



AMGEN TO PRESENT NEW DATA ACROSS RARE AND OTHER SERIOUS AUTOIMMUNE DISEASES AT ACR CONVERGENCE 2026

October 27, 2026

Phase 3 OASIZ-301 Study of Dazodalibep in Sjögren's Disease Shows Statistically Significant and Clinically Meaningful Improvement in Systemic Disease Activity and Patient-Reported Dryness

New Long-Term UPLIZNA Data in IgG4-Related Disease and Real-World Evidence for KRYSTEXXA and TAVNEOS Further Highlight Amgen's Broad Portfolio and Commitment to People Living with Rare Diseases

THOUSAND OAKS, Calif., Oct. 27, 2026 /PRNewswire/ -- Amgen (NASDAQ: AMGN) today announced plans to present new data across its portfolio, including in rare and other serious autoimmune diseases at the American College of Rheumatology (ACR) Convergence 2026.

Key presentations include:

[Dazodalibep Significantly Reduces Systemic Disease Activity in Patients with Sjögren's Disease and Moderate-to-Severe Disease Activity: Results from the Phase 3 OASIZ-301 Trial](#)

Late-Breaking Abstract #22, Wednesday, November 11, from 8:45–9:00 a.m. ET

Sjögren's disease is a systemic autoimmune disease that can affect the entire body. Along with symptoms of extensive dryness, other serious manifestations may include profound fatigue, chronic pain, major organ involvement, neuropathy, and an increased risk of lymphoma. There are currently no FDA-approved medicines for Sjögren's disease.

Amgen will present late-breaking results from the Phase 3 OASIZ-301 study evaluating dazodalibep in adults living with Sjögren's disease and moderate-to-severe systemic disease activity. Dazodalibep is a CD40L antagonist that disrupts interactions between T cells, glandular epithelial cells, B cells and other antigen-presenting cells.

Patients entered the OASIZ-301 study with an average European Alliance of Associations for Rheumatology Sjögren's Syndrome Disease Activity Index (ESSDAI) score of 10.2. Results show that at Week 48 both dazodalibep dosing regimens (1,500 mg every four weeks and 3,000 mg every 12 weeks) demonstrated statistically significant and clinically meaningful reductions in systemic disease activity compared with placebo. Treatment effects were observed as early as four weeks. Disease activity scores improved by a least-squares mean change from baseline of -5.6 points in patients receiving dazodalibep every four weeks (difference vs placebo, -1.8; adjusted $p < 0.001$) and -5.2 points in those receiving treatment every 12 weeks (difference vs placebo, -1.4; adjusted $p = 0.010$), compared with -3.8 points for placebo.

Additionally, dazodalibep every four weeks also demonstrated statistically significant and clinically meaningful improvements in the key secondary endpoint of patient-reported dryness compared with placebo. Patients reported greater reductions in dryness, as measured by both the EULAR Sjögren's Syndrome Patient Reported Index (ESSPRI) dryness score (least-squares mean change from baseline, -2.50 vs. -1.33 for placebo; adjusted $p < 0.001$) and the Diary for Assessing Sjögren's Patient Reported Index (DASPRI) dryness score (least-squares mean change from baseline, -1.98 vs. -1.05 for placebo; adjusted $p < 0.001$). Treatment emergent adverse events (TEAEs), serious adverse events and TEAEs leading to discontinuation were observed at similar rates across treatment groups.

"For patients living with Sjögren's disease, systemic disease activity and symptoms can have a significant impact on their health and daily lives, yet treatment options remain limited," said Dr. Teresa K. Tarrant, MD, Associate Professor of Medicine, Duke University. "The rapid improvements in ESSDAI, as well as self-reported dryness, observed with dazodalibep are particularly encouraging. These findings represent meaningful progress in our understanding of how we may be able to better manage both the systemic and symptomatic manifestations of this complex disease."

Beyond dazodalibep, Amgen's scientific program at ACR Convergence 2026 will also include data from Phase 3 MITIGATE open-label extension describing the long-term safety profile and sustained efficacy of UPLIZNA in IgG4-RD. The company will also present real-world evidence from KRYSTEXXA® and TAVNEOS® in uncontrolled gout and ANCA-associated vasculitis, respectively.

