AMGEN TO PRESENT NEW RESEARCH ACROSS SERIOUS INFLAMMATORY AND BONE DISEASES AT ACR 2022

November 7, 2022

New Real-World Evidence Highlights AMGEVITA® Utilization, Treatment Satisfaction and Persistence in European Patients

New Data From First-in-Class Treatment TAVNEOS®, Evaluating Renal Function Among Adults Living With Severe Active ANCA-Associated Vasculitis

THOUSAND OAKS, Calif., Nov. 7, 2022 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced that clinical and real-world data across its broad portfolio of established treatments and pipeline assets will be presented at the annual American College of Rheumatology Convergence (ACR), taking place in Philadelphia on Nov. 10-14, 2022.

Among 22 abstracts, noteworthy presentations will include real-world evidence for AMGEVITA®* (adalimumab), underscoring treatment satisfaction and persistence in German patients with rheumatic diseases. Additional data will highlight utilization in European patients with moderate to severe rheumatoid arthritis, ankylosing spondylitis and psoriatic arthritis.

Other research highlights include data on TAVNEOS® (avacopan) in severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis, notably an oral presentation on evaluation of recovery of renal function among patients with baseline estimated glomerular filtration rate (eGFR) at or below 20; renal function is impaired in the majority of people with the disease. Additionally, two real-world evidence posters report on the effects of Otezla® (apremilast) on cardiometabolic parameters in patients with psoriatic disease.

"Given the uptake of biosimilars, we are looking forward to presenting real-world evidence data from the experiences of patients using AMGEVITA, since it was approved in Europe four years ago," said David M. Reese, M.D., executive vice president of Research and Development at Amgen. "The breadth of data being presented reflects our deep commitment to driving innovation in inflammatory diseases."

*AMJEVITA™ outside the US is marketed as AMGEVITA. AMJEVITA is currently not available commercially and will not be commercially available in the United States until on or after January 31, 2023.

Abstracts and Presentation Times:

AMGEVITA® (adalimumab) Abstracts

- **Real-World Utilization of Adalimumab Biosimilar (ABP 501) in Patients with Rheumatoid Arthritis, Ankylosing Spondylitis and Psoriatic Arthritis in Europe**
  - Abstract #1387, Virtual Poster Session, Sunday, Nov. 13 from 1-3 p.m. EST
- **Treatment Persistence and Switching Patterns of ABP 501 (AMGEVITA®) in German Patients with Rheumatic Diseases**
  - Abstract #1425, Virtual Poster Session, Sunday, Nov. 13 from 1-3 p.m. EST

SLE/AMG 592 Abstracts

- **Unmet Need in Systemic Lupus Erythematosus (SLE) Therapy: High Corticosteroid Use and Poor Adherence and Persistence to SLE Treatments in the US**
  - Abstract #1275040, Oral Poster Session, Monday, Nov. 14 from 3-4:30 p.m. EST
- **Real-World Treatment Patterns, Healthcare Resource Utilization (HCRU) and Costs in Patients with Systemic Lupus Erythematosus (SLE) in the US**
  - Abstract #1274556, Virtual Poster Session, Saturday, Nov. 12 from 1-3 p.m. EST
- **Regulatory T Cell Defects in SLE and Therapy with a Novel IL-2 Mutein: Phase 1 Clinical Results with Efavaleukin Alfa**
  - Abstract #0989, Ignite Poster Talk, Monday, Nov.14 from 1-1:55 p.m. EST, Virtual Poster Presentation, Sunday, Nov. 13 from 9-10:30 a.m. EST

Enbrel® (etanercept) Abstracts

- **Outcomes of Etanercept and Janus Kinase Inhibitor Treatment After First-line Use of Adalimumab in Patients with Rheumatoid Arthritis**
  - Abstracts #1588, Oral Poster Session, Sunday, Nov. 13 from 3-4:30 p.m. EST
- **Lower Healthcare Costs for Commercially Insured Patients with Rheumatoid Arthritis in Remission**
  - Abstracts #0060, Virtual Poster Session, Saturday, Nov. 12 from 1-3 p.m. EST
- **Maintenance of Disease Activity and Treatment Persistence in Patients with Rheumatoid Arthritis Who Switched from Combination to TNF inhibitor Monotherapy: Results from the Rheumatology Informatics System for Effectiveness (RISE) Registry**

    - Abstracts #0306, Virtual Poster Session, Saturday, Nov. 12 from 1-3 p.m. EST
- **Change in Disease Activity and Occurrence of Adverse Events After Initiation of Etanercept in Pediatric Patients with Juvenile Psoriatic Arthritis in the CARRA Registry**
    - Abstracts #1418, Virtual Poster Session, Sunday, Nov. 13 from 1-3 p.m. EST
- **Outcomes in Patients with Rheumatoid Arthritis Initiating Monotherapy with Etanercept, Adalimumab, or Janus Kinase Inhibitors**
    - Abstracts #1420, Virtual Poster Session, Sunday, Nov. 13 from 1-3 p.m. EST

