



**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

Leading Autoimmune Patient Advocacy Group Survey Finds Overwhelming Majority of Patients Lack Understanding of Biosimilar Drugs

*American Autoimmune Related Diseases Association Publishes White Paper to
Educate Patients About Biosimilar Medicines and Potential Safety Concerns*

EAST DETROIT (February 11, 2015) – The American Autoimmune Related Diseases Association (AARDA), a national nonprofit health organization dedicated to increasing awareness of autoimmune diseases, today issued a white paper to educate its membership and the patient community about biosimilar medicines after a survey found most patients were generally unaware of this new category of medicines which may soon be approved in the U.S.

“Unlike chemically based drugs, 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,” said Virginia Ladd, President and Executive Director of AARDA. “The results of our member survey illuminated just how limited awareness is around these life-saving medications – especially among those who need them most.”

The white paper provides a comprehensive overview of biologic medicines, which are used to treat serious illnesses including autoimmune diseases, immune deficiencies and cancer, and comes as the U.S. Food and Drug Administration (FDA) works to finalize its guidelines for the approval of biosimilars – drugs that are similar but not identical to original biologic medicines. The survey of 362 AARDA members – 96 percent of whom reported living with an autoimmune disease – found that more than **80 percent of respondents did not know what biosimilar medicines were** and about **52 percent did not understand how biologics differ from chemical drugs**.

In order to increase awareness among its member community, AARDA’s white paper offers insight into:

- biologic medicines, which are made from complex molecules of living material rather than chemical compounds, and the significance of these therapies for patients with severe medical conditions,

- how biologic medicines effectively treat patients with a number of autoimmune diseases,
- why biosimilar drugs are not “generic” versions of biologics,
- what are the safety concerns for patients when switching between biologic and biosimilar products,
- what are the policy issues surrounding the approval of biosimilar medicines in the U.S.

The Affordable Care Act (ACA) established a pathway for the FDA to approve biosimilar drugs in the U.S. for interchangeable use with brand name biologic medicines. As biologic therapies reach the end of their patent protection, the FDA is preparing to release standards for the approval of biosimilar drugs on the basis of analytical and clinical comparison to the already marketed biologic product.

Ladd continued, “It is our hope that biosimilars will increase patient access to these treatments by lowering the cost of this class of drugs. However, patient safety must come first. The white paper will help to ensure all patients living with complex medical conditions are able to understand this category of drugs, be aware of their treatment options and safety issues and work to ensure that the FDA enacts policies that protect patient safety.”

The white paper is available as a free, PDF download on AARDA’s web site: www.aarda.org.

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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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