"The data we're presenting at ACR demonstrate the breadth of Amgen's portfolio and pipeline across rare and other serious autoimmune diseases," said Paul Burton, M.D., Ph.D., senior vice president and chief medical officer at Amgen. "By advancing investigational therapies, generating long-term clinical evidence and building on our understanding of medicines in real-world settings, we're working to address significant unmet needs for patients living with some of the most complex and serious diseases."

Additional Amgen-sponsored abstracts:

UPLIZNA® (inebilizumab-cdon)

- **[Efficacy and Safety of Inebilizumab for the Treatment of IgG4-RD Across Age Subgroups: Analysis from the Open-label Period of the MITIGATE Trial](#)**

Abstract #2107; Poster Session C; Tuesday, November 10, 2026, 10:30 a.m.–12:30 p.m. ET

- **[Efficacy and Safety of Inebilizumab in Newly Diagnosed and Recurrent IgG4-RD Patients: Results From the Open-Label Period of the MITIGATE Study](#)**

Abstract #1129; Poster Session B; Monday, November 9, 2026, 10:30 a.m. –12:30 p.m. ET

- **[Long-Term Efficacy and Safety of Inebilizumab in IgG4-Related Disease: Primary Results from the Year 1 Open-Label Period of a Phase 3 Trial \(Encore\)](#)**

Abstract #0177; Poster Session A; Sunday, November 8, 2026, 10:30 a.m. –12:30 p.m. ET

TAVNEOS® (avacopan)

- [Effectiveness and Safety of Avacopan Added to Standard of Care \(SOC\) Versus SOC Alone in ANCA-associated Vasculitis](#)

Abstract #2133; Poster Session C; Tuesday, November 10, 2026, 10:30 a.m.–12:30 p.m. ET

- [Glucocorticoid-Associated Conditions in Patients With Granulomatosis With Polyangiitis and Microscopic Polyangiitis With Prolonged Moderate-to-High Dose Glucocorticoid Use \(Encore\)](#)

Abstract #1156; Poster Session B; Monday, November 9, 2026, 10:30 a.m. –12:30 p.m. ET

KRYSTEXXA® (pegloticase)

- [Induction and Maintenance of Gout Remission During Intensive Urate-Lowering with Pegloticase: Post Hoc Analysis of a 2.5 Year Open-Label Extension Study](#)

Abstract #0714; Poster Session A; Sunday, November 8, 2026, 10:30 a.m.–12:30 p.m. ET

- [Real-World Attainment and Durability of Gout Remission Following Pegloticase Initiation in a U.S. Practice Based Rheumatology Network](#)

Abstract #0853; Poster Session A; Sunday, November 8, 2026, 10:30 a.m.–12:30 p.m. ET

- [Induction of Clinical Remission in Patients with Uncontrolled Gout Treated with Pegloticase and Immunomodulation: Experience in Two Community Rheumatology Practices](#)

Abstract #2648; Poster Session C; Tuesday, November 10, 2026, 10:30 a.m.–12:30 p.m. ET

- [The Pattern and Severity of Gout Flares Prior to and During Pegloticase Treatment in the MIRROR and AGILE Clinical Trials](#)

Abstract #2657; Poster Session C; Tuesday, November 10, 2026, 10:30 a.m.–12:30 p.m. ET

- [Real-World Use of Immunomodulation Co-therapy Among Pegloticase New Users](#)

Abstract #2653; Poster Session C; Tuesday, November 10, 2026, 10:30 a.m.–12:30 p.m. ET

About Dazodalibep

Dazodalibep is a potential first-in-class CD40L antagonist fusion protein that is designed to target immune activation by disrupting interactions between T cells, glandular epithelial cells, B cells and other antigen-presenting cells. Dazodalibep is being studied in two Sjögren's disease patient groups: those with moderate-to-severe systemic disease and those with high symptom burden and low systemic disease who suffer from dryness, fatigue, and/or pain that profoundly impact daily life.

