January 14, 2011

Course Direction:
Joseph P. Balthasar, PhD

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Registration Details
Fee: Individual fee: 950 euros before December 1, 2010, which includes course documentation, mid-session refreshments, and lunches (1000 euros after this date).

Registration: Please register ASAP in view of the limited course capacity. Confirmation of registration will be returned upon receipt, together with an invoice for the course fee. Registration will not be final until payment is received.

Cancellations: Cancellations with a full refund may be made until December 14, 2010. No refund is possible on cancellations received after this date. Substitutions may be made at any time.

Payment: By check only (for French public) to l’agent Comptable de l’université Paris Descartes
Or by bank transfer only

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Registration Form: January 14, 2011, Day workshop on monoclonal antibody

Pharmacokinetics & Pharmacodynamics

Employer Details

Address
City
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Telephone
Fax
Title (Mr, Mrs)
First Name
Last Name
Email

Personal Details

Date, Signature

Course Location and Registration

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formation.continue@pharmacie.parisdescartes.fr
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Dr. Balthasar is Professor of Pharmaceutical Sciences at the University at Buffalo, State University of New York and Director of the Center for Protein Therapeutics. His PK/PD modeling interests and capabilities include the development and preclinical evaluation of anti-toxin immunotherapies, the development and preclinical evaluation of anti-cancer immunotherapies (including immunoconjugate immunotherapies), and the development and preclinical evaluation of novel immunotherapies for humoral autoimmune conditions (immune thrombocytopenia, myasthenia gravis). He serves as a consultant to the NIH and the pharmaceutical industry.

This workshop has been designed to provide a detailed discussion of issues relevant to the pharmacokinetic / pharmacodynamic (PK/PD) modeling of antibody drugs. Lectures will address primary determinants of antibody pharmacokinetics (PK) and pharmacodynamics (PD), the design and implementation of pre-clinical investigations of antibody PK/PD, and state-of-the-art mathematical models to characterize and predict antibody PK and PD. Special emphasis is placed on discussion of the role of FcRn on the absorption, distribution, and elimination of antibodies, on the mathematical modeling of target-mediated antibody disposition, and on physiologically-based modeling of antibody pharmacokinetics. The workshop content is provided as a combination of formal lectures and informal review sessions.

Subjects that will be presented include:

**Determinants of antibody pharmacokinetics and pharmacodynamics**: mechanisms of antibody elimination, the role of convection in the kinetics of antibody distribution, the role of FcRn in antibody absorption, distribution, and elimination

**Interspecies Scaling of Antibody PK & PD**

**Target-Mediated Antibody Disposition**: modeling, implications for interspecies scaling, implications for First-in-Human studies

**Modeling of bimolecular antibody-ligand interaction**

**Physiologically-based pharmacokinetic modeling**: Incorporation of FcRn-mediated antibody transport in PBPK models, incorporation of target-mediated disposition, use of PBPK and preclinical data to predict antibody disposition in humans.