Data To Be Presented At ACR/ARHP 2016 Annual Meeting Show Amgen's Ongoing Commitment To Therapies For Patients With Serious Inflammatory And Bone Diseases

November 7, 2016

21 Abstracts to be Featured Provide Real-World and Disease State Insights, Highlight Clinical and Health Economic Impact of Rheumatologic Diseases and Osteoporosis

THOUSAND OAKS, Calif., Nov. 7, 2016 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced that it will present data from multiple studies related to Enbrel® (etanercept), Prolia® (denosumab) and AMJEVITA ™(adalimumab-atto), as well as investigational candidates, including ABP 710 (infliximab biosimilar candidate) and romosozumab, at the American College of Rheumatology (ACR) and Association of Rheumatology Health Professionals (ARHP) Annual Meeting in Washington, D.C., Nov.11-16, 2016.

In addition to highlighting key data from its clinical programs, Amgen studies will provide real-world insights on the patient journey and related unmet needs of those living with serious rheumatologic and bone diseases. Presentations also include long-term data assessing the clinical and economic impact of these diseases on patients and the overall healthcare system.

"As a leader in rheumatology and bone health, we remain committed to not only establishing the full therapeutic potential of our investigational products, but also to investing in continued research of our marketed products and establishing their value," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "We are pleased to be presenting a wide breadth of data across our diverse treatment portfolio to spark important dialogue about addressing patient needs in devastating diseases, such as rheumatoid arthritis, psoriatic arthritis and osteoporosis."

Romosozumab is being developed in collaboration with UCB globally, as well as Astellas in Japan.

SELECTED ABSTRACTS OF INTEREST

Prolia Late-Breaking Abstract of Interest

- **Effect of Denosumab Compared with Risedronate in Glucocorticoid-Treated Individuals: Results from the 12-Month Primary Analysis of a Randomized, Double-Blind, Active-Controlled Study**
  Abstract 2L, ACR Late-breaking Abstract Session, Tuesday, Nov. 15, 4:30 – 6 p.m. ET, Hall D

Prolia Oral Presentation

- **Discontinuation of Denosumab and Associated Vertebral Fracture Incidence: Analysis from a Phase 3 Placebo-Controlled Study of Denosumab and Its Open-Label Extension**
  Abstract 1028, ACR Concurrent Abstract Session, Sunday, Nov. 13, 4:30 – 6 p.m. ET, 145 A

Prolia Abstracts of Interest

- **Effect of 10 Years of Denosumab Treatment on Bone Histology and Histomorphometry in the Freedom Extension Study**
  Abstract 323, ACR Poster Session A, Sunday, Nov. 13, 9 – 11 a.m. ET, Hall C
- **The Risk of Subsequent Osteoporotic Fractures Is Decreased in Patients Experiencing Fracture While on Denosumab**
  Abstract 336, ACR Poster Session A, Sunday, Nov. 13, 9 – 11 a.m. ET, Hall C
- **Denosumab Treatment for 10 Years in Postmenopausal Women with Osteoporosis Was Associated with Substantially Lower Fracture Incidence Relative to Their Baseline FRAX-Predicted Probability**
  Abstract 337, ACR Poster Session A, Sunday, Nov. 13, 9 – 11 a.m. ET, Hall C

Romosozumab Oral Presentations

- **Fracture Risk Reduction with Romosozumab: Results of a Phase 3 Study in Postmenopausal Women with Osteoporosis**
  Abstract 1023, ACR Concurrent Abstract Session, Sunday, Nov. 13, 4:30 – 6 p.m. ET, 145 A
- **Superior Gains in Bone Mineral Density and Estimated Strength at the Hip for Romosozumab Compared with Teriparatide in Women with Postmenopausal Osteoporosis Transitioning from Bisphosphonate Therapy: Results of a Phase 3, Open-Label Clinical Trial**
  Abstract 1024, ACR Concurrent Abstract Session, Sunday, Nov. 13, 4:30 – 6 p.m. ET, 145 A

Romosozumab Abstract of Interest

- **Results of a Phase 3 Clinical Trial to Evaluate the Efficacy and Safety of Romosozumab in Men with Osteoporosis**
  Abstract 321, ACR Poster Session A, Sunday, Nov. 13, 9 – 11 a.m. ET, Hall C