About OASIZ 301 and the Dazodalibep Development Program

OASIZ 301 is a Phase 3, randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of dazodalibep in patients with Sjögren's disease with moderate-to-severe systemic disease activity (ESSDAI ≥ 5) (n=approximately 621). The primary endpoint of the study is change from baseline in ESSDAI score at Week 48.

Key secondary endpoints evaluated dryness, tender and swollen joints, fatigue, and ESSDAI[5] response, defined as a decrease of at least 5 points from baseline.

Additionally, Amgen is conducting OASIZ 303, a Phase 3, randomized, double-blind, placebo-controlled study evaluating the efficacy and safety of dazodalibep in patients with high symptom burden with low systemic Sjögren's disease activity. The OASIZ 303 study is expected to complete in Q4 2026.

Amgen is also conducting OASIZ 304, an open-label, long-term extension study evaluating the long-term safety and tolerability of dazodalibep in eligible participants from OASIZ 301 and OASIZ 303.

About Sjögren's Disease

Sjögren's disease (SjD) is a heterogeneous autoimmune disease, where patients can experience persistent dryness, fatigue, and pain, often alongside systemic involvement that can be progressive. Although SjD is the second most common autoimmune rheumatic disease, it remains widely underrecognized, with the full extent of its systemic severity and debilitating symptomatic impact on patients' lives often underestimated. Despite this burden, there are currently no approved therapies for SjD, and many patients continue to experience persistent systemic disease activity and debilitating symptoms.

About UPLIZNA® (inebilizumab-cdon)

UPLIZNA is a humanized monoclonal antibody (mAb) that causes targeted and sustained depletion of key cells that contribute to underlying disease process (autoantibody-producing CD19+ B cells, including plasmablasts and some plasma cells). The precise mechanism by which UPLIZNA exerts its therapeutic effects in IgG4-RD is unknown. After two initial infusions, patients need one dose of UPLIZNA every six months.

About TAVNEOS® (avacopan)

TAVNEOS is an orally administered small molecule indicated as an adjunctive treatment for adult patients with severe active ANCA-associated vasculitis (GPA/MPA). It is a selective complement 5a receptor (C5aR) antagonist that targets inflammation by blocking the activity of C5a, a key driver of neutrophil activation. By inhibiting C5aR, TAVNEOS helps reduce inflammation while preserving other complement system functions. The precise mechanism by which TAVNEOS exerts its therapeutic effects in ANCA-associated vasculitis has not been fully established.

About KRYSTEXXA® (pegloticase)

KRYSTEXXA is the first 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.

UPLIZNA® (inebilizumab-cdon) U.S. INDICATIONS

UPLIZNA® (inebilizumab-cdon) is indicated in adult patients for the treatment of: anti-aquaporin-4 (AQP4) antibody positive neuromyelitis optica spectrum disorder (NMOSD); Immunoglobulin G4-related disease (IgG4-RD); anti-acetylcholine receptor (AChR) or anti-muscle specific tyrosine kinase (MuSK) antibody positive (Ab+) generalized myasthenia gravis (gMG).

UPLIZNA U.S. IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

UPLIZNA® (inebilizumab-cdon) is contraindicated in patients with a history of a life-threatening infusion reaction to UPLIZNA, active hepatitis B infection, or active or untreated latent tuberculosis.

WARNINGS AND PRECAUTIONS

- **Infusion Reactions:** Infusion reactions, including anaphylaxis, can occur. Symptoms can include headache, nausea, somnolence, dyspnea, fever, myalgia, rash, or palpitations. Infusion reactions were observed in 9.3%, 7.4%, and 10.1% of patients treated with UPLIZNA during the randomized controlled periods (RCPs) of Study 1 in patients with NMOSD, Study 2 in patients with IgG4-RD, and Study 3 in patients with gMG, respectively. Infusion reactions were most common with the first infusion but were also observed during subsequent infusions.

Administer pre-medication with a corticosteroid, an antihistamine, and an antipyretic. For life-threatening infusion reactions, immediately and permanently stop UPLIZNA and administer appropriate supportive treatment. For less severe infusion reactions, management may involve temporarily stopping the infusion, reducing the infusion rate, and/or administering symptomatic treatment.

