Amgen Backs States' Efforts To Enact Biosimilar Legislation That Allows For Substitution And Supports Patient Safety

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Biologics and Biosimilars are Complex Drugs, and Their Presence in the Marketplace Requires Appropriate Public Policy at the Federal and State Levels

THOUSAND OAKS, Calif., Jan. 25, 2013 /PRNewswire/ -- In conjunction with our oncology biosimilars partner Actavis' announcement earlier today of our four oncology biosimilars products, Amgen (NASDAQ:AMGN) today stated that it supports state biosimilars initiatives that focus on sound science and patient safety. As a biotech company developing both innovator biologics and biosimilars, Amgen believes that patient safety does not stop at drug approval.

"Amgen endorses state policies that would put patients first and, in doing so, increase confidence in the biosimilar pathway. It is important to have consistent policies in place at the federal and state level," said Scott Foraker, vice president and general manager of biosimilars at Amgen.

States' efforts to create safe substitution rules for interchangeable biologics will help accelerate the successful implementation of the U.S. biosimilars pathway. Regulatory authorities in Europe and the U.S. have emphasized the need for long-term safety monitoring of biologics. Biologic medicines are different than traditional chemical drugs in several important ways. Biologics are so complex that they can usually only be made by a living cell. In fact, when made by different manufacturers, they differ from each other. They are also very large compared to chemical drugs and can be more sensitive to storage and handling. As a result biologic medicines have the potential to cause an unwanted immune response, which can show up months after taking the medicine. This emphasizes why Amgen believes state pharmacy acts must enhance safety monitoring of substituted biologics.

Amgen is helping educate state policymakers on these considerations to ensure that physicians, patients and pharmacists share important information about biologic substitution. To provide appropriate safeguards, patient medical records must accurately reflect the biologic medicine a patient receives, by requiring that physicians be informed within a reasonable time after an interchangeable biologic substitution has occurred. Furthermore physicians and pharmacists must work collaboratively to serve patients and protect patient safety.

Amgen believes that a notification process that does not impose an undue burden on the pharmacist is in the patient's best interest. Some proposed state legislation includes these important safeguards such as after-the-fact notification to facilitate accurate record keeping and attribution of adverse events. The company said it is critical that efficient measures close the gap in biologic traceability that could otherwise be created.

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 millions of people around the world in the fight against cancer, kidney disease, rheumatoid arthritis, bone disease and other serious illnesses. With a deep and broad pipeline of potential new medicines, Amgen remains committed to advancing science to dramatically improve people's lives. To learn more about our pioneering science and vital medicines, visit www.amgen.com. Follow us on www.twitter.com/amgen.

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