Stanley Seung Suh Hong, J Bioanal Biomed 2017, 9:3(Suppl)
http://dx.doi.org/10.4172/1948-593X-C1-026

Evidence-based approach of CT-P13 to meet the expectations of different stakeholders

Stanley Seung Suh Hong
Celltrion Healthcare Co. Ltd., South Korea

Background: CT-P13, a biosimilar of infliximab, is the world's first biosimilar monoclonal antibody approved in the USA, EU, Japan and many other countries for the treatment of autoimmune diseases. Biosimilars are known to have the potential to improve patient access and reduce healthcare costs. To capture these benefits, there has been a growing trend to encourage the use of biosimilars among health authorities. The National Institute for Health and Care Excellence of the United Kingdom has recommended choosing the least expensive treatment option for RA and UC, and the Italian Medicines Agency published a report on the opportunities laid by biosimilars in addressing the sustainability of care, for instance. However, other stakeholders including physicians and patients, in contrast, showed reluctance to this move due to concerns on safety and efficacy of biosimilars.

Approach: To reassure various stakeholders, CT-P13 has taken evidence based approach and has been generating data to solve most concerned area in the use of biosimilars, which are biosimilarity, extrapolation, and switching. As of September 2016, 7,759 patients were treated with CT-P13, and the efficacy and safety of CT-P13 including those in switching condition were observed and compared with its reference group.

Conclusion & Significance: Based on the positive real world evidence and clinical data supporting biosimilarity, extrapolation, and switching of CT-P13, there was an evolution of perception. This positive change has consequently resulted in the increased acceptance towards CT-P13 and fast uptake, enabling greater access to infliximab treatment via reallocation of healthcare budget.

Biography

Stanley Seung Suh Hong is a Senior Adviser at the Celltrion Healthcare and has played an important part in its development and success. He was the President of Research and Development at Celltrion, Inc., where he was responsible for the entire R&D including product discovery as well as biosimilar development. His team led the successful development of REMSIMA™, the world's first biosimilar, and gained approval for the product in Korea, Japan, Canada, European Union and USFDA. He was also responsible for the development of other biosimilars in Celltrion, and has presented data on biosimilars at national and international medical meetings. He was also the President and CEO of Celltrion Healthcare.

SeungSuh.Hong@celltrion.com

Notes: