



Amgen And Simcere Announce Strategic Collaboration To Co-Develop And Commercialize Biosimilars In China

September 26, 2017

THOUSAND OAKS, Calif. and NANJING, China, Sept. 26, 2017 /PRNewswire/ -- Amgen (NASDAQ: AMGN) and Simcere Pharmaceutical Group today announced the execution of an exclusive agreement to co-develop and commercialize four biosimilars in China. The collaboration includes undisclosed biosimilars in the areas of inflammation and oncology.

Under the terms of the agreement, Amgen will remain responsible for the co-development, marketing approval applications and manufacturing of the biosimilars. Simcere will be responsible for distribution and commercialization in China, while Amgen will have a limited right to co-promote the products. The biosimilars included in the agreement are a part of Amgen's existing biosimilars portfolio.

"We are pleased to enter this strategic collaboration with Simcere as we continue to enhance patient access through broader adoption of more competitive therapeutic options worldwide," said Scott Foraker, vice president and general manager of Biosimilars at Amgen. "This agreement brings together Amgen's long-standing development and biologics manufacturing expertise with Simcere's local development experience and strong commercial presence in China in the areas of inflammation and oncology."

"This agreement furthers Amgen's efforts to reach more patients in Asia by bringing high quality biosimilars medicines to patients suffering from debilitating and potentially life-threatening conditions," said Penny Wan, regional vice president and general manager of Amgen's Japan and Asia-Pacific Region. "We look forward to working with Simcere on these four biosimilar programs where we can build on their network and experience in China to make a big difference for patients."

"This strategic partnership between a world-renowned biotechnology company and a leading Chinese pharma will help to accelerate development and launch of United States and European approved biosimilars in China. By leveraging our sales network, it will also help to improve the accessibility of high quality therapeutic antibodies for Chinese patients," said Honggang Feng, president of Simcere. "This collaboration will allow both companies to further penetrate inflammation and oncology markets in China."

Dr. Hua Mu, chief scientific officer of Simcere said, "Recently, China Food and Drug Administration (CFDA) has formally joined the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and implemented major reforms on drug evaluation and approval systems, encouraging and supporting research and development of innovative, high quality medicines. This strategic alliance combines Amgen's leading global research and development capabilities in biosimilars and Simcere's domestic drug development and registration experience. It aims to bring more high quality and effective medicines to Chinese patients to meet the pressing unmet medical needs. It is also another important milestone in our international collaboration strategy to enrich Simcere's biologics pipeline."

Specific financial terms of the agreement were not disclosed.

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 suffering from serious illnesses. Biosimilars offer the potential to increase patient access to 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.

About Simcere Pharmaceutical Group

Simcere is a research and development-driven Chinese pharmaceutical company committed to bringing high quality and more effective therapies to patients by combining in house R&D with partnerships. Simcere focuses its efforts on therapeutic areas of oncology, neurology, inflammation/immunology, cardiovascular and infectious diseases.

Simcere is dedicated to research & development of innovative pharmaceuticals and branded generic drugs in China, with a State Key Lab of Translational Medicine and Innovative Drug Development. By leverage of its commercial capability, all top products of the company have leading market share in China.

By leveraging partnering experience with multinational pharmaceutical companies and innovative biotech companies, Simcere continues to advance [international medical scientific achievements transformation] and create value for partners in China.

For more information, visit www.simcere.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, 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. 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.

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