial of Subjects with Sjögren's Disease Having Unacceptable Symptomatic Burden but Limited Extraglandular Organ Involvement**
  Abstract #L10, Late-Breaking Abstract Posters: Poster Session C, Tuesday, Nov. 14 from 9-11 am PST
- **CD40L Inhibition with Dazodalibep Rapidly Reduces Blood Biomarkers of T and B Cell Costimulation in Subjects with Sjögren's Having High Disease Activity or High Symptom Burden**
  Abstract #1638, Oral Abstract Session: Sjögren's Syndrome – Basic & Clinical Science, Monday, Nov. 13 from 2-3:30pm PST
- **Treatment Patterns and Drivers of Biologic Prescriptions in Patients with Primary Sjögren's Disease: Results from a Multinational, Real-World Survey**
  Abstract #1369, Poster Session B: Sjögren's Syndrome – Basic & Clinical Science Poster I, Monday, Nov. 13 from 9-11am PST
- **Population Pharmacokinetic/Pharmacodynamic Modeling of Dazodalibep, a CD40L Antagonist, in Healthy Volunteers and Patients with Rheumatoid Arthritis and Sjögren's Syndrome**
  Abstract #1379, Poster Session B: Sjögren's Syndrome – Basic & Clinical Science Poster I, Monday, Nov. 13 from 9-11am PST
- **Disease Burden of Patients with Primary Sjögren's Disease: Results from a Multinational Real-World Survey**
  Abstract #2179, Poster Session C: Sjögren's Syndrome – Basic & Clinical Science Poster II, Tuesday, Nov. 14 from 9-11am PST

Partner-Led Abstracts

EVENITY® (romosozumab-aqqg)

- **Osteoporosis Treatment Attributes and Levels for an Online Decision-Making Tool for Patients: Findings from Adaptive Choice-Based Conjoint Analysis**
  Abstract #2025, Poster Session C: Patient Outcomes, Preferences, & Attitudes Poster III, Tuesday, Nov. 14 from 9-11am PST

TAVNEOS® (avacopan)

- **Efficacy and Safety Experience with Avacopan Beyond 52 Weeks in the Early Access Program (EAP)**
  Abstract #0688, Poster Session A: Vasculitis – ANCA-Associated Poster I: Treatment Outcomes, Sunday, Nov. 12 from 9-11am PST

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 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.

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. While the precise mechanism in ANCA-associated vasculitis (GPA/MPA) has not been definitively established, TAVNEOS, by blocking the complement 5a receptor (C5aR) for the pro-inflammatory complement system fragment known as C5a on destructive inflammatory cells such as blood neutrophils, is presumed to arrest the ability of those cells to do damage in response to C5a activation, which is known to be a driver of ANCA-associated vasculitis (GPA/MPA).

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, treatment for ANCA-associated vasculitis was limited to courses of immuno-suppressants (cyclophosphamide or rituximab), combined with the administration of daily glucocorticoids (steroids) for prolonged periods of time, which can be associated with significant clinical consequences.

TAVNEOS U.S. PRESCRIBING INFORMATION

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 Dazodalibep
Dazodalibep is a CD40 ligand antagonist that blocks T cell interaction with CD40-expressing B cells, disrupting the overactivation of the CD40 ligand co-stimulatory pathway. Several autoimmune diseases are associated with the overactivation of this pathway. Amgen also plans to investigate dazodalibep in focal segmental glomerulosclerosis, a rare kidney disorder characterized by scarring of glomeruli.

About Sjögren's Syndrome
Sjögren's syndrome is a chronic, systemic autoimmune disease affecting exocrine glands, primarily the salivary and tear glands, with severe cases affecting multiple organs. Like other autoimmune diseases, Sjögren's syndrome primarily affects women. The disease also has an increased risk of non-Hodgkin's B-cell lymphoma and there is an unmet medical need for patients with extraglandular disease manifestations, as currently there is no therapy that can improve or slow the course of the disease. Disease manifestations include dry mouth, dry eyes, arthritis and kidney or lung dysfunction.

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 2023, Amgen was named one of "America's Greatest Workplaces" by Newsweek, one of "America's Climate Leaders" by USA Today and one of the "World's Best Companies" by TIME.

For more information, visit Amgen.com and follow us on X (formerly known as Twitter), 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), the Teneobio, Inc. acquisition, the ChemoCentryx, Inc. acquisition, or the Horizon Therapeutics plc acquisition (including the prospective performance and outlook of Horizon's business, performance and opportunities and any potential strategic benefits, synergies or opportunities expected as a result of such acquisition), 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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