EVENITY® (romosozumab-aqqg) Abstracts

- **Effect of Romosozumab in Postmenopausal Women with Knee Osteoarthritis: Results from the FRAME Clinical Trial**
    - Abstract #1278232, Virtual Poster Session, Sunday, Nov. 13 from 1-3 p.m. EST

Otezla® (apremilast) Abstracts

- **Characterization of Joint Distribution and Disease Burden in Patients with Early Oligoarticular Psoriatic Arthritis: Results from the Ongoing FOREMOST Study (EULAR 2022 Encore)**
    - Abstract #1289024, Virtual Poster Session, Sunday, Nov. 13 from 9-10:30 a.m. EST
- **Diabetes Burden and Effects of Apremilast on Changes in Cardiometabolic Parameters in Patients with Psoriasis (PsO) or Psoriatic Arthritis (PsA) in a Real-World Setting**
    - Abstract #1290834, Virtual Poster Session, Sunday, Nov. 13 from 1-3 p.m. EST
- **Effectiveness by Disease Severity in Patients with Psoriatic Arthritis Treated with Apremilast in the CorEvitas Psoriatic Arthritis/Spondyloarthritis (PsA/SpA) Registry**
    - Abstract #1289089, Virtual Poster Session, Sunday, Nov. 13 from 9-10:30 a.m. EST
- **Obesity Burden and Effects of Apremilast on Changes in Cardiometabolic Parameters by Obesity Status in Patients with Psoriasis (PsO) or Psoriatic Arthritis (PsA) in a Real-World Setting**
    - Abstract #1291242, Virtual Poster Session, Sunday, Nov. 13 from 1-3 p.m. EST
- **Exposure-Adjusted Incidence Rate for Adverse Events of Special Interest in Patients with Psoriatic Arthritis Treated with Apremilast**
    - Abstract #1289316, Virtual Poster Session, Monday, Nov. 14 from 1-3 p.m. EST

Prolia® (denosumab) Abstracts

- **Comparative Effectiveness of Osteoporosis (OP) Therapies Among a Population of Postmenopausal Women in the United States (U.S.) (Encore)**
    - Abstract #1276817, Oral Presentation Session, Sunday, Nov. 13 from 8:30-8:40 a.m. EST
- **Myocardial Infarction and Stroke Risks Among Patients Who Initiated Treatment with Denosumab or Zoledronic Acid for Osteoporosis (Encore)**
    - Abstract #1276817, Oral Presentation Session, Sunday, Nov. 13 from 8:15-8:25 a.m. EST

TAVNEOS® (avacopan) Abstracts

- **Recovery of Renal Function Among ANCA-Associated Vasculitis Patients with Baseline eGFR ≤20 in the Avacopan ADVOCATE Trial**
    - Abstract #0525, Oral Presentation Session, Saturday, Nov. 12 from 3:15-3:25 p.m. EST
- **ANCA-Associated Vasculitis Treated with Avacopan versus a Standard Prednisone Taper: Glucocorticoid Toxicity Index Scores by Domain**
    - Abstract #1076, Ignite Talk Session, Sunday, Nov. 13 from 10:15-10:20 a.m. EST
- **Safety of Avacopan in ANCA-Associated Vasculitis: Combined Data from Three Clinical Trials**
    - Abstract #1077, Ignite Talk Session, Sunday, Nov. 13 from 10:15-10:20 a.m. EST
- **Glucocorticoid Use and Related Adverse Events in ADVOCATE Trial of Avacopan in ANCA-Associated Vasculitis**
    - Abstract #1078, Poster Session, Sunday, Nov. 13 from 9-10:30 a.m. EST

Abstracts can be found on the ACR website.

ABOUT AMJEVITA® (adalimumab-atto) in the U.S.
AMJEVITA is a biosimilar to adalimumab, an anti-TNF-α monoclonal antibody. The active ingredient of AMJEVITA is an anti-TNF-α monoclonal antibody that has the same amino acid sequence as, and is highly similar to, adalimumab. AMJEVITA will be delivered in prefilled syringe and autoinjector presentations to support dosing in each of the approved indications.

AMJEVITA is not currently available commercially. This not an offer for sale. The following information is derived from the approved label.

AMJEVITA is indicated, alone or in combination with methotrexate or other non-biologic DMARDs, for reducing signs and symptoms, inducing major

clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active rheumatoid arthritis.

AMJEVITA is indicated, alone or in combination with methotrexate, for reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis in patients 4 years of age and older.

AMJEVITA is indicated, alone or in combination with non-biologic DMARDs, for reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active psoriatic arthritis.

