Amgen Announces Moderate-To-Severe Plaque Psoriasis Data To Be Presented At The 23rd Congress Of The European Academy Of Dermatology And Venereology

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Featured Presentations Highlight Data From Approved and Investigational Agents Across Amgen's Dermatology Portfolio

THOUSAND OAKS, Calif., Oct. 1, 2014 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced that it will present several studies related to brodalumab, Enbrel® (etanercept) and ABP 501 (adalimumab biosimilar) at the 23rd Congress of the European Academy of Dermatology and Venereology (EADV) in Amsterdam, Oct. 8-12, 2014. These data reinforce Amgen's continued commitment to delivering medicines that may help to improve the lives of people suffering from devastating dermatologic diseases.

"As a pioneer in psoriasis research and development, we are pleased to share scientific insights from our growing dermatology portfolio that may help improve care for the millions of people worldwide[1] affected by this serious skin disease," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "The data being presented at this year's congress demonstrate the breadth and depth of our biologics expertise in advancing treatments that address critical unmet needs for patients living with psoriasis."

Brodalumab data to be presented include an exploratory analysis of the Phase 2 trial evaluating efficacy and safety of brodalumab in moderate-to-severe plaque psoriasis patients with prior biologic exposure, along with an analysis from the open-label extension study of that same Phase 2 study evaluating patient response to treatment after nearly three years. Brodalumab is being co-developed by Amgen and AstraZeneca. Kyowa Hakko Kirin, which has an exclusive license to develop and commercialize brodalumab in Japan, China and certain other Asian countries, will present efficacy and safety data from its Phase 2 study evaluating brodalumab in Japanese patients with moderate-to-severe plaque psoriasis.

ENBREL data focus on step-down dosing compared with a high-dose regimen and patient-reported outcomes of treatment with ENBREL compared to treatment with ENBREL in combination with topical therapies. Additional data include the functional equivalence of proposed biosimilar ABP 501 to adalimumab and an analysis of the incidence of symptoms such as itching and pain in patients with psoriasis.

SELECTED ABSTRACTS OF INTEREST

Abstracts are available to registered journalists at www.eadvamsterdam2014.org/press and updated data will be presented at the meeting.

Brodalumab Abstracts of Interest

- **Brodalumab Phase 2 Study for Moderate-to-Severe Plaque Psoriasis: Subanalysis of Efficacy and Safety in Subjects with Prior Biologic Exposure**, Poster 1666, available to view beginning Thursday, Oct. 9, at 9:30 a.m. CEST (Europe Foyer 1)
- **Clinical Efficacy and Safety of Brodalumab (KHK4827), Anti-Interleukin-17-Receptor A Monoclonal Antibody, in Japanese Patients with Moderate-to-Severe Plaque Psoriasis: a Phase 2, Randomized, Double-Blind, Placebo-Controlled Study (4827-002 Study)**, Poster 1572, available to view beginning Thursday, Oct. 9, at 9:30 a.m. CEST (Europe Foyer 1)
- **An Analysis of the Efficacy of Brodalumab (KHK4827) in Treating Nail and Scalp Psoriasis and Impact on Quality of Life Measures**, Poster 1566, available to view beginning Thursday, Oct. 9, at 9:30 a.m. CEST (Europe Foyer 1)
- **Maintenance of Clinical Response with Long-Term Brodalumab (AMG 827) Therapy for Psoriasis: Week 144 Results from an Open-Label Extension Study**, Abstract 0253 (FC05.03), Free Communications Presentation, Friday, Oct. 10, 3:03–3:12 p.m. CEST (G106)

ENBREL (Amgen-sponsored) Abstracts of Interest

- **Efficacy of Etanercept Following Step-Down Dosing Compared with Continued High-Dose Regimen in Patients with Plaque Psoriasis**, Poster 1581, available to view beginning Thursday, Oct. 9, at 9:30 a.m. CEST (Europe Foyer 1)
- **Patient-Reported Outcomes in Psoriasis Patients Treated with Etanercept 50 mg Twice Weekly (BIW) or Etanercept 50 mg Once Weekly (QW) with Topical Therapies: Results from REFINE**, Poster 1574, available to view beginning Thursday, Oct. 9, at 9:30 a.m. CEST (Europe Foyer 1)

