



# 3RD ANNUAL DRUG DISCOVERY AND DEVELOPMENT SYMPOSIUM FOR PULMONARY HYPERTENSION

July 11-12, 2016  
Bethesda North Marriott  
Hotel & Conference Center  
5701 Marinelli Road,  
North Bethesda, MD, 20852

## **THE PATHWAY TO BREAKTHROUGH THERAPIES**

This meeting will focus on promising therapies in clinical development, new targets, and changes in clinical trial designs that can lead to successful clinical trials and faster drug approval. The faculty includes world renowned academic experts and members of the FDA.



INSIGHTS FROM  
LEADERS IN  
ACADEMIA,  
INDUSTRY, AND  
REGULATORY

PROMISING TARGETS  
READY FOR CLINICAL  
DEVELOPMENT

INNOVATIVE CLINICAL  
TRIAL DESIGNS FOR  
FASTER APPROVAL

PULMONARY  
VASCULAR DISEASES

RIGHT HEART  
FAILURE

SPONSORED BY THE  
PULMONARY  
VASCULAR RESEARCH  
INSTITUTE

AND THE  
THE FOOD AND DRUG  
ADMINISTRATION

## **3rd ANNUAL DRUG DISCOVERY AND DEVELOPMENT SYMPOSIUM FOR PULMONARY HYPERTENSION**

The Drug Discovery and Development for Pulmonary Hypertension Symposium is held annually each summer to bring leading scientists in the fields of pulmonary vascular disease, right heart failure, and clinical trial designs together with the pharmaceutical industry and regulatory authorities to help identify the most promising treatments for future development. For each meeting we assemble a faculty with exceptional achievements and expertise, and choose topics in areas that will influence the development of therapies immediately. Each topic will be critically reviewed by an expert panel, and open dialogue will allow your voice to be heard.

This symposium serves as a unique forum for stakeholders interested in treatment of pulmonary vascular diseases for the sharing of cutting-edge science with the input of international thought leaders. For researchers involved in the treatment of pulmonary hypertension this meeting should stimulate new ideas and approaches. For the pharmaceutical and biotechnology industries that have an interest in pulmonary vascular diseases, right heart failure or orphan diseases, it is a meeting that should not be missed.

### **Comments from those who attended the previous symposium:**

- “This was the finest scientific meeting on pulmonary hypertension I have ever attended.”
- “The meeting was fantastic.....the presentations were first rate.”
- “The discussions were very provocative.....perhaps the best part of the meeting.”
- “I will be attending this meeting every year....people involved in developing therapies for pulmonary hypertension or right ventricular failure should not miss this.”
- “What a great symposium.....please let me know when next year’s meeting is.”

### **PROGRAM CHAIRPERSONS:**

**Serpil C. Erzurum, M.D.**

**John H. Newman, M.D.**

**Stuart Rich, M.D.**

# Meeting Agenda

**Day 1: Monday, July 11<sup>th</sup> 2016**

**7:30 to 8:15**      **Registration**

**8:15 to 8:30**      Introductory Remarks

**Session #1: 8:30 to 12:30**

**Drugs for New Targets in Pulmonary Hypertension Entering Clinical Trials**

**Moderator:** John Newman

**Expert Panel:** Joe G.N. Garcia, Mark Gladwin, Kurt Stenmark

- **8:30 – 9:30**      **Bardoxolone Methyl for PAH**  
(ClinicalTrials.gov Identifier: NCT02036970)  
Ron Oudiz
- **9:30 – 10:30**      **Rituximab for Scleroderma APAH**  
(ClinicalTrials.gov Identifier: NCT01086540)  
Mark Nicolls
- **10:30 – 11:30**      **Anastrozole for PAH**  
(ClinicalTrials.gov Identifier: NCT01545336)  
Steven Kawut
- **11:30 – 12:30**      **ASK-1 inhibitor for PAH**  
(ClinicalTrials.gov Identifier: NCT02234141)  
Andrew Peacock

**12:30pm – 1:30pm**      **Lunch**

## Session #2: 1:30 – 5:30

### New Targets for Pulmonary Vascular Diseases Ready for Clinical Trials

**Moderator:** Serpil Erzurum

**Expert Panel:** Jeffrey Feinstein, Ioana Preston, Erika Rosenzweig

- **1:30 – 2:30**            **Bendavia for Right Heart Failure from PH**  
(Sponsor: Stealth BioTherapeutics Inc.)  
  