AMJEVITA is indicated for reducing signs and symptoms in adult patients with active ankylosing spondylitis.

AMJEVITA is indicated for reducing signs and symptoms and inducing and maintaining clinical remission in adult patients with moderately to severely active Crohn's disease who have had an inadequate response to conventional therapy, and reducing signs and symptoms and inducing clinical remission in these patients if they have also lost response to or are intolerant to infliximab.

AMJEVITA is indicated for inducing and sustaining clinical remission in adult patients with moderately to severely active ulcerative colitis who have had an inadequate response to immunosuppressants such as corticosteroids, azathioprine, or 6-mercaptopurine. The effectiveness of adalimumab products has not been established in patients who have lost response to or were intolerant to TNF blockers.

AMJEVITA is indicated for the treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate. AMJEVITA should only be administered to patients who will be closely monitored and have regular follow-up visits with a physician.

IMPORTANT U.S. SAFETY INFORMATION

SERIOUS INFECTIONS

Patients treated with AMJEVITA are at increased risk for developing serious infections that may lead to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids.

Discontinue AMJEVITA if a patient develops a serious infection or sepsis.

Reported infections include:

- **Active tuberculosis (TB), including reactivation of latent TB. Patients with TB have frequently presented with disseminated or extrapulmonary disease. Test patients for latent TB before AMJEVITA use and during therapy. Initiate treatment for latent TB prior to AMJEVITA use.**
- **Invasive fungal infections, including histoplasmosis, coccidioidomycosis, candidiasis, aspergillosis, blastomycosis, and pneumocystosis. Patients with histoplasmosis or other invasive fungal infections may present with disseminated, rather than localized, disease. Antigen and antibody testing for histoplasmosis may be negative in some patients with active infection. Consider empiric anti-fungal therapy in patients at risk for invasive fungal infections who develop severe systemic illness.**
- **Bacterial, viral, and other infections due to opportunistic pathogens, including Legionella and Listeria.**

Carefully consider the risks and benefits of treatment with AMJEVITA prior to initiating therapy in patients: 1. with chronic or recurrent infection, 2. who have been exposed to TB, 3. with a history of opportunistic infection, 4. who resided in or traveled in regions where mycoses are endemic, 5. with underlying conditions that may predispose them to infection. Monitor patients closely for the development of signs and symptoms of infection during and after treatment with AMJEVITA, including the possible development of TB in patients who tested negative for latent TB infection prior to initiating therapy.

- Do not start AMJEVITA during an active infection, including localized infections.
- Patients older than 65 years, patients with co-morbid conditions, and/or patients taking concomitant immunosuppressants may be at greater risk of infection.
- If an infection develops, monitor carefully and initiate appropriate therapy.
- Drug interactions with biologic products: A higher rate of serious infections has been observed in rheumatoid arthritis (RA) patients treated with rituximab who received subsequent treatment with a TNF blocker. An increased risk of serious infections has been seen with the combination of TNF blockers with anakinra or abatacept, with no demonstrated added benefit in patients with RA. Concomitant administration of AMJEVITA with other biologic DMARDs (e.g., anakinra or abatacept) or other TNF blockers is not recommended based on the possible increased risk for infections and other potential pharmacological interactions.

MALIGNANCY

Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers including adalimumab products. Postmarketing cases of hepatosplenic T-cell lymphoma (HSTCL), a rare type of T-cell lymphoma, have been reported in patients treated with TNF blockers including adalimumab products. These cases have had a very aggressive disease course and have been fatal. The majority of reported TNF-blocker cases have occurred in patients with Crohn's disease or ulcerative colitis and the majority were in adolescent and young adult males. Almost all of these patients had received treatment with azathioprine or 6-mercaptopurine concomitantly with a TNF blocker at or prior to diagnosis. It is uncertain whether the occurrence of HSTCL is related to use of a TNF blocker or a TNF blocker in combination with these other immunosuppressants.

- Consider the risks and benefits of AMJEVITA prior to initiating or continuing therapy in a patient with known malignancy.
- In clinical trials of some TNF blockers, including adalimumab products, more cases of malignancies were observed among TNF-blocker-treated patients compared to control patients.
- Non-melanoma skin cancer (NMSC) was reported during clinical trials for adalimumab-treated patients. Examine all patients, particularly those with a history of prolonged immunosuppressant or PUVA therapy, for the presence of NMSC prior to and during treatment with AMJEVITA.
- In adalimumab clinical trials, there was an approximate 3-fold higher rate of lymphoma than expected in the general U.S. population. Patients with chronic inflammatory diseases, particularly those with highly active disease and/or chronic exposure to immunosuppressant therapies, may be at higher risk of lymphoma than the general population, even in the absence of TNF blockers.
- Postmarketing cases of acute and chronic leukemia were reported with TNF blocker use. Approximately half of the postmarketing cases of malignancies in children, adolescents, and young adults receiving TNF blockers were lymphomas; other cases included rare malignancies associated with immunosuppression and malignancies not usually observed in children and adolescents.

