HESI®

ILSI Health and Environmental Sciences Institute

Workshop: Developmental Immunotoxicity Testing of Pharmaceuticals

Date and Time: May 3-4, 2010

Location: Westin D.C. City Center
1400 M Street N.W.
Washington, DC 20005

Organizers: Immunotoxicology Technical Committee (ITC) of the
ILSI Health and Environmental Sciences Institute (HESI)

MAY 3RD

8:30AM – 8:45AM **INTRODUCTORY REMARKS -** Mark Collinge, Pfizer

8:45AM-10:45AM **SESSION 1: SITUATIONS OR CAUSES FOR CONCERN THAT WOULD TRIGGER DIT TESTING**

Lauren Black, Charles River Laboratories
What Drives us to Assess the Immunotoxic Risks to the Children of Patients Treated with Drugs or Biologics?

Helen Haggerty, Bristol Myers Squibb
Triggers for Developmental Immunotoxicity Testing: Case Study for Abatacept, a selective Co-stimulation Modulator

Discussion session

- Moderator: Mark Collinge, Pfizer

10:45AM -11:00AM **BREAK**

11:00AM-1:00PM **SESSION 2: CONSIDERATION OF BIOLOGICALS VS LOW MW COMPOUNDS**

Pauline Martin, Centocor
Considerations for Biopharmaceuticals in DIT Testing– Placental Transfer Considerations
Laura Andrews, Genzyme
Use of Homologous Proteins and Transgenic Animals as an Alternative to Traditional Approaches

Discussion session

- Moderator: Daniel Wierda, Lilly Research Laboratories

(over)

1:00-2:00PM **LUNCH**

2:00PM-4:00PM **SESSION 3: PROTOCOLS FOR DIFFERENT SITUATIONS AND ENDPOINTS/CONSIDERATION OF GAPS IN THE SCIENCE AND METHODS**

Anu Vaidyanathan, Genentech
Developmental Immunotoxicology with Rituximab

Suezanne Parker, Biogen Idec
Case Study: Developmental Effects of an Immunomodulatory Biologic

Discussion session

- Moderators: Gary Chellman, Charles River Laboratories, and Jacintha Shenton, MedImmune

4:00PM-4:30PM **Concluding Remarks**

MAY 4TH

9:00AM-12:00PM **Morning session: Regulatory Perspective**

9:00AM-9:10AM Introductory remarks – Leigh Ann Burns-Naas, Pfizer

9:10AM-10:40AM *Session Speakers*:
Whitney Helms, US Food and Drug Administration
Adam Wasserman, US Food and Drug Administration
Beatriz Silva Lima, Lisbon University, European Medicines Agency Safety Working Party

10:40AM-11:00AM Break

11:00AM-12:00PM Discussion Session, Moderator: Leigh Ann Burns-Naas

12:00 PM **Close of Workshop**