**Title: Immunogenicity Assessment of Therapeutic Monoclonal Antibodies – Lab Testing and Clinical Impact Assessment**

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***Abstract***

Immune response to a protein therapeutic is not uncommon. Assessment of immunogenicity including its impact on clinical safety, efficacy and pharmacokinetics of a therapeutic antibody is critically essential for biotherapeutic development. An appropriate immunogenicity testing strategy along with validated bioanalytical methods is highly expected to be implemented for the assessment and characterization of potential immune responses during the clinical trials and possibly after the marketing approval. This topic covers assay strategy for immunogenicity testing and clinical impact evaluation of unwanted immunogenicity.

***Biography***

Patrick Liu, M.D., Ph.D. is Vice President, Biologics R&D and the Head of Global Bioassays and Technology at Teva Pharmaceuticals. As a global head across countries, he leads a biologics development team with focus on product biological and immunological characterization, PK/PD bioanalytics and immunogenicity assessment for both innovative biologics and biosimilars development.

Prior to joining Teva, Dr. Liu was a Director with increasing responsibilities at Tanox, Inc. and Genentech/Roche playing a leadership role in R&D for the development and commercialization of biological new molecule entities (NMEs) in the therapeutic areas of oncology, hematology, immunology, allergy and infectious diseases. He contributed to the success of developing multiple blockbuster therapeutics including Lonquex, Granix, Copaxone, Avastin, Lucentis, Herceptin, Perjeta and Xolair,. He also filed numerous patent applications and wrote many publications. Dr. Liu has practiced medicine, specializing in Endocrinology and holds a Ph.D. in Molecular Biology.