

Tutorial: Immunogenicity Prediction of Antibody and Protein Therapeutics

Monday, June 1, 2009 • 8:30 am-2:00 pm

Tutorial Schedule:

This session runs from 8:30 am-2:00 pm. There will be a 30 minute refreshment break at 10:15 and lunch from 11:45 am-12:45 pm.

8:30 Tutorial Leaders' Opening Remarks

One of the great surprises of the biologics revolution has been the discovery that recombinant proteins, including monoclonals of human origin, can cause immune responses when administered to immune-competent subjects. Evaluation of the immunogenicity of biologics has been primarily focused on humoral immune response and as a result, the critical contribution of T cells to the development of anti-monoclonal antibodies (also known as anti-drug antibodies or ADA) has been overlooked. The contributions of effector T cells and regulatory T cells to the development of anti-drug antibodies are relevant to good biologics drug design. This review will focus on the role of T-cell-dependent (Td) immunogenicity assessment in the pre-clinical and clinical phases of drug development. Recent published studies that describe regulatory T-cell epitopes contained in the Fc and CH1 domains of IgG (monoclonals) would suggest that the role of Td immune response deserves greater emphasis in the context of immunogenicity screening and assessment for bioengineered protein therapeutics. Recommendations for Td immunogenicity screening and assessment may contribute to the development of safer protein-based drugs for human use.

You will learn about:

- T-cell dependent and T-cell independent immunogenicity
- Immunogenicity screening approaches in the pre-clinical and clinical setting
- The relevance of regulatory T-cell responses to autologous proteins in the context of immunogenicity screening
- "Best practices" for immunogenicity screening
- How to identify assays that are beginning to be requested by regulatory agencies
- Tools and techniques used in preclinical immunogenicity screening that have successfully predicted clinical outcomes.

Tutorial Leaders:

Anne S. De Groot, M.D., Adjunct Associate Professor of Medicine, Brown University and Founder, CEO & CSO, EpiVax, Inc., USA



Matthew Baker, Ph.D., Chief Scientific Officer and CEO, Antitope Ltd., United Kingdom

Additional Speakers/Q&A Panelists:

Immune Responses to Beta Interferon and the Effect on Clinical Efficacy

Michaela Lerner, Senior Manager, Preclinical and Clinical Development Sciences, Biogen Idec, Inc., USA

Taruna Arora, Ph.D., Principal Scientist, Protein Science, Amgen, Inc., USA

Catherine Wang, Ph.D., Manager, Clinical Immunology, Biopharm R&D, GlaxoSmithKline



2:00 Close of Tutorial

Please note: Simultaneous translation will not be provided for this tutorial.

Part of the Antibody Discovery and Protein Science Summit
at IBC's Drug Discovery & Development Japan

www.IBCLifeSciences.com/Japan

Tutorial: Immunogenicity Prediction of Antibody and Protein Therapeutics

Registration Form

Part of
IBC's 4th Annual International Conference
**DRUG DISCOVERY
& DEVELOPMENT
JAPAN**



www.IBCLifeSciences.com/Japan

5 EASY WAYS TO REGISTER

Mail the attached registration form with your cheque to **IBC Asia (S) Pte Ltd**, No. 1 Grange Road, #08-02, Orchard Building, Singapore 239693.
Customer Service Hotline: (65) 6514 3180
FAX: (65) 6733 5087 or (65) 6736 4312
E-MAIL: register@ibcasia.com.sg
WEB: www.IBCLifeSciences.com/Japan

| Registration Fees | On or before March 6, 2009 | On or before April 3, 2009 | On or before May 1, 2009 | Standard Rate After May 1, 2009 |
|---|----------------------------------|----------------------------------|----------------------------------|------------------------------------|
| Immunogenicity Tutorial Only (June 1) | | | | <input type="checkbox"/> USD750 |
| 3 Day Conference (June 1-3) | <input type="checkbox"/> USD1499 | <input type="checkbox"/> USD1599 | <input type="checkbox"/> USD1699 | <input type="checkbox"/> USD1799 |
| 2 Day Conference (June 1-2) | <input type="checkbox"/> USD1199 | <input type="checkbox"/> USD1299 | <input type="checkbox"/> USD1399 | <input type="checkbox"/> USD1499 |
| RNAi as a Therapeutic Modality Only (June 3) | | | | <input type="checkbox"/> USD750 |

Present a Poster USD100 - Commercial FREE - Academic

Attend Networking Dinner USD100 (June 2, 5:45pm)

Academia/Government Discounts

Academic and government employees are eligible for over 40% savings off the above registration packages. Visit the registration page at www.IBCLifeSciences.com/Japan for academic packages and discounted pricing information. Rate extended to full-time employees of government, universities and university-affiliated hospitals who have NO affiliation to a for profit entity.