HYPERSENSITIVITY

Anaphylaxis and angioneurotic edema have been reported following administration of adalimumab products. If a serious allergic reaction occurs, stop AMJEVITA and institute appropriate therapy.

HEPATITIS B VIRUS REACTIVATION

Use of TNF blockers, including AMJEVITA, may increase the risk of reactivation of hepatitis B virus (HBV) in patients who are chronic carriers. Some cases have been fatal. Evaluate patients at risk for HBV infection for prior evidence of HBV infection before initiating TNF blocker therapy. Exercise caution in patients who are carriers of HBV and monitor them during and after AMJEVITA treatment. Discontinue AMJEVITA and begin antiviral therapy in patients who develop HBV reactivation. Exercise caution when resuming AMJEVITA after HBV treatment.

NEUROLOGIC REACTIONS

TNF blockers, including adalimumab products, have been associated with rare cases of new onset or exacerbation of central nervous system and peripheral demyelinating diseases, including multiple sclerosis, optic neuritis, and Guillain-Barré syndrome. Exercise caution when considering AMJEVITA for patients with these disorders; discontinuation of AMJEVITA should be considered if any of these disorders develop.

HEMATOLOGICAL REACTIONS

Rare reports of pancytopenia, including aplastic anemia, have been reported with TNF blockers. Medically significant cytopenia has been infrequently reported with adalimumab products. Consider stopping AMJEVITA if significant hematologic abnormalities occur.

CONGESTIVE HEART FAILURE

Worsening or new onset congestive heart failure (CHF) has been reported with TNF blockers. Cases of worsening CHF have been observed with adalimumab products; exercise caution and monitor carefully.

AUTOIMMUNITY

Treatment with adalimumab products may result in the formation of autoantibodies and, rarely, in development of a lupus-like syndrome. Discontinue treatment if symptoms of a lupus-like syndrome develop.

IMMUNIZATIONS

Patients on AMJEVITA should not receive live vaccines. Pediatric patients, if possible, should be brought up to date with all immunizations before initiating AMJEVITA therapy. Adalimumab is actively transferred across the placenta during the third trimester of pregnancy and may affect immune response in the *in utero* exposed infant. The safety of administering live or live-attenuated vaccines in infants exposed to adalimumab products *in utero* is unknown. Risks and benefits should be considered prior to vaccinating (live or live-attenuated) exposed infants.

ADVERSE REACTIONS

The most common adverse reactions in adalimumab clinical trials (>10%) were: infections (e.g., upper respiratory, sinusitis), injection site reactions, headache, and rash.

Please see full AMJEVITA Prescribing Information, including Medication Guide.

INDICATIONS

- AMJEVITA is indicated, alone or in combination with methotrexate or other non-biologic DMARDs, for reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active rheumatoid arthritis.
- AMJEVITA is indicated, alone or in combination with methotrexate, for reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis in patients 2 years of age and older.
- AMJEVITA is indicated, alone or in combination with non-biologic DMARDs, for reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active psoriatic arthritis.
- AMJEVITA is indicated for reducing signs and symptoms in adult patients with active ankylosing spondylitis.

- AMJEVITA is indicated for the treatment of moderately to severely active Crohn's disease in adults and pediatric patients 6 years of age and older.
- AMJEVITA is indicated for the treatment of moderately to severely active ulcerative colitis in adult patients. The effectiveness of adalimumab products has not been established in patients who have lost response to or were intolerant to TNF blockers.
- AMJEVITA is indicated for the treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate. AMJEVITA should only be administered to patients who will be closely monitored and have regular follow-up visits with a physician.

About Systemic Lupus Erythematosus & AMG 592 (efavaleukin alfa)
Systemic Lupus Erythematosus (SLE) is a chronic autoimmune disease that can impact multiple organ systems. Efavaleukin alfa is an IL-2 mutein Fc fusion protein. It is being investigated for the treatment of inflammatory diseases, including SLE.

About ENBREL (etanercept)
ENBREL is a soluble form of a tumor necrosis factor (TNF) receptor with a clinical efficacy and safety profile established over 20 years of collective clinical experience. ENBREL was first approved in 1998 for moderate-to-severe rheumatoid arthritis. ENBREL was approved in 1999 to treat moderate-to-severe polyarticular juvenile idiopathic arthritis, in 2002 to treat psoriatic arthritis, in 2003 for the treatment of patients with ankylosing spondylitis, in 2004 to treat moderate-to-severe plaque psoriasis in adults, and in 2016 the moderate-to-severe plaque psoriasis indication was expanded to include patients 4 years or older. Prescription ENBREL is given by injection.