- **Infections:** Serious, including life-threatening or fatal, bacterial, fungal, and new or reactivated viral infections have been observed during and following completion of treatment with B-cell depleting therapies, including UPLIZNA. The most common infections reported by UPLIZNA-treated patients in the NMOSD randomized and open-label clinical trial periods for NMOSD were urinary tract infection (20%), nasopharyngitis (13%), upper respiratory tract infection (8%), and influenza (7%). In the IgG4-RD RCP, the most common infections reported by UPLIZNA-treated patients were urinary tract infection, influenza, and pneumonia. In the gMG RCP, the most common infections reported by UPLIZNA-treated patients were urinary tract infection and nasopharyngitis. Delay UPLIZNA administration in patients with an active infection until the infection is resolved.

Possible Increased Risk of Immunosuppressant Effects with Other Immunosuppressants: If combining UPLIZNA with another immunosuppressive therapy, consider the potential for increased immunosuppressive effects.

Hepatitis B Virus (HBV) Reactivation: HBV reactivation has been observed with B-cell-depleting therapies, including UPLIZNA. Fulminant hepatitis, hepatic failure, and death caused by HBV reactivation have occurred in patients treated with B-cell depleting therapies. HBV reactivation was observed in a patient treated with UPLIZNA during the gMG clinical trial and in the postmarketing setting. Patients with active or chronic HBV infection were excluded from clinical trials. Perform HBV screening in all patients before initiation of treatment. Do not administer to patients with active HBV confirmed by positive results for HBsAg and anti-HB tests. For patients who are negative for HBsAg and positive for HBcAb, or who are carriers of HBV (i.e., HBsAg+), consult liver disease experts before starting and during treatment.

Progressive Multifocal Leukoencephalopathy (PML): Although no confirmed cases of PML were identified in UPLIZNA clinical trials, JC virus infection resulting in PML has been observed in patients treated with other B-cell-depleting antibodies and other therapies that affect immune competence. In UPLIZNA clinical trials one subject died following the development of new brain lesions for which a definitive diagnosis could not be established, though the differential diagnosis included an atypical NMOSD relapse, PML, or acute disseminated encephalomyelitis. At the first sign or symptom suggestive of PML, withhold UPLIZNA and perform an appropriate diagnostic evaluation. MRI findings may be apparent before clinical signs or symptoms. Typical symptoms associated with PML are diverse, progress over days to weeks, and include progressive weakness on one side of the body or clumsiness of limbs, disturbance of vision, and changes in thinking, memory, and orientation leading to confusion and personality changes.

Tuberculosis

Patients should be evaluated for tuberculosis risk factors and tested for latent infection prior to initiating UPLIZNA. Consider anti-tuberculosis therapy prior to initiation of UPLIZNA in patients with a history of latent active tuberculosis in whom an adequate course of treatment cannot be confirmed, and for patients with a negative test for latent tuberculosis but having risk factors for tuberculosis infection. Consult infectious disease experts regarding whether initiating anti-tuberculosis therapy is appropriate before starting treatment.

Vaccinations

Administer all immunizations according to immunization guidelines at least 4 weeks prior to initiation of UPLIZNA. The safety of immunization with live or live-attenuated vaccines following UPLIZNA therapy has not been studied, and vaccination with live-attenuated or live vaccines is not recommended during treatment and until B-cell repletion.

Vaccination of Infants Born to Mothers Treated with UPLIZNA During Pregnancy

In infants of mothers exposed to UPLIZNA during pregnancy, do not administer live or live-attenuated vaccines before confirming recovery of B-cell counts in the infant. Depletion of B cells in these exposed infants may increase the risks from live or live-attenuated vaccines. Non-live vaccines, as indicated, may be administered prior to recovery from B-cell and immunoglobulin level depletion, but consultation with a qualified specialist should be considered to assess whether a protective immune response was mounted.

