Understand the regulatory landscape, valuation approaches and how to successfully develop a drug to secure a priority review voucher

November 2-3, 2016 | Hilton Crystal City at Reagan National Airport | Arlington, VA

Top Five Reasons to Attend:

- Understand the different priority review voucher programs and their respective eligibility requirements
- Navigate the changing regulatory landscape and effectively anticipate the future of the program
- Discuss the various valuation models to use when buying or selling a priority review voucher
- Examine the challenges of clinical study design, operational logistics and patient engagement for developing rare pediatric and infectious disease therapeutics
- Learn how the Priority Review Voucher Program has changed the way investors look at neglected tropical diseases and pediatric indications

FEATURED SPEAKERS

David Ridley, Faculty Director, Health Sector Management, Fuqua School of Business, DUKE UNIVERSITY

Andrew S. Robertson, Ph.D., J.D., Director, Global Regulatory Policy, MERCK

Curt H. LaBelle, M.D., MBA, President, GLOBAL HEALTH INVESTMENT FUND

Paul Melmeyer, Associate Director of Public Policy, NATIONAL ORGANIZATION FOR RARE DISORDERS

Tanya Radhakrishna, Director, Business Development, KNIGHT THERAPEUTICS

Myriam Theeuwes, D.D.S., Compound Development Team Leader, JANSSEN

Sponsor:

Mapi
Dear Colleague,

In order to receive a priority review voucher (PRV), a product application must meet the criteria of the Neglected Tropical Disease or Rare Pediatric Disease PRV Programs and receive FDA approval. Neglected tropical diseases affect more than a billion people in 149 countries, most of which are in the developing world. A rare pediatric disease is a disease that affects fewer than 200,000 individuals in the United States, of which greater than 50% of the affected population is 18 or under. Redeeming a voucher provides sponsors with a time advantage and the ability to gain market access faster than competitors. This extra time can help a company establish brand recognition, set its preferred price and gain a valuable foothold in the market. It also allows them to leverage this potential asset to raise funds and attract interest from investors.

ExL Events’ Priority Review Voucher Summit is the ONLY event that provides attendees with the best strategies to ensure the successful development of a product that meets the criteria of either PRV program and leverage a voucher to attract investor interest. Return to work with a better understanding of the overall challenges and efficacy of the incentive program.

VENUE
Hilton Crystal City at Reagan National Airport | 2399 Jefferson Davis Hwy | Arlington, VA 22202

To make reservations, please call 1-800-695-7551 and request the negotiated group rate for ExL’s November Meetings. The group rate is available until October 6, 2016. Please book your room early, as rooms available at this rate are limited.

*ExL Events, Inc. is not affiliated with Exhibition Housing Management (EHM)/Exhibitors Housing Services (EHS) or any third-party booking agencies, housing bureaus, or travel and event companies. In the event that an outside party contacts you for any type of hotel or travel arrangements, please disregard these solicitations and kindly email us at info@exlevents.com. ExL has not authorized these companies to contact you and we do not verify the legitimacy of the services or rates offered. Please book your guest rooms through ExL’s reserved guest room block using the details provided.

WHO SHOULD ATTEND:
This conference is designed for representatives from pharmaceutical and biotechnology companies with responsibilities in the following areas:
- Regulatory Intelligence/Affairs
- Policy/General Counsel
- Strategic Planning
- Strategic/Competitive Intelligence
- Business Development
- Strategic Alliance/Alliance Management
- Licensing
- Due Diligence
- Scientific Assessment
- Research and Development
- Drug Development
- Clinical Operations/Development
- Rare/Orphan Program Management
- Pipeline/Portfolio Management
- Medical Information/Affairs

This conference is also of interest to:
- Nonprofits/Patient Advocacy Groups
- Social Enterprises
- Strategic/Management Consultants
- Investment Community Members
- Law Firms
- Regulatory Strategy Advisers
- Valuation Experts
- Drug Development Service Providers
- Clinical Research Organizations