ENBREL U.S. Important Safety Information

Patients treated with ENBREL are at increased risk for developing serious infections that may lead to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids or were predisposed to infection because of their underlying disease. ENBREL should not be initiated in the presence of sepsis, active infections, or allergy to ENBREL or its components. ENBREL should be discontinued if a patient develops a serious infection or sepsis. Reported infections include: 1) Active tuberculosis (TB), including reactivation of latent TB. Patients with TB have frequently presented with disseminated or extrapulmonary disease. Patients should be tested for latent TB before ENBREL use and periodically during therapy. Treatment for latent infection should be initiated prior to ENBREL use, 2) Invasive fungal infections, including histoplasmosis, coccidioidomycosis, candidiasis, aspergillosis, blastomycosis, and pneumocystosis. Patients with histoplasmosis or other invasive fungal infections may present with disseminated, rather than localized, disease. Antigen and antibody testing for histoplasmosis may be negative in some patients with active infection. Empiric antifungal therapy should be considered in patients at risk for invasive fungal infections who develop severe systemic illness, and 3) Bacterial, viral, and other infections due to opportunistic pathogens, including Legionella and Listeria.

The risks and benefits of treatment with ENBREL should be carefully considered prior to initiating therapy in patients 1) with chronic or recurrent infection, 2) who have been exposed to TB, 3) who have resided or traveled in areas of endemic TB or endemic mycoses, or 4) with underlying conditions that may predispose them to infections such as advanced or poorly controlled diabetes. Patients should be closely monitored for the development of signs and symptoms of infection during and after treatment with ENBREL, including the possible development of TB in patients who tested negative for latent TB prior to initiating therapy.

Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with tumor necrosis factor (TNF) blockers, including ENBREL.

In adult clinical trials of all TNF blockers, more cases of lymphoma were seen compared to control patients. The risk of lymphoma may be up to several-fold higher in RA patients. The role of TNF blocker therapy in the development of malignancies is unknown. Cases of acute and chronic leukemia have been reported in association with postmarketing TNF blocker use in RA and other indications. The risk of leukemia may be higher in patients with RA (approximately 2-fold) than the general population. Melanoma and non-melanoma skin cancer (NMSC) have been reported in patients treated with TNF blockers, including ENBREL. Periodic skin examinations should be considered for all patients at increased risk for skin cancer. In patients who initiated therapy at ≤ 18 years of age, approximately half of the reported malignancies were lymphomas (Hodgkin's and non-Hodgkin's lymphoma). Other cases included rare malignancies usually associated with immunosuppression and malignancies that are not usually observed in children and adolescents. Most of the patients were receiving concomitant immunosuppressants.

Treatment with TNF-blocking agents, including ENBREL, has been associated with rare (< 0.1%) cases of new onset or exacerbation of central nervous system demyelinating disorders, some presenting with mental status changes and some associated with permanent disability, and with peripheral nervous system demyelinating disorders. Cases of transverse myelitis, optic neuritis, multiple sclerosis, Guillain-Barré syndromes, other peripheral demyelinating neuropathies, and new onset or exacerbation of seizure disorders have been reported in post marketing experience with ENBREL therapy. Prescribers should exercise caution in considering the use of ENBREL in patients with preexisting or recent-onset central or peripheral nervous system demyelinating disorders.

Cases of worsening congestive heart failure (CHF) and, rarely, new-onset cases have been reported in patients taking ENBREL. Caution should be used when using ENBREL in patients with CHF. These patients should be carefully monitored. Rare cases of pancytopenia, including aplastic anemia, some fatal, have been reported. The causal relationship to ENBREL therapy remains unclear. Exercise caution when considering ENBREL in patients who have a previous history of significant hematologic abnormalities. Advise patients to seek immediate medical attention if they develop signs or symptoms of blood dyscrasias or infection. Consider discontinuing ENBREL if significant hematologic abnormalities are confirmed. Reactivation of hepatitis B has been reported in patients who were previously infected with hepatitis B virus (HBV) and received concomitant TNF-blocking agents, including ENBREL. Most reports occurred in patients also taking immunosuppressive agents, which may contribute to hepatitis B reactivation. Exercise caution when considering ENBREL in these patients.

