Workshop on Cytokine Release: State-of-the-Science, Current Challenges and Future Directions
Organized by the HESI Immunotoxicology Technical Committee

22 October 2013
Sheraton Silver Spring
Silver Spring, MD

Background & Objectives:

The risk of cytokine storm triggered by biotherapeutic modalities remains a significant safety concern in the clinic. Many organizations have developed customized assay systems to assess the potential risk for cytokine release, with the primary goal to determine the level of caution that should be taken in a clinical setting. Currently there are no clear guidelines with regards to assay conditions and experimental design, data interpretation and the overall predictive value using current in vitro methodologies is not well-understood. The ILSI HESI Immunotoxicology Technical Committee is sponsoring a one-day workshop focused on cytokine storm risk assessments. The objective of this workshop is to bring together academic, industry and regulatory agency scientists to discuss current technologies, practices and scientific challenges. Topics to be covered include:

- Assessments for novel platforms (e.g. Bispecific antibodies, Fc amino acid mutations/modifications, Immunomodulatory mAbs, Bispecific T-cell Engagers (BiTEs™), Antibody-drug conjugates)
- Translatability/impact on dosing in the clinic/challenges with data interpretation
- Use of preclinical animal species to predict cytokine release
- Emerging/novel technologies for cytokine measurements
- Regulatory perspective
Program:

9:00-9:25 Welcome & Introduction

9:25-9:50 Cytokine release assays: current practices and future directions
Dr. Deborah Finco – Pfizer, Inc.

9:50-10:15 Severity of the TGN1412 trial disaster cytokine storm correlated with IL-2 release
Dr. Richard Stebbings – UK NIBSC

10:15-10:40 Assessment of Cytokine Release for MEDI-565 (AMG 211), a novel CEA/CD3-bispecific single-chain BiTE® antibody
Dr. Patricia Ryan – MedImmune

10:40-10:55 Break

10:55-11:20 Comparison of three cytokine release assay (CRA) platforms for hazard identification of cytokine release syndrome potential
Dr. Madeline Fort – Amgen

11:20-11:45 Optimizing a cytokine release assay with statistical analyses and predictive modeling
Dr. Mindi Walker - Janssen

11:45-12:10 A novel bioassay using autologous endothelial cells and PBMCs in co-culture to detect cytokine storm antibodies
Dr. Daniel Reed – Imperial College London

12:10-1:10 Lunch

1:10-1:35 Forecasting a Storm: New and improved models for assessing adverse events associated with therapeutic mAbs
Dr. Daniel Gliddon – Huntingdon Life Sciences

1:35-2:00 Translatability of cytokine data: from animals to human
Dr. Marie-Soleil Piché – Charles River Laboratories

2:00-2:15 Break
2:15-2:40  Tentative: Cytokine Assessment from a FDA Pharmacology/Toxicology Reviewer’s Perspective
Speaker to be announced

2:40-3:05  Cytokine release data – regulatory experience in the EU
Dr. Gabriele Reichmann - Paul-Ehrlich-Institute

3:05-4:15  Panel Discussion

Poster session & reception to follow
5:30-7:00pm Eastern