- **Reductions in Immunoglobulins:** There may be a progressive and prolonged hypogammaglobulinemia or decline in the levels of total and individual immunoglobulins such as immunoglobulins G and M (IgG and IgM) with continued UPLIZNA treatment. Monitor the levels of quantitative serum immunoglobulins during treatment with UPLIZNA, especially in patients with opportunistic or recurrent infections, and until B-cell repletion after discontinuation of therapy. Consider discontinuing UPLIZNA therapy if a patient with low immunoglobulin G or M develops a serious opportunistic infection or recurrent infections, or if prolonged hypogammaglobulinemia requires treatment with intravenous immunoglobulins.
- **Fetal Risk:** Based on animal data, UPLIZNA can cause fetal harm due to B-cell lymphopenia and reduce antibody response in offspring exposed to UPLIZNA even after B-cell repletion. Transient peripheral B-cell depletion and lymphocytopenia have been reported in infants born to mothers exposed to other B-cell-depleting antibodies during pregnancy. Advise females of reproductive potential to use effective contraception while receiving UPLIZNA and for at least 6 months after the last dose.

ADVERSE REACTIONS

- The most common adverse reactions (at least 10% of patients treated with UPLIZNA and greater than placebo): urinary tract infection and arthralgia in NMOSD; urinary tract infection and lymphopenia in IgG4-RD; headache and infusion-related reactions in gMG.

[Please see UPLIZNA® full Prescribing Information](#)

TAVNEOS (avacopan) U.S. INDICATION

TAVNEOS (avacopan) 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.

WARNINGS AND PRECAUTIONS

- **Hepatotoxicity:** Serious cases of hepatic injury have been observed in patients taking TAVNEOS, including life-threatening events. In the postmarketing setting, vanishing bile duct syndrome (VBDS) as a consequence of liver injury, including cases with a fatal outcome, has been reported. These events occurred predominantly in Japan in patients aged 65 years and older, but VBDS may affect patients of any age or ethnicity who are receiving TAVNEOS. Obtain liver test panel before initiating TAVNEOS, every 4 weeks after start of therapy for 6 months and as clinically indicated thereafter. For patients of Japanese descent, consider more frequent laboratory testing: every 2 weeks after the start of therapy for the first 3 months, followed by laboratory testing every 4 weeks for the next 3 months of treatment, and as clinically indicated thereafter. If a patient receiving treatment with TAVNEOS presents with an elevation in alanine aminotransferase [ALT] or aspartate aminotransferase [AST] to >3 times the upper limit of normal, evaluate promptly and consider pausing treatment as clinically indicated. If AST or ALT is > 5 times the upper limit of normal (ULN), or ALT or AST > 3 times the ULN with total bilirubin > 2 times the ULN, or alkaline phosphatase ≥ 2 times the ULN, or if the patient has clinical symptoms such as jaundice or pruritus, discontinue TAVNEOS until TAVNEOS-induced liver injury is ruled out. Immediately and permanently discontinue TAVNEOS if VBDS is suspected. 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 risks and benefits before administering this drug to a patient with liver disease.
- **Serious Hypersensitivity Reactions:** Cases of angioedema occurred in a clinical trial, including 1 serious event requiring

hospitalization. Discontinue immediately if angioedema occurs and manage accordingly. TAVNEOS must not be readministered 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 6 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 the 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 ($\geq 5\%$ 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 co-administration 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. Consider dose reduction of CYP3A4 substrates when co-administering TAVNEOS. Co-administration of avacopan and 40 mg simvastatin increases the systemic exposure of simvastatin. While taking TAVNEOS, limit simvastatin dosage to 10 mg daily (or 20 mg daily for patients who have previously tolerated simvastatin 80 mg daily for at least one year without evidence of muscle toxicity). Consult the concomitant CYP3A4 substrate product information when considering administration of such products together with TAVNEOS.

TAVNEOS is available as a 10 mg capsule.

Please see [Full Prescribing Information](#) and [Medication Guide](#) for TAVNEOS.

To report a suspected adverse event, call 1-833-828-6367. You may report to the FDA directly by visiting www.fda.gov/medwatch or calling 1-800-332-1088.

