

## PROGRAMME

8.30 - 8.45

### WELCOME

**Alan Hay**, Francis Crick Institute, London, UK & **Frederick Hayden**,  
University of Virginia School of Medicine, Charlottesville, VA, USA

8.45 - 9.30

### SESSION 1:

#### OPENING LECTURE

Chairs: **Frederick Hayden**, University of Virginia School of Medicine,  
Charlottesville, VA, USA & **Alan Hay**, Francis Crick Institute, London, UK

#### Perspectives on Advancing Respiratory Virus Therapeutics

**Robert Johnson**, BARDA, Washington, DC, USA

9.30 - 11.00

### SESSION 2:

#### SYMPOSIUM - PRECLINICAL TOPICS

Chairs: **Amy Krafft**, NIAID/NIH, Rockville, MD, USA & **Richard Plemper**  
Georgia State University, Atlanta, GA, USA

#### Eritoran, a TLR4 Antagonist That Protects Therapeutically Against Influenza Infection and Secondary Bacterial Infection

**Stefanie Vogel**, University of Maryland, Baltimore, MD, USA

#### Repurposing of Drugs as Novel Influenza (and Other Respiratory Viruses) Inhibitors from Clinical Gene Expression Infection Signatures

**Andres Pizzorno**, Centre International de Recherche en Infectiologie (CIRI-Team  
VirPath) & Signia Therapeutics, Lyon, France

#### Repurposing Host Targets for Influenza Therapy

**Kevin Harrod**, University of Alabama, Birmingham, AL, USA

#### HA Minibinders Proof-of-Concept in Mice and Ferrets

**Deborah Fuller**, University of Washington, Seattle, WA, USA

11.00 - 11.30

COFFEE/TEA BREAK

11.30 - 13.00

### SESSION 3:

#### ORAL ABSTRACTS Session 1- Preclinical Development

Chairs: **Robert Krug**, University of Texas at Austin, Austin, TX, USA &  
**Jeremy Jones**, St. Jude Children's Research Hospital, Memphis, TN, USA

#### Preclinical Characterization of CC-42344, a Broad Spectrum, Potent Influenza A PB2 Inhibitor for Potential Triple Route (Oral, Inhalation, and IV) Treatment

**Sam Lee**, Cocystal Pharma Inc., Bothell, WA, USA

#### The Therapeutic Potential of Reducing Neutrophil Activation and Migration Using Different Strategies in Models of Murine Influenza A Infection

**Cristian Garcia**, Fundação Oswaldo Cruz, Rio de Janeiro, Brazil

#### Chemical Intervention of Influenza Virus RNA Nuclear Export

**Matthew Esparza**, University of Texas Southwestern Medical Center,  
Dallas, TX, USA

#### VH244: a Novel Broad Spectrum Antiviral for Respiratory Virus Infections with a Wide Therapeutic Window In Vivo

**Isabel Najera**, Virion Biotherapeutics Ltd, London, UK

#### Small Molecules Targeting HRSV M2-1

**Ralf Altmeyer**, Shandong University, Qingdao, China

#### Targeting Host-Cell Metabolism to Address Respiratory Viruses

**Eain Murphy**, FORGE Life Science, Doylestown, PA, USA



13.00 - 14.15

LUNCHTIME SEMINAR - Sponsored by Janssen

**Clinical Outcome Endpoints in Trials of Respiratory Viral Illness: Needs & Novel Ideas**

Moderator: **Frederick Hayden**, University of Virginia School of Medicine, Charlottesville, VA, USA

**Clinical Outcome Endpoints for Respiratory Viral Illness – Learning from the Past**

**John Beigel**, NIAID, Bethesda, MD, USA

**Clinical Outcome Endpoints for Respiratory Viral Illness – Recent Advancements**

**Michael Ison**, Northwestern University, Chicago, IL, USA

**Hospital Recovery Scale – The Pimodivir Experience with an Ordinal Scale Endpoint**

**Lorant Leopold**, Janssen Pharma R&D, Titusville, NJ, USA

14.15 - 15.15

**SESSION 4:**

**SYMPOSIUM - CLINICAL TRIAL DESIGN ISSUES**

Chairs: **Wendy Carter**, FDA, Silver Spring, MD, USA & **Bin Cao**, China-Japan Friendship Hospital, Beijing, China

**Clinical Pharmacology Considerations for Influenza and RSV Trials**

**Su-Young Choi**, FDA, Silver Spring, MD, USA

**Considerations of use of PROs in SARI and Hospitalized Influenza Studies**

**Michelle Campbell**, FDA, Silver Spring, MD, USA

**The Trials and Tribulations of Hospitalized Influenza Clinical Studies**

**Kimberly Armstrong**, BARDA, Washington DC, USA

15.15 - 15.45

COFFEE/TEA BREAK

15.45 - 17.15

**SESSION 5:**

**ORAL ABSTRACTS Session 2 -**

**Antivirals and Monoclonal Antibodies**

Chairs: **Martin Friede**, WHO, Geneva, Switzerland & **Elena Govorkova**, St. Jude Children's Research Hospital, Memphis, TN, USA

**Orally Available Broad-Spectrum Anti-Influenza Ribonucleoside Analog Inhibitor with Potent Efficacy in Ferrets and Differentiated Human Airway Epithelia**