Vallerie McLaughlin
- **2:30 – 3:30**            **Ataluren for Pulmonary Arterial Hypertension**  
(Sponsor: PTC Therapeutics)  
  
Michaela Aldred
- **3:30 – 4:30**            **Pulmonary Artery Denervation for PH in Left Heart Failure**  
(ClinicalTrials.gov identifier: NCT02220335)  
  
Shao-Liang Chen
- **4:30 – 5:30**            **Metformin for Reducing Oxidant Stress in PAH**  
(ClinicalTrials.gov Identifier: NCT01884051)  
  
Anna Hennes

**5:30 – 7:00**

**Cocktail Reception**

## **Day 2: Tuesday July 12<sup>th</sup>, 2016**

### **Session #3: 8:30 – 12:30**

#### **Controversial Issues in Clinical Trials for Pulmonary Vascular Diseases**

**Moderator:** Stuart Rich

**Expert Panel:** Robert Frantz, Hunter Gillies, Robert Temple

- **8:30 – 9:30**                      **FDA Regulatory Approach To Orphan Diseases**  
Ellis F. Unger
  
- **9:30 – 10:30**                      **Clinical Trials for Exercise Induced Pulmonary Hypertension Are Warranted**  
  
Aaron Waxman
  
- **10:30 – 11:30**                      **Treatment-Related Biomarkers in Pulmonary Hypertension as Outcome Assessments**  
  
Tim McMahon
  
- **11:30 – 12:30**                      **CardioMems Monitoring of PA Pressure as an Endpoint in Clinical Trials.**  
(NHLBI VITA Project)  
  
Raymond Benza

**12:30pm**

**Lunch**

## Invited Faculty

### **Micheala A. Aldred PhD**

Associate Staff  
Genomic Medicine Institute  
Lerner Research Institute  
Cleveland Clinic Foundation

### **Raymond L. Benza, MD**

Professor of Medicine  
James Magovern Chair for Cardiovascular Research  
Gerald McGinnis Cardiovascular Institute  
Drexel University, College of Medicine

### **Shao-Liang Chen, MD, PhD**

Professor of Internal Medicine and Cardiology  
Director of Cardiology and Cath Lab, Nanjing First Hospital  
Vice President of Nanjing First Hospital, Nanjing Medical University,

### **Serpil C. Erzurum, MD**

The Alfred Lerner Memorial Chair in Innovative Biomedical Research  
Department of Pathobiology  
Lerner Research Institute  
The Cleveland Clinic Foundation

### **Jeffrey A. Feinstein, MD, MPH**

The Dunlevie Family Professor of Pediatrics (Cardiology) and, by courtesy,  
BioEngineering  
Director, Vera Moulton Wall Center for Pulmonary Vascular Disease  
Stanford University School of Medicine

### **Robert P. Frantz, MD**

Professor of Medicine  
Director, Pulmonary Hypertension Clinic  
Mayo Medical School,  
Mayo Clinic College of Medicine

**Joe G. N. "Skip" Garcia, MD**

Professor of Medicine

Senior Vice President for Health Sciences

Arizona Health Sciences Center

Merlin K. DuVal, MD Endowed Chair for Leadership and Innovation

University of Arizona College of Medicine

**Mark Gladwin, MD**

Jack D. Myers Professor and Chair

Chairman of the Department of Medicine

Director, Pittsburgh Heart, Lung, Blood and Vascular Medicine Institute

UPMC and the University of Pittsburgh School of Medicine

**Hunter Gillies MD, MSc, DSEM**

Former Senior Director of PAH Clinical Research

Gilead Sciences Inc.

Foster City, CA

**Anna R. Hemnes, MD**

Assistant Professor of Medicine

Assistant Director, Pulmonary Vascular Center

Division of Allergy, Pulmonary, and Critical Care Medicine

Vanderbilt University Medical Center

**Steven M. Kawut, MD, MS**

Associate Professor of Medicine and Epidemiology

Director, Pulmonary Vascular Disease Program

Perelman School of Medicine

University of Pennsylvania

**Vallerie V. McLaughlin MD**

Kim A. Eagle, M.D. Endowed Professor of Cardiovascular Medicine

Director, Pulmonary Hypertension Program

Frankel Cardiovascular Center

University of Michigan Health Science Center

**Timothy J. McMahon, MD, PhD**

Associate Professor of Medicine

Division of Pulmonary, Allergy, and Critical Care Medicine

Duke University Medical Center

**John H. Newman, M.D.**

Professor of Medicine  
Elsa S. Hanigan Chair in Pulmonary Medicine,  
Vanderbilt University School of Medicine

**Mark Nicolls, MD**

Associate Professor of Medicine  
Chief, Pulmonary and Critical Care Medicine  
Chairman of the Board, Palo Alto Veterans Administration Institute for Research  
Stanford University School of Medicine

**Ronald J. Oudiz, MD**

Professor of Medicine  
The David Geffen School of Medicine at UCLA  
Director, Liu Center for Pulmonary Hypertension  
LA Biomedical Research Institute at Harbor-UCLA Medical Center

