Marcelo Kauffman, J Bioequiv Availab 2011, 3:7
doi: http://dx.doi.org/10.4172/0975-0851.1000108

OMICS Group Conferences
Accelerating Scientific Discovery

International Conference & Exhibition on
Pharmaceutical Regulatory Affairs
6-7 September 2011 Baltimore, USA

Pre-clinical and clinical development of an interferon beta 1a biosimilar for the treatment of multiple sclerosis

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Blastoferon® is a pharmaceutical product of interferon beta 1a currently marketed in Argentina and Latin America as a biosimilar to the innovator interferon beta 1a for the treatment of Multiple Sclerosis. Although regulatory requirements for biosimilars are on debate, there is consensus about the necessity to obtain evidence of the effectiveness and safety of these drugs on pre-clinical and clinical grounds. In order to fulfil these requirements, the manufacturer of Blastoferon® has done different studies in animal models and humans that assess the safety and effectiveness of this biosimilar in the treatment of Multiple Sclerosis. Among them, it can be mentioned a safety study in *Cebus apella primates*, a whole-genome comparative pharmacodynamic trial, a comparative relative bioavailability human trial, a comprehensive and intensive pharmacovigilance program with immunogenicity surveillance and a pragmatic post-marketing effectiveness clinical trial. This presentation will present the results of these studies and discuss challenges and perspectives of the development and marketing of a biosimilar product in emerging markets.

Biography

Dr. Marcelo Kauffman is a neurologist with MSc and PhD degrees in Molecular Biology. He has been the person in charge of the pre-clinical and clinical development of Blastoferon as an advisor of Bio Sidus S.A. Clinical Research Department. He has been the author of 5 papers presenting the results of the different pre-clinical and clinical Blastoferon studies. Currently, he holds the position of Chief of the Neurogenetic Clinic of Hospital JM Ramos Mejia in Buenos Aires, Argentina and is a lecturer in the School of Medicine of the University of Buenos Aires.