Please tell us which sessions you will primarily attend (You have access to both sessions on days you are registered)

June 1: R&D Strategies Antibody/Protein Summit **June 2:** From Discovery to POC Antibody/Protein Summit

Yes! I/We will attend **Drug Discovery & Development of Innovative Therapeutics JAPAN • Keio Plaza Hotel • Tokyo, Japan**

R9162T

Name: Dr/Mr/Ms _____

E-Mail _____

Job Title _____

Mobile no _____

Department _____

Company _____

Address _____

Post Code _____

Tel _____

Name & Title of Approving Manager _____

Name & Title of Training Manager _____

Main Business/Activity _____

Please tick: I enclose my Cheque/Draft payable to IBC Asia (S) Pte Ltd

I am paying by bank transfer (copy attached)

Payment by Credit Card: Amex Visa Mastercard

Card Holder _____

Signature _____

Card Number _____ Expiry Date _____

I cannot attend this event but

I would like to purchase the conference documentation @ US\$399/S\$618

Please put me on your mailing list.

Please note: The invoice you receive for your registration will list the Singapore dollar equivalent of the listed registration fees since billing is done by IBC's Singapore office.

Fee includes luncheons, cocktail refreshments and complete set of documentation. It does not include the cost of accommodation and travel.

CANCELLATIONS/SUBSTITUTIONS:

If you are unable to attend, a substitute delegate will be very welcome in your place. If this is not suitable, a 10% service charge will be payable. Registrations cancelled less than seven days before the event must be paid in full.

Speakers are subject to change without notice.

Venue & Hotel Information

Keio Plaza Hotel Shinjuku

2-2-1 Nishi-Shinjuku • Shinjuku-ku, Tokyo • 160-8330 Japan

Tel: +81-3-3344-0111 • Fax: +81-3-3345-8269 • www.keioplaza.com

Make Your Hotel Reservation Online:

Step 1: Go to <http://www.keioplaza.com/index.html>

Step 2: Click on "Corporate Login" at the bottom of the hotel home page

Step 3: Enter Account Name: ibc0601 and Password: ibc0601

Step 4: The booking form will appear to make your reservations at the discounted IBC rates of JPY20,000 (May 31-June 5) and JPY22,000 (May 30 and June 6)

Conference Registration Details

TEAM DISCOUNTS: Register 3 at the Standard Rate and the 4th goes FREE! Save up to USD1799. When three members from the same company register and pay for the conference at the same time, the fourth attends for FREE. This discount is valid only based on the standard rate (after May 1, 2009). For more information on the group rates or to register your group, please contact customer service at register@ibcasia.com.sg

Payment

Payments should be made in US dollars

• Payments by USD bank draft or cheque should be made payable to "IBC Asia (S) Pte Ltd".

• Payment by telegraphic transfer in USD must be made to:

IBC Asia (S) Pte Ltd
A/C No.:260-457866-178 (USD)
The Hongkong and Shanghai
Banking Corporation Limited
21 Collyer Quay, HSBC Building,
Singapore 049320

Important Note

Please quote the name of the delegate and event title on the remittance advice when remitting payment. Bank charges are to be deducted from participating organisations own accounts.

Attendance will only be permitted upon receipt of full payment. Participants wishing to register at the door are responsible to ensure all details are as published. IBC Asia will not be responsible for any event re-scheduled or cancelled.

General Information

DATA PROTECTION:

The personal information entered during your registration/order, or provided by you, will be held on a database and may be shared with companies in the Informa Group in the UK and internationally. Sometimes your details may be obtained from or shared with external companies for marketing purposes. If you do not wish your details to be used for this purpose, please contact the Database Manager Catherine Shen on catherine.shen@ibcasia.com.sg, Ph: +65 6835 5141 or Fax: +65 6734 4053.