Allergic reactions associated with administration of ENBREL during clinical trials have been reported in < 2% of patients. If an anaphylactic reaction or other serious allergic reaction occurs, administration of ENBREL should be discontinued immediately and appropriate therapy initiated. Live vaccines

should not be administered to patients on ENBREL. Pediatric patients, if possible, should be brought up to date with all immunizations prior to initiating ENBREL. In patients with exposure to varicella virus, temporarily discontinue ENBREL and consider prophylactic treatment with Varicella Zoster Immune Globulin. Autoantibodies may develop with ENBREL, and rarely lupus-like syndrome or autoimmune hepatitis may occur. These may resolve upon withdrawal of ENBREL. Stop ENBREL if lupus-like syndrome or autoimmune hepatitis develops. The use of ENBREL in patients with Wegener's granulomatosis receiving immunosuppressive agents (e.g., cyclophosphamide) is not recommended. Based on a study of patients treated for alcoholic hepatitis, exercise caution when using ENBREL in patients with moderate-to-severe alcoholic hepatitis.

The most commonly reported adverse reactions in RA clinical trials were injection site reaction and infection. In clinical trials of all other adult indications, adverse reactions were similar to those reported in RA clinical trials. In general, the adverse reactions in pediatric patients were similar in frequency and type as those seen in adult patients. The types of infections reported in pediatric patients were generally mild and consistent with those commonly seen in the general pediatric population.

The use of ENBREL in patients receiving concurrent cyclophosphamide therapy is not recommended. The risk of serious infection may increase with concomitant use of abatacept therapy. Concurrent therapy with ENBREL and anakinra is not recommended. Hypoglycemia has been reported following initiation of ENBREL therapy in patients receiving medication for diabetes, necessitating a reduction in anti-diabetic medication in some of these patients.

Please see ENBREL full Prescribing Information.

About EVENITY® (romosozumab-aqqg)
EVENITY is a bone-building humanized monoclonal antibody. It is designed to work by inhibiting the activity of sclerostin, which simultaneously results in increased bone formation and to a lesser extent decreased bone resorption. The EVENITY development program includes 19 clinical studies that enrolled more than 14,000 patients. EVENITY has been studied for its potential to reduce the risk of fractures in an extensive global Phase 3 program that included two large fracture trials comparing EVENITY to either placebo or active comparator in nearly 12,000 postmenopausal women with osteoporosis. Amgen and UCB are co-developing EVENITY.

EVENITY® U.S. Indication

EVENITY® is indicated for the treatment of osteoporosis in postmenopausal women at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy.

The anabolic effect of EVENITY® wanes after 12 monthly doses of therapy. Therefore, the duration of EVENITY® use should be limited to 12 monthly doses. If osteoporosis therapy remains warranted, continued therapy with an antiresorptive agent should be considered.

EVENITY® Important U.S. Important Safety Information

POTENTIAL RISK OF MYOCARDIAL INFARCTION, STROKE AND CARDIOVASCULAR DEATH

EVENITY® may increase the risk of myocardial infarction, stroke and cardiovascular death. EVENITY® should not be initiated in patients who have had a myocardial infarction or stroke within the preceding year. Consider whether the benefits outweigh the risks in patients with other cardiovascular risk factors. Monitor for signs and symptoms of myocardial infarction and stroke and instruct patients to seek prompt medical attention if symptoms occur. If a patient experiences a myocardial infarction or stroke during therapy, EVENITY® should be discontinued.

In a randomized controlled trial in postmenopausal women, there was a higher rate of major adverse cardiac events (MACE), a composite endpoint of cardiovascular death, nonfatal myocardial infarction and nonfatal stroke, in patients treated with EVENITY® compared to those treated with alendronate.

Contraindications: EVENITY® is contraindicated in patients with hypocalcemia. Pre-existing hypocalcemia must be corrected prior to initiating therapy with EVENITY®. EVENITY® is contraindicated in patients with a history of systemic hypersensitivity to romosozumab or to any component of the product formulation. Reactions have included angioedema, erythema multiforme, and urticaria.

Hypersensitivity: Hypersensitivity reactions, including angioedema, erythema multiforme, dermatitis, rash, and urticaria have occurred in EVENITY®-treated patients. If an anaphylactic or other clinically significant allergic reaction occurs, initiate appropriate therapy and discontinue further use of EVENITY®.

Hypocalcemia: Hypocalcemia has occurred in patients receiving EVENITY®. Correct hypocalcemia prior to initiating EVENITY®. Monitor patients for signs and symptoms of hypocalcemia, particularly in patients with severe renal impairment or receiving dialysis. Adequately supplement patients with calcium and vitamin D while on EVENITY®.

Osteonecrosis of the Jaw (ONJ): ONJ, which can occur spontaneously, is generally associated with tooth extraction and/or local infection with delayed healing, and has been reported in patients receiving EVENITY®. A routine oral exam should be performed by the prescriber prior to initiation of EVENITY®. Concomitant administration of drugs associated with ONJ (chemotherapy, bisphosphonates, denosumab, angiogenesis inhibitors, and corticosteroids) may increase the risk of developing ONJ. Other risk factors for ONJ include cancer, radiotherapy, poor oral hygiene, pre-existing dental disease or infection, anemia, and coagulopathy.

