Amgen Launches AMGEVITA™ (Biosimilar Adalimumab) In Markets Across Europe

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First Inflammation Biosimilar From Amgen's Portfolio to Launch in Europe

THOUSAND OAKS, Calif., Oct. 15, 2018 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced that AMGEVITA™, a biosimilar to adalimumab, will launch in markets across Europe beginning on Oct. 16, 2018. AMGEVITA is the first adalimumab biosimilar to be approved by the European Commission (EC). AMGEVITA is authorized for the treatment of inflammatory diseases in adults, including moderate-to-severe rheumatoid arthritis; psoriatic arthritis; severe active ankylosing spondylitis (AS); severe axial spondyloarthritis without radiographic evidence of AS; moderate-to-severe chronic plaque psoriasis; moderate-to-severe hidradenitis suppurativa; non-infectious intermediate, posterior and panuveitis; moderate-to-severe Crohn's disease and moderate-to-severe ulcerative colitis. AMGEVITA is also authorized for the treatment of pediatric inflammatory diseases, including moderate-to-severe Crohn's disease (ages six and older), severe chronic plaque psoriasis (ages four and older), enthesitis-related arthritis (ages six and older) and polyarticular juvenile idiopathic arthritis (ages two and older).

"The launch of AMGEVITA in Europe is an important milestone for our biosimilars portfolio, expanding the range of treatment options for the millions of patients living with chronic inflammatory diseases," said David M. Reese, M.D., executive vice president of Research and Development at Amgen. "AMGEVITA is Amgen's second biosimilar to launch in Europe, demonstrating our commitment to providing patients with serious illnesses access to high-quality biological therapies."

Amgen is committed to developing high-quality biosimilars with a robust analytic and clinical package. The EC approved AMGEVITA's comprehensive data package supporting biosimilarity to adalimumab based on analytical, pharmacokinetic and clinical data, including results from two Phase 3 confirmatory studies conducted in moderate-to-severe plaque psoriasis and moderate-to-severe rheumatoid arthritis patients. The Phase 3 studies each met their primary endpoint showing no clinically meaningful differences from adalimumab. Safety and immunogenicity of AMGEVITA were also comparable to adalimumab, and the data included a double-blind randomized switch from adalimumab to AMGEVITA. AMGEVITA was also evaluated in a long-term Phase 3 study in moderate-to-severe rheumatoid arthritis patients, which found that efficacy was maintained with no new safety findings. AMGEVITA is provided in a citrate-free formulation.

"Building on our strong inflammatory disease presence in the United States, we are excited to develop our inflammation capabilities in Europe," said Scott Foraker, vice president and general manager of Biosimilars at Amgen. "As the first inflammation biosimilar from our portfolio to launch in Europe, AMGEVITA will extend our reach and help more patients gain access to this important class of therapies."

Amgen has a total of 10 biosimilars in its portfolio, three of which have been approved by the EC. AMGEVITA will launch in the 28 countries that are members of the European Union as well as in Norway, Iceland and Liechtenstein, which are members of the European Economic Area.

About AMGEVITA™ (biosimilar adalimumab) in Europe
AMGEVITA is a biosimilar to adalimumab, a fully human immunoglobulin G1 monoclonal antibody that binds and neutralizes human tumor necrosis factor alpha (TNFα), a cytokine which mediates the inflammatory response. The amino acid sequence of AMGEVITA is identical to that of the reference product, adalimumab. AMGEVITA will be available in a prefilled syringe and pre-filled pen (SureClick® autoinjector) to support dosing according to the approved dosage recommendations in each indication.

AMGEVITA, in combination with methotrexate, is indicated for:

- the treatment of moderate-to-severe, active rheumatoid arthritis in adult patients when the response to disease-modifying anti-rheumatic drugs including methotrexate has been inadequate.
- the treatment of severe, active and progressive rheumatoid arthritis in adults not previously treated with methotrexate.

AMGEVITA can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate. AMGEVITA reduces the rate of progression of joint damage as measured by X-ray and improves physical function, when given in combination with methotrexate.

