

SDRAN PROGRAM ANNOUNCEMENT

SDRAN Networking & Meeting Presentations

“The Value of and Strategies for Including Asia in Global Clinical Development Plans”

Date: Wednesday, February 24, 2010

Time: 5:30 PM - 6:00 PM - Networking and Snacks
6:00 PM - 7:00 PM - Presentations

Location: Amylin Pharmaceuticals (directions below)
9360 Towne Centre Drive
San Diego, CA 92121-3030
(858) 552-2200

Speakers: Albert Liou
Corporate Vice President & General Manager, Asia Pacific
PAREXEL APEX International
San Diego, CA

Carissa Schumacher
Director, Corporate Development and Clinical Relations
NovaRx Corporation
San Diego, CA

Moderator: Cathryn Bennett
President, BENNETT Clinical Research Solutions
San Diego, CA

Speaker Presentation Abstracts

Albert Liou

The Asian clinical development landscape has changed over the last few years and those changes are continuing. There are many challenges for the pharmaceutical and biotechnology industries to conduct clinical trials and meet regulatory requirements in Asia and beyond. Of the many changes in Asia, regulatory changes can be an important challenge but also represent opportunities for companies to conduct multinational clinical studies. The value of and strategies for incorporating Asian countries into a global drug development program will be the focus of the presentation. In addition a key case study will be discussed.

Carissa Schumacher

After a decade of economic liberalization and unprecedented growth, Asia has become a preferred clinical research destination for multinational pharmaceutical and biotechnology corporations. Three similar but distinct Asian regions, India and South Asia, East Asia, and China, each present unique risks and benefits to sponsors. The advantages and disadvantages to conducting clinical trials in these regions must be carefully assessed when deciding whether and where to open studies in Asia. In each region, the sponsor should consider criteria that impact regulatory approval, clinical site activation, and patient recruitment. Operational parameters should be reviewed in the context of each sponsor's unique product and position. This presentation aims to provide an analysis of what it takes to conduct clinical trials in Asia based on NovaRx Corporation's experience conducting a global pivotal Phase III study. Effective troubleshooting of unforeseen cost, time, regulatory, and clinical barriers to successful study operations will be discussed.

Speaker Biographies

Albert Liou serves as Corporate Vice President and General Manager for Clinical Research Services in Asia-Pacific and is responsible for the overall business and operations for the region.

Before joining PAREXEL, Albert founded APEX International Clinical Research, which PAREXEL acquired in 2007. Under his leadership, APEX grew rapidly over nine years to become one of the largest CROs in the Asia-Pacific region with a presence in China, Taiwan, Hong Kong, South Korea, Malaysia, Thailand, Singapore, Australia, Indonesia and India.

Mr. Liou has over 22 years of clinical research experience, of which 11 years were spent in the United States and 11 years in Asia. After working at Harvard Medical School as a Senior Statistician, he had a managerial role in biopharmaceutical Liposome Technology which later became part of Johnson & Johnson. He then worked at Amgen where he was a member of the senior management team, responsible for clinical data management. He then returned to Asia and founded APEX International which became a leading CRO in the Asia/Pacific region.

In addition to his professional responsibilities, Albert is an Advisor Committee member in the Development Center for Biotechnology of the Republic of China. He also has served as an Assistant Professor at Fu-Jen Catholic University since 2006.

Carissa Schumacher is Director of Corporate Development and Clinical Relations at NovaRx Corporation. Ms Schumacher specializes in clinical site and investigator recruitment, contracting, and budgeting for global late-stage trials, as well as strategy for global oncology trial development and patient enrollment acceleration measures. At NovaRx, she also spearheads all Public, Media, Industry, Advocacy, and Physician Relations initiatives and materials, as well as undertakes Business Development planning and organization.

Since 2006, Ms. Schumacher served the same corporate function as NovaRx at Castle & Cooke, Inc. Prior to that, she was a recognized strategic planning consultant in the healthcare industries focused on biotechnology private equity and venture capital, public and clinical affairs, and medical nonprofit organizational development. She has served as Principal to Infostrategies Consulting, and to Medaetas Ventures, a fund focused on cancer prevention research and initiatives. Previously, she worked in the Business Development and Public Affairs at Biogen Idec. Ms. Schumacher earned her BS in Neuroscience and Biotechnology Management at Brown University, and attended the graduate program at the Rijksuniversiteit Groningen in the Netherlands, where she studied International Economics and Business.

She is currently the Managing Director of the global nonprofit, Real Medicine Foundation, and gives lectures on biotechnology management and clinical trial operations strategies for universities and industry groups.

Cathryn Bennett is President of BENNETT Clinical Research Solutions, which provides assistance with operational aspects of global clinical studies from study start-up through clinical study report. Her industry experience includes clinical operations at Cato Research where she held positions of increasing responsibility and Associate Director of Clinical Operations at Phenomix. She was the founding member of the Canadian Chapter of the Association of Clinical Research Professionals (ACRP) and served on the Association Board of Trustees for the ACRP.

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Directions to Amylin Pharmaceuticals:

From I-5

- Take I-5 to La Jolla Village Drive exit going east
- Turn left on Towne Centre Drive
- Turn left at first stop light, which is Executive Drive
- Turn right into first driveway
- Turn right into first parking lot
- Address: 9360 Towne Centre Drive

From Interstate 805

- Exit on La Jolla Village Drive going west
- Turn right at the first stop light, which is Towne Centre Drive
- Turn right at the first stop light, which is Executive Drive
- Turn right into the first driveway
- Turn right into the first parking lot

Registration Form

Yes, I will be attending the SDRAN program on February 24:

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“The Value of and Strategies for Including Asia in Global Clinical Development Plans”

Please make your reservation early. **Pre-registration due date – February 19, 2010**

Name: _____

Title: _____

Company: _____

Address: _____

Phone/FAX: _____

e-mail (required): _____

My mailing address/contact information has changed.

If you want a receipt, check here.

Pre-registration: \$15.00 SDRAN member \$25.00 nonmember

On-site registration: \$20.00 SDRAN member \$30.00 nonmember

NOTE: SDRAN does not accept credit cards or PayPal (internet payments). No refunds. No Bill me.

SEND YOUR REGISTRATION FORM AND PAYMENT TO:

Jody Surowiec, SDRAN
P.O. Box 927595
San Diego, CA 92192-7595
e-mail: jodyuro@hotmail.com