Development of Inhaled Antibacterial Treatments for Cystic Fibrosis and Non-Cystic Fibrosis Bronchiectasis; Public Workshop—June 27, 2018

Speakers and Panelists

**Timothy Aksamit, MD**  
Associate Professor of Medicine  
Pulmonary Disease and Critical Care Medicine  
Mayo Clinic  
Rochester, MN

**Jeff Alder, PhD**  
Anti-Infective Consulting, LLC  
Margaretville, NY

**Maria Allende, MD**  
Medical Officer  
Division of Anti-Infective Products (DAIP), Office of Antimicrobial Products (OAP), Office of New Drugs (OND)  
CDER, FDA, Silver Spring, Maryland

**Alan Barker, MD**  
Professor of Medicine, Division of Pulmonary and Critical Care Medicine  
Oregon Health & Science University  
Portland, OR

**James Chalmers, PhD**  
Professor  
Department of Respiratory Medicine  
Ninewells Hospital and Medical School, University of Dundee  
British Lung Foundation Chair of Respiratory Research  
Dundee, UK

**Wen-Hung Chen, PhD**  
Reviewer  
Clinical Outcome Assessment Staff  
OND, CDER, FDA, Silver Spring, MD

**Edward Cox, MD, MPH**  
Director  
OAP  
OND, CDER, FDA, Silver Spring, MD
**Rajiv Dhand, MD**  
Professor and Chairman  
Department of Medicine  
University of Tennessee Graduate School of Medicine  
Knoxville, TN

**Susan Ellenberg, PhD**  
Professor  
Biostatistics, Department of Biostatistics and Epidemiology  
University of Pennsylvania School of Medicine  
Philadelphia, PA

**Patrick Flume, MD**  
Professor  
Medicine and Pediatrics  
Medical University of South Carolina  
Charleston, SC

**Dean Follmann, PhD**  
Chief  
Biostatistics Research Branch  
National Institute of Allergy and Infectious Diseases  
Bethesda, MD

**Juergen Froehlich, MD**  
Chief Medical Officer  
Aradigm Corporation  
Hayward, CA

**Nicole Hamblett, PhD**  
Professor, Department of Pediatrics  
Adjunct Professor, Department of Biostatistics  
University of Washington  
Co-Executive Director, Cystic Fibrosis Therapeutics Development Network (CF TDN)  
Coordinating Center  
Seattle Children's Research Institute  
Seattle, WA

**Chip Hawkins**  
Patient Representative- Cystic Fibrosis  
Baltimore, MD
Chris Kadoorie, PhD
Statistical Reviewer
Division of Biometrics IV
Office of Biostatistics
Office of Translational Sciences (OTS),
CDER, FDA

Peter Kim, MD
Medical Officer
DAIP, OAP
OND, CDER, FDA, Silver Spring, MD

Deepika Lakhani, PhD
Team Lead
Respiratory and Pulmonary Devices Branch, Office of Device Evaluation
Center for Devices and Radiologic Health, FDA
Silver Spring, MD

Robert Lim, MD
Lead Medical Officer
Division of Pulmonary, Allergy, and Rheumatology Products
OND, CDER, FDA, Silver Spring, MD

Shrimant Mishra, MD, MPH
Medical Officer
DAIP, OAP
OND, CDER, FDA, Silver Spring, MD

Sumathi Nambiar, MD, MPH
Director
DAIP, OAP
OND, CDER, FDA, Silver Spring, Maryland

Quynh Nguyen, PhD
Associate Director for Human Factors
Division of Medication Error Prevention and Analysis
Office of Surveillance and Epidemiology
CDER, FDA, Silver Spring, MD
David Nichols, MD  
Associate Professor of Pediatrics  
Pediatric Pulmonology  
Seattle Children’s Hospital  
Medical Director  
CF TDN Coordinating Center  
Seattle Children’s Research Institute  
Seattle, WA

Peadar Noone, MD  
Professor of Medicine  
University of North Carolina  
Chapel Hill, NC

Anne O’Donnell, MD  
Professor of Medicine  
Chief, Division of Pulmonary, Critical Care and Sleep Medicine  
Georgetown University Hospital  
Washington DC

Thomas Smith, MD  
Clinical Team Leader  
DAIP, OAP  
OND, CDER, FDA, Silver Spring, MD

Greg Tino, MD  
Chief  
Department of Medicine  
Penn Presbyterian Medical Center  
Associate Professor of Medicine  
Perelman School of Medicine at the University of Pennsylvania  
Philadelphia, PA