For patients requiring invasive dental procedures, clinical judgment should guide the management plan of each patient. Patients who are suspected of having or who develop ONJ should receive care by a dentist or an oral surgeon. In these patients, dental surgery to treat ONJ may exacerbate the condition. Discontinuation of EVENITY® should be considered based on benefit-risk assessment.

Atypical Femoral Fractures: Atypical low-energy or low trauma fractures of the femoral shaft have been reported in patients receiving EVENITY®. Causality has not been established as these fractures also occur in osteoporotic patients who have not been treated.

During EVENITY® treatment, patients should be advised to report new or unusual thigh, hip, or groin pain. Any patient who presents with thigh or groin pain should be evaluated to rule out an incomplete femur fracture. Interruption of EVENITY® therapy should be considered based on benefit-risk assessment.

Adverse Reactions: The most common adverse reactions (≥ 5%) reported with EVENITY® were arthralgia and headache.

EVENITY® is a humanized monoclonal antibody. As with all therapeutic proteins, there is potential for immunogenicity.

Please see EVENITY® full Prescribing Information, including Medication Guide.

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.

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 see Otezla full Prescribing Information.

About Prolia® (denosumab)
Prolia is the first approved therapy that specifically targets RANK Ligand, an essential regulator of bone-removing cells (osteoclasts).
Prolia is approved and marketed in over 80 countries worldwide.

Prolia® U.S. Indications

Prolia® is indicated for the treatment of postmenopausal women with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy. In postmenopausal women with osteoporosis, Prolia® reduces the incidence of vertebral, nonvertebral, and hip fractures.

Prolia® is indicated for treatment to increase bone mass in men with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy.

Prolia® is indicated for the treatment of glucocorticoid-induced osteoporosis in men and women at high risk of fracture who are either initiating or continuing systemic glucocorticoids in a daily dosage equivalent to 7.5 mg or greater of prednisone and expected to remain on glucocorticoids for at least 6 months. High risk of fracture is defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy.

Prolia® is indicated as a treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer. In these patients Prolia® also reduced the incidence of vertebral fractures.

Prolia® is indicated as a treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer.

Prolia® U.S. Important Safety Information

Contraindications

Prolia® is contraindicated in patients with hypocalcemia. Pre–existing hypocalcemia must be corrected prior to initiating Prolia®. Prolia® is contraindicated in women who are pregnant and may cause fetal harm. In women of reproductive potential, pregnancy testing should be performed prior to initiating treatment with Prolia®. Prolia® is contraindicated in patients with a history of systemic hypersensitivity to any component of the product. Reactions have included anaphylaxis, facial swelling and urticaria.

Same Active Ingredient

Prolia® contains the same active ingredient (denosumab) found in XGEVA®. Patients receiving Prolia® should not receive XGEVA®

Hypersensitivity

Clinically significant hypersensitivity including anaphylaxis has been reported with Prolia®. Symptoms have included hypotension, dyspnea, throat tightness, facial and upper airway edema, pruritus, and urticaria. If an anaphylactic or other clinically significant allergic reaction occurs, initiate appropriate therapy and discontinue further use of Prolia®.

Hypocalcemia

Hypocalcemia may worsen with the use of Prolia®, especially in patients with severe renal impairment. In patients predisposed to hypocalcemia and disturbances of mineral metabolism, including treatment with other calcium-lowering drugs, clinical monitoring of calcium and mineral levels is highly

recommended within 14 days of Prolia® injection. Concomitant use of calcimimetic drugs may worsen hypocalcemia risk and serum calcium should be closely monitored. Adequately supplement all patients with calcium and vitamin D.

Osteonecrosis of the Jaw (ONJ)

ONJ, which can occur spontaneously, is generally associated with tooth extraction and/or local infection with delayed healing, and has been reported in patients receiving Prolia®. An oral exam should be performed by the prescriber prior to initiation of Prolia®. A dental examination with appropriate preventive dentistry is recommended prior to treatment in patients with risk factors for ONJ such as invasive dental procedures, diagnosis of cancer, concomitant therapies (e.g., chemotherapy, corticosteroids, angiogenesis inhibitors), poor oral hygiene, and co-morbid disorders. Good oral hygiene practices should be maintained during treatment with Prolia®. The risk of ONJ may increase with duration of exposure to Prolia®.

For patients requiring invasive dental procedures, clinical judgment should guide the management plan of each patient. Patients who are suspected of having or who develop ONJ should receive care by a dentist or an oral surgeon. Extensive dental surgery to treat ONJ may exacerbate the condition. Discontinuation of Prolia® should be considered based on individual benefit-risk assessment.

Atypical Femoral Fractures

Atypical low-energy, or low trauma fractures of the shaft have been reported in patients receiving Prolia®. Causality has not been established as these fractures also occur in osteoporotic patients who have not been treated with antiresorptive agents.

