Amgen Launches The ENBREL Mini™ Single-Dose Prefilled Cartridge With AutoTouch™ Reusable Autoinjector That Is Ergonomically Designed For Patients

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Innovative Reusable Autoinjector Provides Additional Administration Option for Enbrel® (Etanercept) Users Awarded Arthritis Foundation Ease of Use (SM) Commendation

THOUSAND OAKS, Calif., Nov. 17, 2017 /PRNewswire/ -- Amgen (NASDAQ:AMGN) announced that the ENBREL Mini™ with AutoTouch™ is now available in the United States (U.S.). Awarded the Arthritis Foundation Ease of Use℠ Commendation, this new and innovative delivery system provides an additional administration option for appropriate ENBREL patients.

The AutoTouch™ reusable autoinjector has an ergonomic design that includes features that were designed with patients in mind, including an ergonomic handle, a needle designed to stay hidden during the injection, a sensor to detect placement on skin, a speed switch with three injection speeds, a progress bar and a speaker. The AutoTouch™ reusable autoinjector is used with ENBREL Mini™ single-dose prefilled cartridges (50 mg/mL) that utilize a new drug formulation of ENBREL that was associated with substantially significant lower mean injection site pain than the current formulation.

"As a leader in the inflammation space, we continually strive to innovate to address real needs among the patients we serve. The first step in this is talking and listening to the community, both patients and healthcare professionals, to fully understand the challenges they are facing," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "These conversations highlighted the value of features that we believe enhance the patient experience. From there, the ENBREL Mini™ with AutoTouch™ and the new formulation, were born.'

ENBREL is an injectable biologic approved for the treatment of several chronic conditions including moderate-to-severe rheumatoid arthritis (RA), moderate-to-severe polyarticular juvenile idiopathic arthritis (JIA), psoriatic arthritis (PsA), ankylosing spondylitis (AS) and moderate-to-severe plaque psoriasis (PsO) in patients four years or older.

"We are happy to award the ENBREL Mini™ cartridge with AutoTouch™ reusable autoinjector with our Ease of Use℠ Commendation," said Cindy McDaniel, senior vice president, Consumer Affairs, The Arthritis Foundation. "This distinction is awarded to products proven to help people who have arthritis and other physical limitations."

The ENBREL Mini™ with AutoTouch™ was approved by the U.S. Food and Drug Administration in September 2017.

A Phase 3b multicenter, randomized, double-blind, crossover study was conducted to assess the injection site pain associated with a modified etanercept formulation in adult patients with either moderate-to-severe RA or PsA. In addition to demonstrating a significant reduction in injection site pain, the adverse events were similar to those seen in previous studies in adults with moderate-to-severe RA and PsA.

About Enbrel® (etanercept)
ENBREL is a soluble form of a tumor necrosis factor (TNF) receptor with a clinical efficacy and safety profile established over 19 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 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 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.

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 Prescribing Information and Medication Guide at www.ENBREL.com

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.

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 its 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 Amgen projects. 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 Amgen to complete clinical trials and obtain regulatory approval for product marketing has in the past varied and Amgen expects similar variability in the future. Even when clinical trials are successful, regulatory authorities may question the sufficiency for approval of the trial endpoints Amgen has selected. Amgen develops 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 Amgen may have believed at the time of entering into such relationship. Also, Amgen or others could identify safety, side effects or manufacturing problems with its products, including its devices, after they are on the market.

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