Wednesday, November 2, 2016

Main Conference, Day One

<table>
<thead>
<tr>
<th>Time</th>
<th>Session/Panel</th>
<th>Description/Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>8:00</td>
<td>Registration and Continental Breakfast</td>
<td></td>
</tr>
<tr>
<td>9:15</td>
<td>Co-Chairpersons’ Opening Remarks</td>
<td></td>
</tr>
</tbody>
</table>
| 9:30  | Panel: Capital Raising for a Pre-NDA PRV Candidate: Moxidectin for Onchocerciasis | - Assess the development pathway of Moxidectin and the unmet medical need being addressed  
- Gain an overview of the capital raising activities and timeframe  
- Review the global health impact obligations within the agreements  
- Understand the post-PRV plans to build a sustainable global health biotechnology company  
Mark Sullivan, Founder, Managing Director, MEDICINES DEVELOPMENT FOR GLOBAL HEALTH |
| 9:45  | Co-Chairpersons’ Remarks | David Ridley, Faculty Director, Health Sector Management, Fuqua School of Business, DUKE UNIVERSITY |
| 9:50  | Andrew S. Robertson, Ph.D., J.D., Director, Global Regulatory Policy, MERCK | |
| 10:15 | Panel: Amending the Neglected Tropical Disease PRV Program: Redefining Novelty, Improving Access and Expanding Voucher Eligibility | - Assess the proposed amendments advocated by a consortium of NGOs that would only reward novel, new therapeutics and require sponsors to ensure access to the drug in disease-endemic countries  
- Evaluate the impacts of expanding eligibility beyond NTDs and pediatric cancers to include medical counter-measures and US public health diseases  
- Provide an overview of the proposed or enacted amendments to the PRV program and the likely consequences of these changes  
Jeffrey Moe, Ph.D., Professor of the Practice of Global Health, DUKE GLOBAL HEALTH INSTITUTE  
Zachary Brennan, Managing Editor, Regulatory Focus, REGULATORY AFFAIRS PROFESSIONALS SOCIETY (RAPS) |
| 11:00 | Networking Break | |
| 11:45 | Panel: Priority Review Vouchers: Do They Truly Stimulate Innovation? | - Investigate if PRVs truly stimulate innovative drug development  
- Discuss whether there are strong incentives to further develop these drugs and improve their administration or utility in resource-limited settings  
Charles Keller, M.D., Scientific Director, CHILDREN’S CANCER THERAPY DEVELOPMENT INSTITUTE |
| 12:30 | Luncheon | |
| 1:45  | The Value of a Priority Review Voucher | - Describe a recent Nature Reviews Drug Discovery study estimating the commercial value of a voucher based on speed to market  
- Report on how the value of a voucher diminishes with each additional voucher supplied  
- Forecast the price of a voucher and the implications for pipeline development strategy  
David Ridley, Faculty Director, Health Sector Management, Fuqua School of Business, DUKE UNIVERSITY |
| 3:15  | Bedaquiline for MDR-TB: The Challenges of Clinical Development for a Neglected Tropical Disease | - Navigate the discovery and early development pitfalls for an NTD  
- Pioneer a clinical development pathway in uncharted territory  
- Address capacity building and health systems strengthening during the development process outside the US or EU  
- Drive internal support for competing resources  
Myriam Theeuwes, D.D.S., Compound Development Team Leader, JANSSEN |
| 4:00  | Panel: Priority Review Vouchers: A New Paradigm for Funding Research | - Describe how the Priority Review Voucher program has changed the way investors look at neglected tropical diseases and pediatric indications  
- Explore the different grants and government programs that can complement other capital for PRV-focused programs  
- Determine whether to opt for early collaboration, joint ventures or outside investment  
Curt H. LaBelle, M.D., MBA, President, GLOBAL HEALTH INVESTMENT FUND  
Charles Keller, M.D., Scientific Director, CHILDREN’S CANCER THERAPY DEVELOPMENT INSTITUTE |
| 5:00  | Day One Concludes | |
Registration Information

Registration Fees for Attending ExL's Priority Review Voucher Summit

<table>
<thead>
<tr>
<th>Early Bird Pricing</th>
<th>Conference: $1,895</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard Pricing</td>
<td>Conference: $2,095</td>
</tr>
<tr>
<td>Onsite Pricing</td>
<td>Conference: $2,195</td>
</tr>
</tbody>
</table>

TERMS AND CONDITIONS: By registering for an ExL Events, Inc. ("ExL") event, you agree to the following set of terms and conditions listed below:

REGISTRATION FEE: The fee includes the conference, all program materials, and designated continental breakfasts, lunches and refreshments.

PAYMENT: Please make checks payable to "ExL". You may also use Visa, MasterCard, Discover or American Express. Payments must be received in full by the conference date. Any discount applied cannot be combined with any other offer and must be paid in full at the time of order. Parties must be employed by the same organization and register simultaneously to realize group discount pricing options.

**Please Note: There will be an administrative charge of $300 to substitute, exchange and/or replace attendee badges with a colleague occurring within five business days of any ExL conference.**

CANCELLATION AND REFUND POLICY: If you cancel your registration for an upcoming ExL event, the following policies apply, derived from the Start Date of the event:

- Four weeks or more: A full refund (minus a $295 processing fee) or a voucher to another ExL event valid for 12 months from the voucher issue date.
- Less than four weeks: A voucher to another ExL event valid for 12 months from the voucher issue date.
- Five days or less: A voucher (minus a $395 processing and documentation fee) to another ExL event valid for 12 months from the voucher issue date.

To receive a refund or voucher, please contact our offices at (201) 871-0474.

CREDIT VOUCHERS: Credit vouchers are valid for 12 months from date of issue. Credit vouchers are valid toward one (1) ExL event of equal or lesser value. If the full amount of said voucher is not used at time of registration, any remaining balance is not applicable now or in the future. Once a credit voucher has been applied toward a future event, changes cannot be made. In the event of cancellation on the attendees' behalf, the credit voucher will no longer be valid.