Biosimilars Abstracts of Interest

- **An Evaluation of Functional Equivalence of Proposed Biosimilar ABP 501 to Adalimumab**, Poster 337, available to view beginning Thursday, Oct. 9, at 9:30 a.m. CEST (Europe Foyer 1)

Additional Abstracts of Interest

- **Qualitative Assessment of the Experience of Pain in Patients with Moderate-to-Severe Plaque Psoriasis**, Poster 1664, available to view beginning Thursday, Oct. 9, at 9:30 a.m. CEST (Europe Foyer 1)
- **Qualitative Assessment of the Experience of Itch in Patients with Moderate-to-Severe Plaque Psoriasis**, Poster 1665, available to view beginning Thursday, Oct. 9, at 9:30 a.m. CEST (Europe Foyer 1)

About Psoriasis

Psoriasis is a non-contagious chronic disease in which the immune system causes skin cells to grow at an accelerated rate.[2] Instead of being shed, skin cells pile up, causing painful and itchy, red, scaly patches.[3] Approximately 125 million people worldwide have psoriasis, and 80 percent of those patients have plaque psoriasis.[1,4]

About Brodalumab (AMG 827)

Brodalumab is a novel human monoclonal antibody that binds to the interleukin-17 (IL-17) receptor and inhibits inflammatory signaling by blocking the binding of several IL-17 ligands to the receptor. By stopping IL-17 ligands from activating the receptor, brodalumab prevents the body from receiving signals that may lead to inflammation. The IL-17 pathway plays a central role in inducing and promoting inflammatory disease processes. In addition to moderate-to-severe plaque psoriasis (Phase 3), brodalumab is currently being investigated for the treatment of psoriatic arthritis (Phase 3) and asthma (Phase 2).

About Enbrel (etanercept)

ENBREL is a soluble form of a fully human 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 2002 to treat psoriatic arthritis, and later approved 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 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 in combination with methotrexate in patients who do not respond adequately to methotrexate alone.
- ENBREL is indicated for reducing signs and symptoms in patients with active ankylosing spondylitis.
- ENBREL is indicated for the treatment of adult patients (18 years or older) with chronic moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

ENBREL indications in the EU:

ENBREL is an anti-inflammatory medicine. It is used for the treatment of the following diseases:

- moderate to severe rheumatoid arthritis (an immune system disease causing inflammation of the joints) in adults (aged 18 years or over). ENBREL is used with methotrexate (a medicine that acts on the immune system) in adults with moderate or severe disease who have not responded adequately to other treatments, or on its own if methotrexate is not suitable for the patient. ENBREL can also be used in patients with severe rheumatoid arthritis who have not taken methotrexate before;
- certain forms of juvenile idiopathic arthritis (a rare childhood disease causing inflammation of many joints) in the following groups:
    - patients aged two to 17 years who have polyarthritis (rheumatoid factor positive or negative) and extended oligoarthritis and have not responded adequately to or cannot take methotrexate;
    - adolescents aged 12 to 17 years who have psoriatic arthritis (a disease causing red, scaly patches on the skin and inflammation of the joints) and have not responded adequately to or cannot take methotrexate;
    - adolescents aged 12 to 17 years who have enthesitis-related arthritis and have not responded adequately to or cannot take standard treatment.
- psoriatic arthritis in adults who have not responded adequately to other treatments;
- severe ankylosing spondylitis (a disease causing inflammation of the joints of the spine) in adults who have not responded adequately to other treatments;
- plaque psoriasis (a disease causing red, scaly patches on the skin) in adults with moderate to severe disease and in patients from the age of six years with long-term severe disease. Enbrel is used in patients who have not responded to or cannot receive other treatments for this disease.
- Severe non-radiographic axial spondyloarthritis (a chronic inflammatory disease of the spine) when there are objective signs of inflammation but no abnormalities seen on x-ray.

