Amgen To Provide Testimony At FDA Stakeholder Hearing On Biosimilars

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

THOUSAND OAKS, Calif., May 11, 2012 /PRNewswire/ -- Amgen (NASDAQ:AMGN) announced today that Joseph P. Miletich, M.D., Ph.D., senior vice president of Research and Development at Amgen will testify at the United States (U.S.) Food and Drug Administration (FDA) stakeholder hearing on biosimilars. Miletich will urge members of the FDA panel charged with implementing a pathway for biosimilars to establish approval standards that advance patient safety and promote confidence in biosimilars marketed in the U.S.

In his opening remarks, Miletich will underscore the wealth of experience Amgen brings to the discussion on biosimilars approval pathway implementation. "As a leading provider of high quality biologic medicines, Amgen appreciates the challenges of developing and manufacturing innovative and biosimilar medicines."

"Put patients first and sound policy will follow," Miletich states. "Amgen appreciates the FDA's efforts on the guidelines and encourages adoption of a thorough review and approval process. However, Amgen believes some changes and additional clarity are needed."

Noting the complexities of biological products and the potential differences in products created from different living cells, Miletich will emphasize that biotechnology is an evolving field. "While much more is known today than 30 years ago, FDA's guidance documents should candidly acknowledge that there are some things we still do not scientifically know today," says Miletich.

Miletich will state that "patient safety must be a non-negotiable priority for FDA and manufacturers, and that focus on patient safety does not end with drug approval." He will outline three key recommendations that the FDA should consider as it finalizes its guidances:

1. Adopt policies to facilitate attribution of adverse events and foster manufacturer accountability
2. Conduct a communications campaign about biologics and biosimilars
3. Foster supply chain stability

On the first recommendation, Miletich will underscore the need for accurate tracking and tracing. "The challenge and importance of accurate tracking and tracing will increase significantly with the arrival of biosimilars in the U.S. marketplace," says Miletich. "We believe prompt identification and resolution of product problems will be facilitated by distinguishable established names. Unlike other identifiers, established names present a risk that two or more products could share the same name, which would affirmatively confound the attribution of adverse events."

Secondly, "The biosimilar approval pathway is a new initiative in the U.S. with many scientific and administrative challenges and nuances," Miletich says. "It will be essential for FDA to clearly communicate to all stakeholders what biosimilar products are and are not. For example, there should be no perception, implied or otherwise, that an FDA-approved biosimilar is somehow less effective or less safe than the reference product. However, at this time, biosimilars are not appropriate for automatic substitution – that is, without the explicit consent of the prescribing physician - unless deemed interchangeable by FDA."

For the third recommendation, Miletich will emphasize that FDA policy should foster supply chain stability.

"Recent medicine shortages have been an opportunity for some manufacturers to suggest that FDA's standards are overly rigorous and a source of the drug shortage problem. This is exactly wrong," Miletich says. "Complex products require high standards. It is by maintaining appropriately robust good manufacturing practices and facility inspection standards that FDA assures the public the reliable supply of high quality products."

On March 23, 2010, President Barack 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 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. As a result of the FDA public hearing in November 2010 and the FDA's draft guidances on biosimilars issued on Feb. 9, 2012, the U.S. is beginning the implementation process.

In response to the FDA draft guidances on biosimilars issued on Feb. 9, 2012, Amgen submitted comments by the FDA's April 16, 2012 deadline. A complete listing of Amgen's comments can be accessed on the regulations.gov website and are posted by docket number:

Scientific Considerations Draft Guidance:
http://www.regulations.gov/#!documentDetail;D=FDA-2011-D-0605-0034

Quality Considerations Draft Guidance:
http://www.regulations.gov/#!documentDetail;D=FDA-2011-D-0602-0030

Q&A Draft Guidance:
http://www.regulations.gov/#!documentDetail;D=FDA-2011-D-0611-0033

Miletich's written testimony was submitted in response to FDA's notice announcing a public hearing and requesting public comments on "Draft Guidances Relating to the Development of Biosimilar Products." His testimony is available at http://www.regulations.gov/#!documentDetail;D=FDA-2011-D-0618-0025. The deadline for submitting written comments following the hearing is May 25, 2012.

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.

Forward-Looking Statements

This news release contains forward-looking statements that involve significant risks and uncertainties, including those discussed below and others that can be found in our Form 10-K for the year ended Dec. 31, 2011, and in our periodic reports on Form 10-Q and Form 8-K. 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. The Company's results may be affected by our ability to successfully market both new and existing products domestically and internationally, clinical and regulatory developments (domestic or foreign) involving current and future products, sales growth of recently launched products, competition from other products (domestic or foreign) and difficulties or delays in manufacturing our products. In addition, sales of our products are affected by 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 health care 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. Furthermore, our research, testing, pricing, marketing and other operations are subject to extensive regulation by domestic and foreign government regulatory authorities. 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. 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. 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, we compete with other companies with respect to some of our marketed products as well as for the discovery and development of new products. Discovery or identification of new product candidates cannot be guaranteed and movement from concept to product is uncertain; consequently, there can be no guarantee that any particular product candidate will be successful and become a commercial product. Further, some raw materials, medical devices and component parts for our products are supplied by sole third-party suppliers. 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.

CONTACT: Amgen
Kelley Davenport: 202-585-9637 (media)
Arvind Sood: 805- 447-1060 (investors)

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