ExL Events, Inc. does not and is not obligated to provide a credit voucher to registered attendee(s) who do not attend the event they registered for unless written notice of intent to cancel is received and confirmed prior to the commencement of the event.

Main Conference, Day Two

11:45 The Potential Impact of Legislative Expansion and Revision of the PRV Program
- Identify how the PRV program has expanded through legislation and policy
- Describe current proposals for further expansion of the PRV program
- Recognize the potential impact these expansions could have on the resale value of the PRV

Andrew S. Robertson, Ph.D., J.D., Director, Global Regulatory Policy, MERCK

12:30 Luncheon

1:45 Rare Pediatric Disease Priority Review Vouchers: Eligibility and Impact
- Review the mandate for a rare pediatric disease PRV
- Define a rare pediatric disease and understand PRV eligibility requirements
- Analyze the future of the rare pediatric disease PRV program

Nancy Goodman, Founder, Executive Director, KIDS V. CANCER

2:45 Panel: Possible Enhancements and Considerations for the Rare Pediatric Disease PRV Program
- Highlight some of the current challenges of the PRV program
- Outline the proposed amendments to the incentive program
- Discuss the impact of legislative expansion

Paul Melmeyer, Associate Director of Public Policy, NATIONAL ORGANIZATION FOR RARE DISORDERS
Jonathan Eric Agin, J.D., Executive Director, THE MAX CURE FOUNDATION

3:30 Co-Chairpersons’ Closing Remarks and Key Takeaways

3:45 Conference Concludes

Group Discount Program

Offers may not be combined. Early bird rates do not apply. To find out more on how you can take advantage of these group discounts, contact our offices at (201) 871-0474.

- **Save 25% per person when registering four**
- **Save 15% per person when registering three**

SUBSTITUTION CHARGES: There will be an administrative charge of $300 to substitute, exchange and/or replace attendee badges with a colleague occurring within five business days of any ExL conference. ExL Events reserves the right to cancel any conference it deems necessary and will not be responsible for airfare, hotel or any other expenses incurred by registrants. ExL Events’ liability is limited to the conference registration fee in the event of a cancellation and does not include changes in program date, content, speakers and/or venue.

The opinions of ExL’s conference speakers do not necessarily reflect those of the companies they represent, nor ExL Events, Inc.

Group Discount Program

Offers may not be combined. Early bird rates do not apply. To find out more on how you can take advantage of these group discounts, contact our offices at (201) 871-0474.

- **Save 25% per person when registering four**
- **Save 15% per person when registering three**

SUBSTITUTION CHARGES: There will be an administrative charge of $300 to substitute, exchange and/or replace attendee badges with a colleague occurring within five business days of any ExL conference. ExL Events reserves the right to cancel any conference it deems necessary and will not be responsible for airfare, hotel or any other expenses incurred by registrants. ExL Events’ liability is limited to the conference registration fee in the event of a cancellation and does not include changes in program date, content, speakers and/or venue.

The opinions of ExL’s conference speakers do not necessarily reflect those of the companies they represent, nor ExL Events, Inc.

Please Note: Speakers and agenda are subject to change without notice. In the event of a speaker cancellation, significant effort to find a suitable replacement will be made. The content in ExL slide presentations, including news, data, advertisements and other information, is provided by ExL’s designated speakers and is designed for informational purposes for its attendees. It is NOT INTENDED for purposes of copying or redistribution to other outlets without the express written permission of ExL’s designated speaking parties. Neither ExL nor its content providers and/or speakers and attendees shall be liable for any errors, inaccuracies or delays in content, or for any actions taken in reliance thereon. EXL EVENTS, INC. EXPRESSLY DISCLAIMS ALL WARRANTIES, EXPRESSED OR IMPLIED, AS TO THE ACCURACY OF ANY CONTENT PROVIDED, OR AS TO THE FITNESS OF THE INFORMATION FOR ANY PURPOSE. Although ExL makes reasonable efforts to obtain reliable content from third parties, ExL does not guarantee the accuracy of, or endorse the views or opinions given by any third-party content provider. ExL’s presentations may point to other websites that may be of interest to you, however ExL does not endorse or take responsibility for the content on such other sites.
[Image]

☑ YES! Register me for this conference!

Name: _______________________________________________
Title: ________________________________________________
Company: ____________________________________________
Dept: ________________________________________________
Address: _____________________________________________
City: ___________________________________________________________________
State: ___________________ Zip: _________________________
Email: _______________________________________________
Phone: ___________________________________________________________________
Fax: ___________________________________________________________________

Please make checks payable to: "PMA"

Method of Payment: ☐ Check ☐ Credit Card

Card Type: ☐ MasterCard ☐ Visa ☐ AMEX
Card Number: ___________________________________________________________________
Exp. Date: ___________________________________________________________________
Name on Card: ___________________________________________________________________
Signature: ___________________________________________________________________

Please contact me:
☑ I'm interested in marketing opportunities at this event
☐ I wish to receive email updates on ExL Pharma's upcoming events

CONFERENCE CODE: C523