KRYSTEXXA (pegloticase) 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 (pegloticase) 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.
- Premedicate with antihistamines and corticosteroids and closely monitor for anaphylaxis for an appropriate period after administration of KRYSTEXXA.
- Monitor serum uric acid levels prior to each infusion and discontinue treatment if levels increase to above 6 mg/dL, particularly when 2 consecutive levels above 6 mg/dL are observed.
- Screen patients at risk for glucose-6-phosphate dehydrogenase (G6PD) deficiency prior to starting KRYSTEXXA. Life threatening hemolytic reactions 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

Anaphylaxis

In a 52-week controlled trial of KRYSTEXXA co-administered with methotrexate (MTX) compared to KRYSTEXXA alone, one patient treated with KRYSTEXXA co-administered with MTX (1%) experienced anaphylaxis during the first infusion and no patients experienced anaphylaxis treated with KRYSTEXXA alone. Patients were pre-treated with infusion reaction prophylaxis and KRYSTEXXA was discontinued following 2 consecutive serum uric acid levels above 6 mg/dL to reduce the risk of anaphylaxis and infusion reactions. These risks are higher in patients whose uric acid level increases to above 6 mg/dL, particularly when 2 consecutive levels above 6 mg/dL are observed.

During pre-marketing clinical trials with KRYSTEXXA alone, KRYSTEXXA was not discontinued following 2 consecutive serum uric acid levels above 6 mg/dL. Anaphylaxis was reported with 6.5% (8/123) of patients treated with KRYSTEXXA every 2 weeks and 4.8% (6/126) for the every 4-week dosing regimen. There were no cases of anaphylaxis in patients receiving placebo. Anaphylaxis generally occurred within 2 hours after treatment.

Diagnostic criteria of anaphylaxis were skin or mucosal tissue involvement, and, either airway compromise, and/or reduced blood pressure with or without associated symptoms, and a temporal relationship to KRYSTEXXA or placebo injection with no other identifiable cause. Manifestations included wheezing, peri-oral or lingual edema, or hemodynamic instability, with or without rash or urticaria, nausea or vomiting. Cases occurred in patients being pre-treated with one or more doses of an oral antihistamine, an intravenous corticosteroid and/or acetaminophen, which may have resulted in an underestimate of anaphylaxis frequency reported. Patients should be informed of the symptoms and signs of anaphylaxis and instructed to seek immediate medical care should anaphylaxis occur after discharge from the healthcare setting.

It is recommended that before starting KRYSTEXXA patients discontinue oral urate-lowering medications and not institute therapy with oral urate-lowering agents while taking KRYSTEXXA.

Infusion Reactions

In the 52-week trial, infusion reactions were reported in 4% of patients in the KRYSTEXXA co-administered with MTX group compared to 31% of patients treated with KRYSTEXXA alone. In both treatment groups, the majority of infusion reactions occurred at the first or second KRYSTEXXA infusion and during the time of infusion.

During pre-marketing 24-week controlled clinical trials with KRYSTEXXA alone, infusion reactions were reported in 26% of patients treated with KRYSTEXXA 8 mg every 2 weeks, and 41% of patients treated with KRYSTEXXA 8 mg every 4 weeks, compared to 5% of patients treated with placebo. These infusion reactions occurred in patients being pre-treated with an oral antihistamine, intravenous corticosteroid and/or acetaminophen, which may have resulted in an underestimate of infusion reaction frequency reported.

Manifestations of these reactions included urticaria (10.6%), dyspnea (7.1%), chest discomfort (9.5%), chest pain (9.5%), erythema (9.5%), and pruritus (9.5%). These manifestations overlap with the symptoms of anaphylaxis, but in a given patient did not occur together to satisfy the clinical criteria for diagnosing anaphylaxis. Infusion reactions occurred at any time during a course of treatment with ~3% occurring with the first infusion, and ~91% occurred during the time of infusion.

KRYSTEXXA should be infused slowly over no less than 120 minutes. In the event of an infusion reaction, the infusion should be slowed, or stopped and restarted at a slower rate.

