Amgen to Provide Testimony at FDA Hearing on Biosimilars

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Company Urges FDA to Put Patients First As Regulators Implement Biosimilar Pathway

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Amgen (Nasdaq: AMGN) Senior Vice President of Research and Development Joe Miletich, M.D., Ph.D., will urge members of a U.S. Food and Drug Administration (FDA) panel charged with implementing a pathway for biosimilars to establish approval standards that ensure patient safety and follow a science-based approach.

"Put patients first and sound policy will follow," Dr. Miletich said. "Amgen believes biosimilars have a meaningful role to play in the health care system. However, biosimilars--unlike generic drugs--are not identical to the innovative biological products." Getting the biosimilar pathway 'right' could benefit the future of biopharmaceuticals, whereas "imprudent policy" could simultaneously put patients unacceptably at risk, undermine the policy goals and set back the promise of new biologic treatments for patients.

Noting the complexities of biological products and the likely differences in products created from different living cells, Dr. Miletich will outline three key recommendations that the FDA should consider as it moves forward:

1. Use well-designed clinical trials to establish biosimilarity;
2. Ensure the product manufacturer and lot number is known for all administered biological; and
3. Set scientific and practical criteria for interchangeability.

"The question before the agency is how we can minimize patient risk and uncertainty associated with the approval of biosimilars," Dr. Miletich said. "The challenge with biosimilars is knowing which structural variations matter clinically and which do not. Many differences probably do not matter, while some differences are important. Other differences remain open questions. Clinical evaluations and experience are necessary to address these questions."

Dr. Miletich added, "Minor changes in structure, formulation or impurities can have a significant impact on patients that cannot always be anticipated with analytical studies."

Underscoring the need for clinical trials, Dr. Miletich stated, "In our 30 year history of making biologicals, we have achieved remarkable breakthroughs, developed complex proteins and supplied them to millions of patients in need. However, in the process we have been humbled by unexpected clinical outcomes after analytical and preclinical studies predicted success."

Dr. Miletich also noted that experience with biosimilar applications in Europe demonstrates the need for clinical trials. Approximately half of the biosimilars developed in Europe have had unexpected clinical outcomes at some point in their development. Clinical trials are an essential step in evaluating differences between medicines that analytical and pre-clinical studies indicate are similar. Equally important, we must ensure accountability through accurate tracking and tracing of all biological products.

During his remarks, Dr. Miletich will express the need to continue evaluating products approved as biosimilars after they reach the market to ensure that subtle differences between biologics are well understood. In his testimony, Dr. Miletich indicated that this would be particularly important prior to any biosimilar being approved as interchangeable, since such a determination may result in patients being repeatedly switched between products.

Dr. Miletich went on to say, "An interchangeability determination, if possible, would be very difficult to make and will require significant time and experience. Interchangeability presents both scientific and public health challenges that would need to be addressed before such a determination could be made."

Amgen believes that the agency should ensure that measures are in place to detect and limit the scope of harm from unexpected adverse events associated with use of any biological product. These measures should include development and implementation of a pharmacovigilance system that provides accurate and comprehensive association and reporting of adverse events with the implicated product, as well as specific labeling to differentiate products that are biosimilar from those that are interchangeable to enable physicians to make informed treatment decisions.

In his concluding comments, Dr. Miletich urged the FDA to outline approval standards through a transparent and public process. "Not all classes of biological products have the same level of complexity or risk, thus class-specific approval standards must be developed," Dr. Miletich stated. "Case-by-case approaches generate uncertainty leading to delays and increased cost. Class-by-class standards are consistent with good review practices. A public process for approval standards creates confidence among patients and physicians."

On March 23, 2010, President Obama signed into law the Patient Protection and Affordable Care Act which contained a provision authorizing the FDA to create an abbreviated approval pathway for biological products shown to be biosimilar to with an already FDA-approved biological medicine. Several countries around the globe have already implemented approval pathways for biosimilars. The European Union and Japan are among those that have successfully devised a set of science-based criteria to permit biosimilars in their jurisdictions. With the FDA's hearing on November 2-3, the United States is beginning the implementation process.

Dr. Miletich's testimony was submitted in response to FDA's notice for public comments on an "Approval Pathway for Biosimilar and Interchangeable Biological Product." The deadline for submitted written comments is Dec. 31, 2010.

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 and 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, 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 our vital medicines, visit www.amgen.com.

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