For more information, see the summary of product characteristics (also part of the EPAR).

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 and psoriasis 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. JIA patients, if possible, should be brought up to date with all immunizations prior to initiating ENBREL. In patients with exposure to varicella virus, consider temporary discontinuation of ENBREL and 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 events in RA clinical trials were injection site reaction, infection, and headache. In clinical trials of all other adult indications, adverse events were similar to those reported in RA clinical trials.

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 biologics manufacturing 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 the world's largest independent biotechnology company, 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.

The views expressed and the techniques presented by the speakers at the 23rd EADV Congress in Amsterdam, The Netherlands are not necessarily shared or endorsed by the European Academy of Dermatology and Venereology.

Forward Looking Statements
This news release contains forward-looking statements that are based on the current expectations and beliefs of Amgen Inc. and its subsidiaries (Amgen, we or us) and are subject to a number of risks, uncertainties and assumptions that could cause actual results to differ materially from those described. 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 Inc., including Amgen Inc.'s most recent annual report on Form 10-K and any subsequent periodic reports on Form 10-Q and Form 8-K. Please refer to Amgen Inc.'s most recent Forms 10-K, 10-Q and 8-K for additional information on the

uncertainties and risk factors related to our business. Unless otherwise noted, we are providing this information as of Oct. 1, 2014, and expressly disclaim any duty to update information contained in this news release.

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 and our partners to complete clinical trials and obtain regulatory approval for product marketing has in the past varied and we expect similar variability in the future. 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 business may be impacted by government investigations, litigation and product liability claims. 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. We depend on third parties for a significant portion of our manufacturing capacity for the supply of certain of our current and future products and limits on supply may constrain sales of certain of our current products and product candidate development.

In addition, sales of our products (including products of our wholly-owned subsidiaries) are affected by the 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 as well as U.S. legislation affecting pharmaceutical pricing and reimbursement. Government and others' regulations and reimbursement policies may affect the development, usage and pricing of our products. In addition, we compete with other companies with respect to some of our marketed products as well as for the discovery and development of new products. We believe that some of our newer products, product candidates or new indications for existing products, may face competition when and as they are approved and marketed. Our products may compete against products that have lower prices, established reimbursement, superior performance, are easier to administer, or that are otherwise competitive with our products. In addition, while we and our partners routinely obtain patents for our and their products and technology, the protection of our products offered by patents and patent applications may be challenged, invalidated or circumvented by our or our partners' competitors and there can be no guarantee of our or our partners' ability to obtain or maintain patent protection for our products or product candidates. We cannot guarantee that we will be able to produce commercially successful products or maintain the commercial success of our existing products. Our stock price may be affected by actual or perceived market opportunity, competitive position, and success or failure of our products or product candidates. Further, 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 integrate the operations of companies we have acquired may not be successful. Cost savings initiatives may result in us incurring impairment or other related charges on our assets. We may experience difficulties, delays or unexpected costs and not achieve anticipated benefits and savings from our recently announced restructuring plans. 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 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.

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References:
1. International Federation of Psoriasis Associations. Psoriasis is a Serious Disease Deserving Global Attention: A report by the International Federation of Psoriasis Associations. www.ifpa-pso.org/getfile.ashx?cid=279366&cc=3&refid=18. Accessed on September 10, 2014.
2. National Psoriasis Foundation. Frequently Asked Questions. http://www.psoriasis.org/about-psoriasis/faqs. Last updated 2014. Accessed on September 10, 2014.
3. Medline Plus Encyclopedia. Psoriasis. http://www.nlm.nih.gov/medlineplus/ency/article/000434.htm. Last updated 10/18/2014. Accessed on September 10, 2014.
4. American Academy of Dermatology. Psoriasis. http://www.aad.org/media-resources/stats-and-facts/conditions/psoriasis. Last updated 2014. Accessed on September 10, 2014.

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