**Andrew Peacock, MD**

Honorary Professor (Institute of Cardiovascular and Medical Sciences)  
Director, Scottish Pulmonary Vascular Unit,  
Golden Jubilee National Hospital, Glasgow, UK

**Ioana R. Preston, MD**

Associate Professor of Medicine  
Co-Director, Pulmonary Hypertension Center  
Tufts University School of Medicine

**Erika S. Berman-Rosenzweig, MD**

Associate Professor of Clinical Pediatrics in Medicine  
Medical Director of the Pulmonary Hypertension Center  
Columbia University Medical Center

**Stuart Rich, M.D.**

Professor of Medicine  
Northwestern University Feinberg School of Medicine  
Director, Pulmonary Vascular Disease Program  
Bluhm Cardiovascular Institute  
Northwestern Memorial Hospital



**Kurt R. Stenmark, MD**

Professor of Pediatrics, Medicine, and Anesthesiology  
Head, Division of Pediatric Critical Care Medicine  
Director, Cardiovascular Pulmonary Research and  
Developmental Lung Biology Laboratories  
University of Colorado Denver - Anschutz Medical Campus

**Robert Temple, M.D.**

Deputy Center Director for Clinical Science  
Acting Deputy Director of the Office of Drug Evaluation I  
Center for Drug Evaluation and Research  
U.S. Food and Drug Administration

**Ellis F. Unger, M.D.**

Director of the Office of Drug Evaluation I  
Office of New Drugs  
Center for Drug Evaluation and Research  
U.S. Food and Drug Administration

**Aaron B. Waxman, MD, PhD**

Associate Professor of Medicine  
Director, Pulmonary Vascular Disease Program,  
Pulmonary Critical Care Medicine,  
Brigham and Women's Hospital  
Harvard Medical School,

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**REGISTRATION:**

**YOU MAY ONLY REGISTER FOR THE MEETING ONLINE AT: [www.pvri.info](http://www.pvri.info)**

**MEETING REGISTRATION FEES:**

Registration fee (includes breakfasts, luncheons and reception) will be accepted online.

**Industry Fee:** \$ 1595

**Academia (Full-time)** US \$ 595

**Discount Fees:**

- Charitable Nonprofit US \$ 395
- Academia PVRI Member US \$ 295
- Government (e.g. NIH) /Regulatory (e.g. FDA or EMA) fees will be waived

**CANCELLATION POLICY:**

**On or before June 24th, 2016 an Administrative Fee will be withheld from refund amount:**

- Industry = \$ 200
- Academia or Nonprofit = \$ 100

Cancellations must be made in writing and be received by the cancellation date above. Registrants who do not cancel by that date and do not attend will be responsible for the full registration fee paid. Registrants are responsible for cancelling their own hotel and airline reservations.

**PAYMENT OPTIONS:**

- **CREDIT CARD** (Visa, MasterCard, Maestro, American Express, Direct Debit) via PayPal

**The PVRI reserves the right to alter the venue, if necessary. If an event is cancelled PVRI is not responsible for any airfare, hotel or other costs incurred by registrants.**

## **TRAVEL AND HOTEL:**

The most convenient airports for the meeting are Washington, DC/Dulles (IAD); Ronald Reagan Washington National Airport (DCA); Baltimore-Washington International (BWI). Attendees should make airline reservations as early as possible to ensure availability.

Bethesda North Marriott Hotel & Conference Center is located at 5701 Marinelli Road, North Bethesda, Maryland 20852. We have secured a block of rooms at the reduced rate of \$169 (single or double occupancy) plus applicable taxes. The deadline for reserving at this rate is **FRIDAY, JUNE 24, 2016**. Room availability at this rate is guaranteed only until this date or until the block is filled.

**RESERVATION METHOD:** Individual Reservations must be made no later than Friday, June 24, 2016.

- **Reservation Link:** <https://resweb.passkey.com/go/b309faf3>
- Discounted room rates apply from an arrival date of July 8, 2016 through a departure date of July 14, 2016.
- A credit card is required for this reservation. If you wish to cancel, please do so 14 days prior to arrival to avoid cancellation penalties.

## **CONTACT INFORMATION:**

Symposium and Event Information please contact:

**Andrea Rich at:** [aarich15@gmail.com](mailto:aarich15@gmail.com) T: 847.337.9019 - F: 847.676.4239

Hotel Information please contact:

**Catalina Cely at:** [catalina.cely@marriott.com](mailto:catalina.cely@marriott.com) T: 301.822.9274 - F: 301.822.9203

<http://www.marriott.com/hotels/travel/wasbn-bethesda-north-marriott-hotel-and-conference-center/>

***We look forward to welcoming you on July 11!***