LaRee Tracy, PhD  
Statistical Reviewer  
Division of Biometrics IV  
Office of Biostatistics, OTS  
CDER, FDA, Silver Spring, MD

Donald VanDevanter, PhD  
Adjunct Professor  
Pediatrics  
Case Western Reserve University School of Medicine
Pamela Zeitlin, MD  
Silverstein Chair  
Department of Pediatrics  
Professor of Pediatrics  
National Jewish Health  
Denver, CO

Jasan Zimmerman  
Patient Representative- Non-CF Bronchiectasis  
Palo Alto, CA

Disclosures

Dr. Aksamit: Chair of US Bronchiectasis and NTM Research Registry

Research clinical study activity:
- US Bronchiectasis and NTM Research Registry
- Bayer, Cipro DPI, Global PI
- Aradigm/Grifols, Cipro liposomal
- Gilead, inhaled aztreonam
- Insmed, inhaled liposomal amikacin

Dr. Alder: Stock in Bayer Pharmaceuticals

Dr. Barker: Receives grant support for a clinical research trial from Grifols. Currently a Consultant/Advisory Boards for the following: Grifols (Cipro liposomal).

Dr. Chalmers: Has received fees for consultancy related to the development of inhaled antibiotics from Aradigm Corporation, Grifols, Bayer Healthcare, Zambon and Insmed. He chairs the European Bronchiectasis Registry which has received research funding from Aradigm, Grifols, Insmed, Bayer Healthcare and Gilead.

Dr. Dhand: Has received remuneration from the following sources: GSK, Astra-Zeneca, UpToDate.

Dr. Flume: Has provided consultative services to the following: Bayer Healthcare AG, Corbus Pharmaceuticals, Eloxx Pharmaceuticals, Horizon Pharma, Insmed, McKesson, Novartis, Proteostasis Therapeutics, and Vertex Pharmaceuticals, Inc. Dr. Flume has received grant support from the following: Bayer Healthcare AG, Corbus Pharmaceuticals, Cystic Fibrosis Foundation Therapeutics, Galapagos, Insmed, National Institutes of Health, Novartis, Novoteris, Proteostasis Therapeutics, Sound Pharmaceuticals, Inc, and Vertex Pharmaceuticals, Inc.

Dr. Hamblett: As per Dr. Hamblett’s role as Co-Executive Director of the Cystic Fibrosis Therapeutics Development Network Coordinating Center, her institution has received funds for


Dr. Nichols: Currently receives independent grant support from the NIH, CF Foundation, Gilead Sciences, and Grifols. Through his role at the TDN Coordinating Center, he consults with several Industry sponsors involved in CF clinical research.

Dr. O’Donnell: Principal Investigator/Grant support to Georgetown University (GU) for the following clinical trials
- Insmed (new therapies for NTM and bronchiectasis)
- Bayer (inhaled antibiotic)  
- Aradigm (inhaled antibiotic)
- Zambon (inhaled antibiotic)
- Foundation support to GU for Bronchiectasis Registry
- COPD Foundation
- Consultant
- Bayer (inhaled ciprofloxacin)
- Grifols (inhaled ciprofloxacin)
- Horizon (Inhaled levofloxacin)
- Xellia Pharmaceuticals (antibiotic manufacture)
- Electromed (Smart Vest)

Dr. Tino: Receives research grant support from the Bronchiectasis Research Registry/COPD Foundation. Dr. Tino has served on advisory boards/as a consultant for the following Pharma companies: Bayer, Grifols and Aradigm.

Dr. VanDevanter: Has served as a paid consultant to Abbvie, Affinium, Agile Biosciences, Albumedix, AN2, Aptalis, Aradigm, Baxter Healthcare, Catabasis, Chiesi USA, CF Foundation, Coleman, Concert, Corbus, CURx, Dannemiller, Debiopharm, Eloxx, Enbiotix, Flatley, Forest, Fortress, Genentech, Gilead Sciences, GlaxoSmithKline, Glycomimetics, Horizon, ICON, Inspire, Kalobios, Laurent, MedImmune, Merck, Mpex, NanoBio, Novartis, NovoClem, Ocularis, Orbimed, Protalix, Proteostasis, PTC Therapeutics, Pulmatrix, Pulmocide, Raptor, Savara, Synedgen, Targeted Genetics, Teva, Tripex, and Vertex.