During Prolia® treatment, patients should be advised to report new or unusual thigh, hip, or groin pain. Any patient who presents with thigh or groin pain should be evaluated to rule out an incomplete femur fracture. Interruption of Prolia® therapy should be considered, pending a risk/benefit assessment, on an individual basis.

Multiple Vertebral Fractures (MVF) Following Discontinuation of Prolia® Treatment

Following discontinuation of Prolia® treatment, fracture risk increases, including the risk of multiple vertebral fractures. New vertebral fractures occurred as early as 7 months (on average 19 months) after the last dose of Prolia®. Prior vertebral fracture was a predictor of multiple vertebral fractures after Prolia® discontinuation. Evaluate an individual's benefit/risk before initiating treatment with Prolia®. If Prolia® treatment is discontinued, patients should be transitioned to an alternative antiresorptive therapy.

Serious Infections

In a clinical trial (N= 7808) in women with postmenopausal osteoporosis, serious infections leading to hospitalization were reported more frequently in the Prolia® group than in the placebo group. Serious skin infections, as well as infections of the abdomen, urinary tract and ear were more frequent in patients treated with Prolia®.

Endocarditis was also reported more frequently in Prolia®-treated patients. The incidence of opportunistic infections and the overall incidence of infections were similar between the treatment groups. Advise patients to seek prompt medical attention if they develop signs or symptoms of severe infection, including cellulitis.

Patients on concomitant immunosuppressant agents or with impaired immune systems may be at increased risk for serious infections. In patients who develop serious infections while on Prolia®, prescribers should assess the need for continued Prolia® therapy.

Dermatologic Adverse Reactions

In the same clinical trial in women with postmenopausal osteoporosis, epidermal and dermal adverse events such as dermatitis, eczema and rashes occurred at a significantly higher rate with Prolia® compared to placebo. Most of these events were not specific to the injection site. Consider discontinuing Prolia® if severe symptoms develop.

Musculoskeletal Pain

Severe and occasionally incapacitating bone, joint, and/or muscle pain has been reported in patients taking Prolia®. Consider discontinuing use if severe symptoms develop.

Suppression of Bone Turnover

In clinical trials in women with postmenopausal osteoporosis, Prolia® resulted in significant suppression of bone remodeling as evidenced by markers of bone turnover and bone histomorphometry. The significance of these findings and the effect of long-term treatment are unknown. Monitor patients for these consequences, including ONJ, atypical fractures, and delayed fracture healing.

Adverse Reactions

The most common adverse reactions (>5% and more common than placebo) in women with postmenopausal osteoporosis are back pain, pain in extremity, musculoskeletal pain, hypercholesterolemia, and cystitis. The most common adverse reactions (> 5% and more common than placebo) in men with osteoporosis are back pain, arthralgia, and nasopharyngitis. Pancreatitis has been reported with Prolia®.

In women with postmenopausal osteoporosis, the overall incidence of new malignancies was 4.3% in the placebo group and 4.8% in the Prolia® group. In men with osteoporosis, new malignancies were reported in no patients in the placebo group and 4 (3.3%) patients in the Prolia® group. A causal relationship to drug exposure has not been established.

The most common adverse reactions (> 3% and more common than active-control group) in patients with glucocorticoid-induced osteoporosis are back pain, hypertension, bronchitis, and headache.

The most common (per patient incidence ≥ 10%) adverse reactions reported with Prolia® in patients with bone loss receiving ADT for prostate cancer or adjuvant AI therapy for breast cancer are arthralgia and back pain. Pain in extremity and musculoskeletal pain have also been reported in clinical trials. Additionally, in Prolia®–treated men with nonmetastatic prostate cancer receiving ADT, a greater incidence of cataracts was observed.

Denosumab is a human monoclonal antibody. As with all therapeutic proteins, there is potential for immunogenicity.

Please see full Prolia® Prescribing Information, including Medication Guide.

About TAVNEOS® (avacopan)
TAVNEOS (avacopan), approved by the FDA as an adjunctive treatment for adults with severe active ANCA-associated vasculitis, is a first-in-class, orally administered small molecule that employs a novel, highly targeted mode of action in complement-driven autoimmune and inflammatory diseases. While the precise mechanism in ANCA-associated vasculitis 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 the driver of ANCA-associated vasculitis.

U.S. PRESCRIBING INFORMATION
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.

IMPORTANT U.S. 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 TAVNEOS Prescribing Information.

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 2022, Amgen was named one of the "World's Best Employers" by Forbes and one of "America's 100 Most Sustainable Companies" by Barron's.

For more information, visit Amgen.com and follow us on Twitter, LinkedIn, Instagram, TikTok and YouTube.

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., or the ChemoCentryx, Inc. 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 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.

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