



American Autoimmune

Related Diseases Association, Inc.

www.aarda.org

A nonprofit association bringing a national focus to autoimmunity, the major cause of chronic disease

FOR IMMEDIATE RELEASE

AMERICAN AUTOIMMUNE RELATED DISEASES ASSOCIATION'S STATEMENT ON FDA'S APPROVAL OF FIRST U.S. BIOSIMILAR DRUG

EAST DETROIT (March 6, 2015) – The American Autoimmune Related Diseases Association (AARDA), a national nonprofit health organization dedicated to increasing awareness of autoimmune diseases, today released the following statement concerning the Food and Drug Administration's (FDA) approval of filgrastim, the first biosimilar product approved in the United States:

“On behalf of the 50 million Americans living with autoimmune disease (AD), AARDA is concerned that the FDA has approved the first U.S. biosimilar drug without first having published any final standards. The FDA has yet to issue final guidance on a range of issues that will impact patient safety, including interchangeability, naming and indication extrapolation.

Biologic medicines have the unique ability to target the underlying cause of a disease, representing a huge breakthrough for patients suffering from many serious autoimmune diseases. Biosimilars will increase patient access to these treatments by lowering the cost of this class of drugs. The Affordable Care Act established a pathway for the FDA to approve biosimilar drugs in the U.S. for interchangeable use with brand name biologics.

However, as biologic therapies reach the end of their patent protection, there must be standards in place for the approval of biosimilar drugs on the basis of analytical and clinical comparison to the already marketed biologic product.

Biosimilars are similar but can never be identical to the original approved branded product. They are not a 'generic' version, like those for chemically-based drugs.

For people whose immune systems are already compromised and prone to attacking their own healthy tissues and cells if it perceives them to be foreign invaders, the introduction of any new substance is potentially life-threatening. The differences in manufacturing, however small, have the potential to cause a similar negative immune response. Known as immunogenicity, this response can cause further disease and damage to the cells, tissues and organs of AD patients.

For this very reason, clarity and transparency about biologics and biosimilars are critical.

For more information, please visit www.aarda.org and download a copy of AARDA's recently published white paper on Biologics and Biosimilars.”

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About AARDA

American Autoimmune Related Diseases Association (AARDA) is the nation's only non-profit organization dedicated to bringing a national focus to autoimmunity as a category of disease and a major women's health issue, and promoting a collaborative research effort in order to find better treatments and a cure for all autoimmune diseases. For more information, please visit www.aarda.org.

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