AMGEVITA, in combination with methotrexate, is indicated for the treatment of active polyarticular juvenile idiopathic arthritis, in patients from the age of two years who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs (DMARDs). AMGEVITA can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate. Adalimumab has not been studied in patients aged less than two years.

AMGEVITA is indicated for the treatment of active enthesitis-related arthritis in patients, six years of age and older, who have had an inadequate response to, or who are intolerant of, conventional therapy.

AMGEVITA is indicated for the treatment of adults with severe active ankylosing spondylitis who have had an inadequate response to conventional therapy.

AMGEVITA is indicated for the treatment of adults with severe axial spondyloarthritis without radiographic evidence of AS but with objective signs of inflammation by elevated CRP and/or MRI, who have had an inadequate response to, or are intolerant of non-steroidal anti-inflammatory drugs.

AMGEVITA is indicated for the treatment of active and progressive psoriatic arthritis in adults when the response to previous disease-modifying anti-rheumatic drug therapy has been inadequate. AMGEVITA reduces the rate of progression of peripheral joint damage as measured by X-ray in patients with polyarticular symmetrical subtypes of the disease and improves physical function.

AMGEVITA is indicated for the treatment of moderate-to-severe chronic plaque psoriasis in adult patients who are candidates for systemic therapy.

AMGEVITA is indicated for the treatment of severe chronic plaque psoriasis in children and adolescents from four years of age who have had an inadequate response to or are inappropriate candidates for topical therapy and phototherapies.

AMGEVITA is indicated for the treatment of active moderate-to-severe hidradenitis suppurativa (HS) (acne inversa) in adult patients with an inadequate response to conventional systemic HS therapy.

AMGEVITA is indicated for the treatment of moderately to severely active Crohn's disease, in adult patients who have not responded despite a full and adequate course of therapy with a corticosteroid and/or an immunosuppressant; or who are intolerant of or have medical contraindications for such therapies.

AMGEVITA is indicated for the treatment of moderately to severely active Crohn's disease in pediatric patients (from six years of age) who have had an inadequate response to conventional therapy including primary nutrition therapy, a corticosteroid, and an immunomodulator, or who are intolerant to or have contraindications for such therapies.

AMGEVITA is indicated for the treatment of moderately to severely active ulcerative colitis in adult patients who have had an inadequate response to conventional therapy including corticosteroids and 6-mercaptopurine (6-MP) or azathioprine (AZA), or who are intolerant of or have medical contraindications for such therapies.

AMGEVITA is indicated for the treatment of non-infectious intermediate, posterior and panuveitis in adult patients who have had an inadequate response to corticosteroids, in patients in need of corticosteroid-sparing, or in whom corticosteroid treatment is inappropriate.

AMGEVITA™ EU Important Safety Information
This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions.

AMGEVITA treatment should be initiated and supervised by specialist physicians experienced in the diagnosis and treatment of conditions for which AMGEVITA is indicated. The most serious side effects that may occur during AMGEVITA treatment include infections such as sepsis or other opportunistic infections, tuberculosis (TB), hepatitis B reactivation (HBV) and other malignancies including leukemia, lymphoma and hepatosplenic T-cell lymphoma (HSTCL). Other rare serious haematological, neurological and autoimmune reactions that may occur during AMGEVITA treatment include pancytopenia, aplastic anaemia, central and peripheral demyelinating events, lupus, lupus-related conditions and Stevens-Johnson syndrome. The most common side effects are infections in the nose and throat, sinuses and upper respiratory tract, injection site reactions (redness, itching, bleeding, pain or swelling), headache and muscle and bone pain.

AMGEVITA is contraindicated in people with sensitivities to the active substance, or certain excipients (e.g., glacial acetic acid, sucrose, polysorbate 80, sodium hydroxide (for pH adjustment) and water for injections); in people with active tuberculosis or other severe infections such as sepsis and opportunistic infections; and those with moderate to severe heart failure (NYHA class III/IV). Patients on AMGEVITA may receive concurrent vaccinations, except for live vaccines.

Please refer to the Summary of Product Characteristics for full European prescribing information.

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 nearly four decades 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.

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 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. 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. 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 acquire other companies or products and to integrate the operations of companies 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 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.

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