ENBREL Abstracts of Interest

- **Changes in the Functional Status of the Rheumatoid Arthritis (RA) Population over the Biologic Era**
  Abstract 526, ACR Poster Session A, Sunday, Nov. 13, 9 – 11 a.m. ET, Hall C
- **Patient-Reported Outcomes for Etanercept Therapy in Adult Patients with Moderate to Severe Rheumatoid Arthritis Who Failed Adalimumab Treatment**
  Abstract 591, ACR Poster Session A, Sunday, Nov. 13, 9 – 11 a.m. ET, Hall C
- **Impact of Adherence to Tumor Necrosis Factor Inhibitors on Radiographic Outcomes in US Veterans with Rheumatoid Arthritis**
  Abstract 592, ACR Poster Session A, Sunday, Nov. 13, 9 – 11 a.m. ET, Hall C
- **Predictors of Persistency with TNFi in Biologic-Experienced Versus Biologic-Naive Psa Patients Enrolled in the Corrona Registry**
  Abstract 1679, ACR Poster Session B, Monday, Nov. 14, 9 – 11 a.m. ET, Hall C
- **Change in Health Care Utilization after Etanercept Initiation in Patients with Rheumatoid Arthritis**
  Abstract 2231, ACR Poster Session C, Tuesday, Nov. 15, 9 – 11 a.m. ET, Hall C
- **Etanercept Treatment Does Not Adversely Affect Traditional Cardiovascular Risk Factors in Patients with Rheumatoid Arthritis**
  Abstract 2579, ACR Poster Session C, Tuesday, Nov. 15, 9 – 11 a.m. ET, Hall C
- **Predictors of Adherence and Costs in First and Second Years after Biologic Initiation in Patients with Rheumatoid Arthritis (RA)**
  Abstract 2233, ACR Poster Session C, Tuesday, Nov. 15, 9 – 11 a.m. ET, Hall C
- **The Longitudinal Impact of Biologic Use on Disability within a RA Registry**
  Abstract 2540, ACR Poster Session C, Tuesday, Nov. 15, 9 – 11 a.m. ET, Hall C
- **Impact of Biologic and Non-Biologic Treatment on the Incidence of Traditional Cardiovascular Risk Factors Among Patients with Rheumatoid Arthritis, Psoriatic Arthritis, or Psoriasis**
  Abstract 2172, ACR Poster Session C, Tuesday, Nov. 15, 9 – 11 a.m. ET, Hall C
- **Models Using Claims-Based Administrative Data Are Poor Predictors of Rheumatoid Arthritis Disease Activity in VA Rheumatoid Arthritis (VARA) Patients**
  Abstract 2230, ACR Poster Session C, Tuesday, Nov. 15, 9 – 11 a.m. ET, Hall C
- **Therapy with Biologic Agents after Diagnosis of Solid Malignancies; Results from the Corrona Registry**
  Abstract 2605, ACR Poster Session C, Tuesday, Nov. 15, 9 – 11 a.m. ET, Hall C

Biosimilar Abstracts of Interest

- **ABP 501 Long-Term Safety/Efficacy: Interim Results from an Open-Label Extension Study**
  Abstract 616, ACR Poster Session A, Sunday, Nov. 13, 9 – 11 a.m. ET, Hall C
- **Pharmacokinetic Similarity of ABP 710 Relative to Infliximab: Results from a Randomized, Single-Blind, Single-Dose, Parallel Group Study in Healthy Subjects**
  Abstract 615, ACR Poster Session A, Sunday, Nov. 13, 9 – 11 a.m. ET, Hall C

About Osteoporosis
Osteoporosis affects many women after menopause as their ability to form new bone cannot counter balance the rate at which bone is being removed.[1,2] This bone loss leads to weakened bones over time, increasing the potential for a break.[3]

It is estimated that one in three women over the age of 50 will experience an osteoporotic fracture.[4,5] Men and women who experience an osteoporosis-related fracture are twice as likely to experience a future fracture.[6] After a fragility fracture, nearly 1 in 4 women experienced another within 5 years.[7] A prior fragility fracture is associated with an 86 percent increased risk of another fracture in both men and women.[8]

The World Health Organization has officially declared osteoporosis a public health crisis,[9,10] and the International Osteoporosis Foundation urges governments worldwide to make osteoporosis a healthcare priority.[11]

About Prolia® (denosumab)
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 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.

Important Safety Information (U.S.)

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. 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, clinical monitoring of calcium and mineral levels is highly recommended within 14 days of Prolia® injection. 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 anti-resorptive 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.

Serious Infections
In a clinical trial (N=7,808) 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 (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.

Prolia® Postmarketing Active Safety Surveillance Program
The surveillance program is available to collect information from prescribers on specific adverse events. Please see www.proliasafety.com or call 1-800-772-6436 for more information.

For more information, please see the Prolia Prescribing Information and Medication Guide.

