

NO TIME TO WAIT

Overcoming Gaps in TB Drug Research and Development

January 11-12, 2007 | The Cornell Club, 6 East 44th Street, New York City



A Médecins Sans Frontières/Doctors Without Borders Symposium supported by Howard P. Milstein and Weill Cornell Medical College's Abby and Howard P. Milstein Program in Chemical Biology

DAY 1: Thursday January 11, 2007

All sessions and breaks will be conducted in the Ivy Room, 4th Floor, unless otherwise noted.

8:00-8:30 Late Registration, Coffee, and Breakfast

8:30-8:35 Welcoming Address: Howard Milstein, JD MBA
Trustee Emeritus and Presidential Councilor, Cornell University

8:35-8:40 Taped Address: Anthony S. Fauci, MD
Director of the National Institute of Allergy and Infectious Diseases (NIAID)

8:40-8:45 Opening remarks: Tido von Schoen-Angerer, MD
Director, Campaign for Access to Essential Medicines, Médecins Sans Frontières

8:45-10:00 Overcoming Gaps in TB Drug Research and Development
Chair: Bernard Pecoul, MD, *Chief Executive Officer, Drugs for Neglected Diseases initiative (DNDi)*

8:45-9:05 Global TB Control: Achievements, Challenges, and the Need for Better Tools
Mario Raviglione, MD
Director, Stop Tuberculosis Department, World Health Organization

9:05-9:25 TB Drugs & Where We are Today, the Vision for Tomorrow
Maria Freire, PhD
President and CEO, Global Alliance for TB Drug Development

9:25-9:45 Insurmountable Challenges in TB Treatment
Francis Varaine, MD
Chairman, TB Working Group, Médecins Sans Frontières

9:45-10:05 Limitations of the Current Pipeline: Lessons from Persisters and Persister Drug PZA Ying Zhang, MD, PhD, *Professor of Molecular Microbiology and Immunology, Johns Hopkins University Bloomberg School of Public Health*

10:05-10:15 Coffee Break

10:15-12:15 Gaps in TB Drug Discovery
Chair: Prof. Dr. Paul Herrling, *Head of Corporate Research, Novartis AG*

10:15-10:35 Accelerating TB Drug Discovery
Ken Duncan, PhD
Senior Program Officer, Bill and Melinda Gates Foundation

10:35-11:10 Bridging the Gaps in TB Drug Discovery & Creating International Medicinal Chemistry Resource Centers

Alan Kozikowski, PhD, *Professor of Medicinal Chemistry and Pharmacology, College of Pharmacy, University of Illinois at Chicago*
Scott Franzblau, PhD, *Director, Institute for Tuberculosis Research, University of Illinois at Chicago*

11:10-11:30 Managing Intellectual Property in Academia to Ensure Future Access to Products

Amy Kapczynski, JD
ISP Samuelson Fellow/EPH Post-Doctoral Fellow, Yale Law School

11:30-12:00 Discussion

Key respondents: Christine Sizemore, PhD, *Chief of TB, Leprosy, and other Mycobacterial Diseases Section, National Institute of Allergy and Infectious Diseases/National Institute of Health*; Federico Gomez de las Heras, PhD, *Research Director of Diseases of the Developing World, GlaxoSmithKline*; Carl Nathan, MD, R.A. Rees Pritchett Professor of Microbiology, *Professor Microbiology, Immunology, and Medicine, Chairman, Department of Microbiology and Immunology, Weill Cornell Medical College*

12:00-13:00 Lunch Break - Fall Creek Room, 5th Floor and Library, 3rd Floor

13:00-14:30 Clinical Trial Capacity

Chair: Prof. Wafaa El-Sadr, MD, MPH, *Director, International Center for AIDS Care and Treatment Programs (ICAP); Director, Center for Infectious Disease Epidemiologic Research (CIDER); Professor, Clinical Medicine and Epidemiology, Mailman School of Public Health; and Chief, Division of Infectious Diseases at Harlem Hospital Center*

13:00-13:20 Evaluating New Drugs Through Clinical Trials: Current Capacity and Future Needs

Neil Schluger, MD
Chairman of the Steering Committee, Tuberculosis Trials Consortium (TBTC), Associate Professor of Medicine and Public Health Chief, Division of Pulmonary, Allergy, and Critical Care Medicine, Columbia University

13:20-13:40 Conforming to GCP/GLP Standards in Resource-Poor Settings: Can We Meet the Challenge?

Christian Leinhardt, MD
Director of Research, International Union Against Tuberculosis and Lung Diseases (IUATLD) and L'Institut de recherche pour le développement (IRD)

13:40-14:30 Panel Discussion

Ann Ginsberg, MD, PhD, *Head of Clinical Development, Global Alliance for TB Drug Development*; Margareth Dalcolmo, MD, PhD, *Outpatient Clinic Coordinator, Brazilian Society of Respiratory Diseases*; Lawrence J. Geiter, PhD, *Senior Director, Epidemiology and Field Studies, Aeras Global TB Vaccine Foundation*; Hannu Laang, PhD, *Scientific Officer for TB, European Commission*

14:30-14:45 Coffee Break

14:45-17:00 Accelerating Clinical Development

Chair: Kenneth Castro, MD
Director, Division of TB Elimination, Centers for Disease Control and Prevention

- 14:45-15:00 Shortening the Clinical Development of Drugs for Tuberculosis**
Leonard Sacks, MD
Office of New Drugs, Center for Drug Evaluation and Research, U.S. Food and Drug Administration
- 15:00-15:15 How TMC207 Progressed through Development**
Karel De Beule, PharMD, MBA
Compound Development Team Leader Tibotec
- 15:15-15:30 Lessons from the Past - Ways to Speed Up Clinical Trials**
William Burman, MD
Director of the Infectious Diseases Clinic and Study Chair Tuberculosis Trials Consortium, Denver Public Health
- 15:30-15:45 Progress in Clinical Development of SUDOTERB (LL-3858): A Novel MDR-TB Molecule of Lupin Laboratories Limited**
Anuradha Kulasekaran
Senior Manager, Clinical Research Unit, Lupin Ltd.
- 15:45-16:00 Tuberculosis The Role of the Rifamycins in Reducing Treatment Duration in Tuberculosis**
Amina Jindani, MD, FRCP, INTERTB, *St. George's Hospital Medical School, London*
- 16:00-16:40 Discussion**
Key respondents: Mel Spigelman, MD, *Director of Research and Development, Global Alliance for TB Drug Development*; D.A. Mitchison, MD, *St. George's Hospital Medical School, London*
- 16:45-17:00 Coffee Break**
- 17:00-18:00 TB and the Global R&D Framework**
Chair: Ellen Ôt Hoen, LLM, *Policy and Advocacy Director, Campaign for Access to Essential Medicines, Médecins Sans Frontières*
- 17:00-17:15 TB R&D: The Gap between Needs & Realities**
Mark Harrington, *Executive Director, Treatment Action Group*
- 17:15-17:30 Strategy for a Treaty on Research and Development**
James Love, MPA, *Director, Consumer Project on Technology*
- 17:30-17:45 The Intergovernmental Working Group on Public Health, Innovation and Intellectual Property**
Dermot Maher, *STOP Tuberculosis Department, World Health Organization*
- 17:45-18.15 Discussion**
- 18:15-18:30 Concluding Remarks:** Tido von Schoen-Angerer, MD, *Director, Campaign for Access to Essential Medicines, Médecins Sans Frontières*
- 18:45 Drinks and Dinner**