Enliven Archive
Intensifying Thoughts

Editorial www.enlivenarchive.org Enliven: Biosimilars and Bioavailablity

Biosimilars - Hype or Hope?

Robert Bell PhD

Drug & Biotechnology Development, University of Florida

*Corresponding author: Robert Bell, Adjunct Professor, University of Florida College of Pharmacy and President of Drug and Biotechnology Development, LLC; E-mail: rgb@drugbiodev.com

Received Date: 29th August 2014
Accepted Date: 01th September 2014
Published Date: 06th September 2014

Citation: Bell R (2014) Biosimilars - Hype or Hope? Enliven: Biosimilars Bioavailab 1(1): e001.

The hope of biosimilars is to provide therapeutically equivalent biologics at a reduced cost. The annual cost for patients with cancer, Crohns or rheumatoid arthritis can run in the tens of thousands of dollars and any cost savings on these therapies would benefit the health care systems. However, the hype assumes a "switch" from the brand to the biosimilar product. At this point, switching is not an option. Substitution of the biosimilar product for the reference biologic is the key driver in the cost reduction associated with biotechnology derived therapies. However, European practice typically does not allow biologic substitution. The BPCI allows the FDA to make the determination of interchangeability in a 351(k) application, assuming the interchangeable substitutable product is shown to be biosimilar to the reference product and meet the other standards described in section 351(k)(4) of the PHS Act. It is not clear the type of additional information (or costs) required by the FDA for interchangeability but may include extensive immunogenicity assessments between the reference and test products. Will the hope of interchageability be thwarted by the costs, time to market and return on investment?

Recently, there have been two submissions to the FDA for biosimilars - filgrastim (Sandoz) and the monoclonal antibody infliximab (Celltrion). This is welcome news since we are behind globally in terms of biosimilar availability - these are the first registrations under the *Biologics Price Competition and Innovation Act* (BPCI Act). If the registrations do not run into any review issues, the biosimilar products could be available in 2015. Europe has developed extensive guidance for biosimilars and have approved at least six biosimilar products. India has approved over a dozen biosimilars including vaccines. Filgrastim has been available as a biosimilar in Europe since 2008 and infliximab since 2013. Filgrastim could become available in the US in 2015 and infliximab could be available as early as 2015 in the US if the patent issues are resolved; if not, the US patent for Remicade® is set to expire September 2018. These registrations are welcome and the US looks forward to more biosimilar submissions and approvals.

Perhaps one of the biggest hurdles for US biosimilars will be the acceptance of biosimilars by the physician and patient communities. The immunogenicity conundrum that clouds biosimilar interchangeability has become the new "NTI" (narrow therapeutic index drug) battle of the new millennium. Twenty states in the US prohibit the substitution of biosimilars for the reference biologic yet there are no approvals. Is the hype a true clinical concern or a way of maintaining market share? There will be a lot of information as well as misinformation regarding biosimilars. It is hoped this journal will expose the hype associated with biosimilars and discuss the hope and issues associated with the development, production and registration of therapeutically equivalent biosimilar products.