

# Amgen And AstraZeneca Highlight Data To Be Presented At European League Against Rheumatism Annual Meeting

# June 12, 2013

THOUSAND OAKS, Calif. and GAITHERSBURG, Md., June 12, 2013 /PRNewswire/ -- Amgen (NASDAQ:AMGN) and AstraZeneca (AZN), with its biologics research and development arm MedImmune, today announced that they will present data from a Phase 2 study evaluating brodalumab, a human monoclonal antibody targeting the IL-17 receptor, being investigated for the treatment of psoriatic arthritis at the 2013 European League Against Rheumatism (EULAR) Annual Meeting in Madrid, June 12-15, 2013.

"The brodalumab data being presented at EULAR demonstrate a positive benefit-risk profile for patients with psoriatic arthritis," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "We are encouraged by these data as we continue to explore brodalumab for its potential to treat patients with inflammatory disease including psoriatic arthritis."

Based on the Phase 2 results, the companies intend to advance brodalumab into Phase 3 clinical studies for the treatment of psoriatic arthritis in 2014.

"This brodalumab data marks a positive step forward for patients with psoriatic arthritis," said Dr. Bahija Jallal, executive vice president, MedImmune. "We look forward to working with Amgen to further evaluate this novel therapy in psoriatic arthritis and potentially other chronic immune-mediated diseases."

## ABSTRACT OF INTEREST:

# Brodalumab Abstract at EULAR:

• Efficacy of Brodalumab, an Anti-IL-17R Antibody, in Subjects with Psoriatic Arthritis Abstract No. OP0103, Oral Presentation, Thursday, June 13, 10:20 a.m. CET, N117

Abstracts are currently available on the EULAR website at www.eular.org.

## About Brodalumab

Brodalumab is a highly-selective human monoclonal antibody that binds to and blocks signaling via the IL-17 receptor. The IL-17 pathway plays an important role in inducing and promoting inflammatory disease processes.

Brodalumab is the first investigational treatment in development that blocks the IL-17 receptor, thereby blocking several of the IL-17 ligands at once. By stopping IL-17 ligands from binding to the receptor, brodalumab prevents the body from receiving signals that may lead to inflammation and other ailments. At this time, other agents in development seek to target a single IL-17 ligand.

In addition to psoratic arthritis, brodalumab is currently being investigated for the treatment of psoriasis (Phase 3) and asthma (Phase 2).

#### **About Psoriatic Arthritis**

Psoriatic arthritis is a chronic disease of the immune system that causes joint pain, stiffness and swelling which can become progressively worse over time, and may also include red patches of skin topped with silvery scales.<sup>1</sup>

The progressive joint damage, pain and swelling coupled with painful, scaly, red skin patches can disrupt a person's ability to perform daily activities, such as using their hands, standing for long periods or walking.<sup>2</sup> Psoriatic arthritis affects 30 to 50 percent<sup>3</sup> of the approximate 125 million people worldwide who have psoriasis.<sup>4</sup>

#### About Amgen

Amgen discovers, develops, manufactures and delivers innovative human therapeutics. A biotechnology pioneer since 1980, Amgen was one of the first companies to realize the new science's promise by bringing safe, effective medicines from lab to manufacturing plant to patient. Amgen therapeutics have changed the practice of medicine, helping people around the world in the fight against serious illnesses. With a deep and broad pipeline of potential new medicines, Amgen remains committed to advancing science to dramatically improve people's lives. For more information, visit <u>www.amgen.com</u> and follow us on <u>www.twitter.com/amgen</u>.

#### About AstraZeneca

AstraZeneca is a global, innovation-driven biopharmaceutical business that focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of cardiovascular, metabolic, respiratory, inflammation, autoimmune, oncology, infection and neuroscience diseases. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. For more information please visit: <a href="http://www.astrazeneca.com">www.astrazeneca.com</a>.

## **Amgen Forward-Looking Statements**

This news release contains forward-looking statements that are based on management's current expectations and beliefs 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 (SEC) reports filed by Amgen, including Amgen'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'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, Amgen is providing this information as of June 12, 2013, and expressly disclaims 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 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 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 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 and there can be no guarantee of our ability to obtain or maintain patent protection for our products or products. 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.

The scientific information discussed in this news release related to our product candidate is preliminary and investigative. Such product candidate is not approved by the U.S. Food and Drug Administration (FDA), and no conclusions can or should be drawn regarding the safety or effectiveness of the product candidate. Only the FDA can determine whether the product candidate is safe and effective for the use(s) being investigated. Healthcare professionals should refer to and rely upon the FDA-approved labeling for the products, and not the information discussed in this news release.

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#### References

<sup>1</sup>Krueger, Gerald G., MD. Clinical Features of Psoriatic Arthritis. The American Journal of Managed Care. 2002; 8:160-170

<sup>2</sup>Krueger G, Koo J, Lebwohl M, et al. The Impact of Psoriasis on Quality of Life: Results of a 1998 National Psoriasis Foundation Patient-Membership Survey. Arch Dermatol. 2001; 137:280-4

<sup>β</sup>International Federation of Psoriasis Associations, Important facts about psoriasis http://www.ifpa-pso.org/web/page.aspx?refid=47

<sup>4</sup>About Psoriasis: Statistics. National Psoriasis Foundation. <u>http://www.psoriasis.org/learn\_statistics</u>

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