Alliance for Safe Biologic Medicines Welcomes Biosimilars Pathway

Urges FDA to put patient safety first as draft guidance finalized

WASHINGTON, Feb. 9, 2012 /PRNewswire-USNewswire/ -- In response to the release of the U.S. Food and Drug Administration's long-awaited draft guidance on the approval of biosimilar medicines in the United States, Dr. Dolinar, Chairman of the Alliance for Safe Biologic Medicines (ASBM) issued the following statement:

"We welcome the FDA's draft guidance on biosimilar product development and approval as an important step forward in expanding access to existing biological therapies.

"Biological medicines are more complex than chemical drugs and highly sensitive to the manufacturing process in ways that could have health consequences for patients. Therefore FDA's regulation of biosimilars appropriately takes into account these special aspects of biologics and the need to ensure patient safety in light of them. In order to do this, FDA appropriately focuses on the need for clinical trials for biosimilar medicines, and labels that provide data doctors need to treat their patients. However, FDA should also require unique names to distinguish every biologic medicine and facilitate effective traceability of these products.

"We look forward to working with the FDA to ensure that biosimilars are as safe and effective as the biologics currently on the market. When it comes to patient safety there can be no shortcuts."

Biologics are made from living organisms and treat serious conditions including cancer, multiple sclerosis and diabetes. In 2010, the U.S. Congress authorized the FDA to develop a pathway to approve biosimilars, which are the nonidentical copies of biologic medicines. For more information or to speak with Dr. Dolinar, please email media@safebiologics.org.

About the Alliance for Safe Biologic Medicines

The Alliance for Safe Biologic Medicines (ASBM) is an organization composed of diverse healthcare groups and individuals from patients to physicians, innovative medical biotechnology companies, and others who are working together to ensure patient safety is at the forefront of the biosimilars policy discussion. We serve as an authoritative resource center of information for the public, medical communities, the FDA and other state and federal policymakers during the implementation of the biosimilars pathway and beyond.

The Alliance for Safe Biologic Medicines provides factual information on biologic medications and advocates for policies that protect patient safety and ensure the accessibility of these products. *More information available at www.safebiologics.org.*

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