

## Biosimilars: Providing New Hope for Patients

GENEVA, SWITZERLAND, February 15, 2016 /EINPresswire.com/ -- In the past decades, innovative biologic therapies have revolutionized the treatment of many severe chronic diseases, such as rheumatoid arthritis, psoriaris, multiple sclerosis, etc. These advanced and complex medicines have improved the health and quality of life of millions of patients worldwide. Nowadays, with expiration of patents for innovative biologics, highly similar molecules called "biosimilars" (or subsequent entry biologics) are progressively introduced on the markets at lower costs.

With a growing number of licensed biosimilars, patients thus have new hope for an increased access to the disease-altering therapies and potentially life-saving treatments they need. Developed to be as effective and safe as off-patent reference biologics, but with a lower price tag, biosimilars promise to generate benefits in patient care, new opportunities for industry, and potentially significant savings for payers.

Nonetheless, biosimilars are facing significant hurdles for gaining acceptance. The main obstacles include challenges in demonstrating bioequivalence and high-quality manufacturing standards for regulatory approval, consenting to clinical evidence extrapolation for multiple indications licensing, establishing similar efficacy and safety as the reference biologics, defining the regulatory, legislative, and ethical frameworks for suitable biosimilar substitution, and proving the clinical, humanistic, and economic value to patients, physicians, health technology assessors, and price-sensitive public and private payers.

Accordingly, recent studies have shown that prior to introducing a biosimilar into a market, it is crucial to identify unmet needs and to address the specific considerations of each stakeholder group. In addition, given evolving acceptance requirements by regulatory authorities, physicians, patients, and payers, comparative research is warranted to assess the clinical effectiveness, safety, and cost-effectiveness of biosimilars compared to reference biologics in real-world contexts.

Dr Danielle Dupont, President, Data Mining America, explained: "Our research agency has developed a state-of-the-art systematic approach to support the introduction of new biosimilars across markets. It includes evidence generation and the development of robust value propositions addressing the benefits of biosimilar agents for patients, health care providers, drug benefit plans, and industry, for stimulating their adoption and guiding their appropriate use."

Given the increasing healthcare demand worldwide, biosimilars represent promising and more affordable alternatives for enhancing access to quality, safe, and effective existing biological molecules, while contributing to curbing healthcare costs. The savings realized will allow continued investments in the development of new innovative medicines, for the benefits of patients, health systems, and society.

## About Data Mining International www.datamining-international.com

Data Mining International SA, an independent international research agency based in Geneva (Switzerland), with a branch in Canada (Data Mining America, <a href="www.datamining-america.com">www.datamining-america.com</a>), is specialized in advanced simulation modelling for decision-making, value and health technology assessment, risk assessment, big data analytics, and business modelling.

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