Gout Flares

In the 52-week trial of KRYSTEXXA co-administered with MTX vs KRYSTEXXA alone, patients were administered gout flare prophylaxis, resulting in 66% and 69% of patients with any flare for the first 3 months, respectively. In the KRYSTEXXA co-administered with MTX group, the percentages of patients with any flare for the subsequent 3 month increments of treatment were 27%, 8%, and 9% during Months 6, 9, and 12, respectively; in the group treated with KRYSTEXXA alone, 14%, 9%, and 21% during Months 6, 9, and 12, respectively.

During the 24-week pre-marketing, controlled trials, with KRYSTEXXA alone the frequencies of gout flares were high in all treatment groups, but more so with KRYSTEXXA treatment during the first 3 months, and decreased in the subsequent 3 months. The percentages of patients with any flare for the first 3 months were 74%, 81%, and 51%, for KRYSTEXXA 8 mg every 2 weeks, KRYSTEXXA 8 mg every 4 weeks, and placebo, respectively. The percentages of patients with any flare for the subsequent 3 months were 41%, 57%, and 67%, for KRYSTEXXA 8 mg every 2 weeks, KRYSTEXXA 8 mg every 4 weeks, and placebo, respectively. Patients received gout flare prophylaxis with colchicine and/or NSAIDs starting at least one week before receiving KRYSTEXXA. Gout flares may occur after initiation of KRYSTEXXA. An increase in gout flares is frequently observed upon initiation of anti-hyperuricemic therapy, due to changing serum uric acid levels resulting in mobilization of urate from tissue deposits. Gout flare prophylaxis with a 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. KRYSTEXXA does not need to be discontinued because of a gout flare. The gout flare should be managed concurrently as appropriate for the individual patient.

Congestive Heart Failure (CHF)

KRYSTEXXA has not been formally studied in patients with CHF, but some patients in the pre-marketing placebo-controlled clinical trials experienced exacerbation. Two cases of CHF exacerbation occurred during the trials in patients receiving treatment with KRYSTEXXA 8 mg every 2 weeks. No cases were reported in placebo-treated patients. Four subjects had exacerbations of pre-existing CHF while receiving KRYSTEXXA 8 mg every 2 weeks during the OLE study. Exercise caution in patients who have congestive heart failure and monitor patients closely following infusion.

Re-treatment with KRYSTEXXA

No controlled trial data are available on re-treatment after stopping treatment for longer than 4 weeks. Due to the immunogenicity of KRYSTEXXA, patients receiving re-treatment may be at increased risk of anaphylaxis and infusion reactions. Therefore, patients receiving re-treatment after a drug-free interval should be monitored carefully.

ADVERSE REACTIONS

The most common adverse reactions (≥5%) are:

Co-administration with MTX:

Gout flares, arthralgia, COVID-19, nausea, and fatigue.

KRYSTEXXA alone:

Gout flares, infusion reactions, nausea, contusion or ecchymosis, nasopharyngitis, constipation, chest pain, anaphylaxis, and vomiting.

Please see [Full Prescribing Information](#), including **Boxed Warning**.

About Amgen

Amgen discovers, develops, manufactures and delivers innovative medicines to fight some of the world's toughest diseases. Harnessing the best of biology and technology, Amgen reaches millions of patients with its medicines.

More than 45 years ago, Amgen helped establish the biotechnology industry at its U.S. headquarters in Thousand Oaks, California, and it remains at the cutting edge of innovation, using technology and human genetic data to push beyond what is known today. Amgen is advancing a broad and deep pipeline and portfolio of medicines to treat cancer, inflammatory conditions, rare diseases, heart disease and obesity and obesity-related conditions.

Amgen has been [consistently recognized](#) for innovation and workplace culture, including honors from Fast Company and Forbes. 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.

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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 BeOne Medicines Ltd.), the performance of Otezla® (apremilast), our acquisitions of ChemoCentryx, Inc., Dark Blue Therapeutics, Ltd. or Horizon Therapeutics plc (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, including those resulting from geopolitical relations and government actions. 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. 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, 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, and may result in unanticipated costs, delays or failures to realize the benefits of the transactions. 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 sustainability 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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