About Romosozumab
Romosozumab is an investigational bone-forming monoclonal agent and is not approved by any regulatory authority for the treatment of osteoporosis. It is designed to work by inhibiting the activity of the protein sclerostin and has a dual effect on bone, both increasing bone formation and decreasing bone breakdown. Romosozumab is being studied for its potential to reduce the risk of fractures in an extensive global Phase 3 program. This program includes two large fracture trials comparing romosozumab to either placebo or active comparator in more than 10,000 postmenopausal women with osteoporosis. Amgen and UCB are co-developing romosozumab.

About the Amgen and UCB Collaboration
Since 2004, Amgen and UCB have been working together under a collaboration and license agreement to research, develop and market antibody products targeting the protein sclerostin. As part of this agreement, the two companies continue to collaborate on the development of romosozumab for the treatment of osteoporosis. This gene-to-drug project demonstrates how Amgen and UCB are joining forces to turn genetic discoveries into new medicine, turning conceptual science into a reality.

About Rheumatoid Arthritis
Rheumatoid arthritis (RA) is a chronic inflammatory disease of unknown etiology that affects approximately one percent of the adult population worldwide.[12] RA can cause pain, stiffness, swelling and limitations in the motion and function of multiple joints.[13] In RA, joint damage can significantly worsen over time, especially if left untreated and may impair function.[14]

About Psoriatic Arthritis
Psoriatic arthritis is an auto-immune disease that causes pain, stiffness and swelling in and around the joints.[13] In addition, psoriatic arthritis patients may experience skin lesions similar to those seen in plaque psoriasis. Approximately 600,000 Americans have psoriatic arthritis.[14] In fact, up to 30 percent of people diagnosed with plaque psoriasis may actually have psoriatic arthritis.[14]

About Psoriasis
Psoriasis is a serious, chronic inflammatory disease that causes raised, red, scaly patches to appear on the skin, typically affecting the outside of the elbows, knees or scalp, though it can appear on any location.[15,16] Approximately 125 million people worldwide have psoriasis and 80 percent of those patients have plaque psoriasis.[17,18] About one-third of psoriasis cases are pediatric.[19]

About Enbrel® (etanercept)
ENBREL is a soluble form of a tumor necrosis factor (TNF) receptor with a clinical efficacy and safety profile established over 15 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, for the treatment of patients with ankylosing spondylitis in 2003, and in 2004 to treat moderate-to-severe plaque psoriasis in adults. Prescription ENBREL is given by injection.

ENBREL indications in the U.S.:

- ENBREL is indicated for reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in patients with moderately-to-severely active rheumatoid arthritis (RA). ENBREL can be initiated in combination with methotrexate (MTX) or used alone.
- ENBREL is indicated for reducing signs and symptoms of moderately-to-severely active polyarticular juvenile idiopathic arthritis in patients ages two and older.
- ENBREL is indicated for reducing signs and symptoms, inhibiting the progression of structural damage of active arthritis, and improving physical function in patients with psoriatic arthritis. ENBREL can be used with or without methotrexate.
- ENBREL is indicated for reducing signs and symptoms in patients with active ankylosing spondylitis.
- Enbrel is indicated for the treatment of patients 4 years or older with chronic moderate to severe plaque psoriasis (PsO) who are candidates for systemic therapy or phototherapy.

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 postmarketing 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.

For more information, please see the ENBREL Prescribing Information and Medication Guide.

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.

AMJEVITA™ U.S. Important 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 patients treated with rituximab who received subsequent treatment with a TNF blocker. Concurrent use of AMJEVITA ™ with 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. Post-marketing 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 TNF-blocker treatment 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 antivira 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) may occur; 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. 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 Prescribing Information, including Medication Guide. This is not an offer for sale. AMJEVITA is not currently available commercially.

About Amgen Biosimilars
Amgen Biosimilars is committed to building upon Amgen's experience in the development and manufacturing of innovative human therapeutics to expand Amgen's reach to patients with serious illnesses. Biosimilars will help to maintain Amgen's commitment to connect patients with vital medicines, and Amgen is well positioned to leverage its more than 35 years of experience in biotechnology to create high quality biosimilars and reliably supply them to patients worldwide.

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

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.

For more information, visit www.amgen.com and follow us on www.twitter.com/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 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 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 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 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. We or others could identify safety, side effects or manufacturing problems with our products after they are on the market. 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 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. 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. 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 acquire other companies or products and to integrate the operations of companies we have acquired may not be successful. We may not be able to access the capital and credit markets on terms that are favorable to us, or at all. We are increasingly dependent on information technology systems, infrastructure and data security. Our stock price is volatile and may be affected by a number of events. 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.

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, the 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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