**Richard Plemper**, Georgia State University, Atlanta, GA, USA

**Pharmacodynamic Effect of Different Dosage Regimes of Oseltamivir in Severe Influenza Patients Requiring Mechanical Ventilation**

**Wai-Tat Wong**, The Chinese University of Hong Kong, Hong Kong SAR, China

**Combination Effects of Baloxavir Acid with Neuraminidase Inhibitors Against Influenza B Virus In Vitro**

**Keiko Baba**, Shionogi & Co., Ltd., Osaka, Japan

**Antiviral Therapy Against Influenza B Virus Infection in Immunocompromised Murine Model**

**Philippe Noriel Pascua**, St. Jude Children's Research Hospital, Memphis, TN, USA

**In Vitro Antiviral Assessments of VIS410, a Monoclonal Antibody to Influenza A Virus, in Combination with Baloxavir and Neuraminidase Inhibitors**

**Kristin Narayan**, Visterra Inc., Waltham, MA, USA

**Composite Peptide Conjugate Vaccines Induced Broadly Reactive Serum and Monoclonal Antibodies to Influenza**

**Clara J Sei**, Longhorn Vaccines and Diagnostics, LLC, Gaithersburg, MD, USA

17.30 - 19.30

WELCOME BUFFET  
RECEPTION

8.30 – 10.35

## PROGRAMME

### SESSION 6:

#### SYMPOSIUM - Updates on Clinical Trials

Chairs: **Kimberly Armstrong**, BARDA, Washington DC, USA & **Tim Uyeki**, CDC, Atlanta, GA, USA

#### Two Randomized, Double-Blind, Placebo-Controlled Trials of the Monoclonal Antibody MHAA4549A for Treatment of Influenza A Infection

**Melicent Peck**, Genentech, South San Francisco, CA, USA

#### Baloxavir Marboxil, a Cap-Dependent Endonuclease Inhibitor - Development Updates

**Takeki Uehara**, Shionogi & Co., Ltd, Osaka, Japan

#### RSV Antiviral Treatment for HCT patients: Results from Recent Phase 2 Studies for Presatovir

**Michael Boeckh**, University of Washington, Seattle, WA, USA

#### Overview of RSV and Influenza Programmes

**James Witek**, Janssen Research and Development, Titusville, NJ, USA

#### Randomized Phase 2 Study Evaluating Nitazoxanide Versus Placebo in Hospitalized Subjects with Severe Acute Respiratory Illness

**John Beigel**, NIAID, Bethesda, MD, USA

10.35 – 11.00  
COFFEE/TEA BREAK

11.00 – 13.00

### SESSION 7:

#### SYMPOSIUM - Clinical Trial and Regulatory Issues

Chairs: **Wendy Carter**, FDA, Silver Spring, MD, USA & **Karl Erlandson**, BARDA, Washington DC, USA

#### FDA Considerations for Influenza Drug Development

**Wendy Carter and LaRee Tracy**, FDA, Silver Spring, MD, USA

#### EMA Perspective

**Radu Botgros**, EMA, London, UK

#### Investigator Perspective (Influenza)

**Michael Ison**, Northwestern University, Chicago, IL, USA

#### FDA Perspective of RSV Drug Development

**Prabha Viswanathan**, FDA, Silver Spring, MD, USA

#### How do we Evaluate Experimental RSV Antivirals: An Investigator Perspective

**John DeVincenzo**, University of Tennessee, Memphis, TN, USA



13.00 - 14.15

### LUNCHTIME SEMINAR - Meet-the-Professor

Chairs: **Amy Sims**, University of North Carolina, Chapel Hill, NC, USA & **Frederick Hayden**, University of Virginia School of Medicine, Charlottesville, VA, USA

#### Clinical Management of MERS

**Yaseen Arabi**, King Saud Bin Abdulaziz University for Health Sciences, Riyadh, Kingdom of Saudi Arabia

14.15 - 15.30

### SESSION 8:

#### ORAL ABSTRACTS Session 3 - Clinical Trials

Chairs: **Norio Sugaya**, Keiyu Hospital, Yokohama, Japan & **Nelson Lee**, University of Alberta, Edmonton, Canada

#### Phase 3 Trial of Baloxavir Marboxil in High Risk Influenza Patients (CAPSTONE-2 Study)

**Simon Portsmouth**, Shionogi, Inc., Florham Park, NJ, USA

#### Safety and Efficacy of mAb VIS410 in Adults with Uncomplicated Influenza A Infection: Results from Randomised, Double-Blind, Placebo-controlled Study VIS410-202

**David Oldach**, Visterra, Inc, Waltham, MA, USA

#### Preliminary Results of an Adaptive Study of the Pharmacokinetics of Favipiravir in Patients with Severe Influenza

**Bin Cao**, China - Japan Friendship Hospital, Beijing, China

#### Clinical Efficacy of Ziresovir (AK0529) with Respect to Signs and Symptoms in Infants Hospitalised with RSV Infection

**Stephen Toovey**, Ark Biosciences, Shanghai, China

#### Umifenovir Therapy Improves Outcomes from Secondary Bacterial Pneumonia Following Influenza

**Irina Leneva**, Mechnokov Research Institute for Vaccines and Sera, Moscow, Russian Federation

15.30 - 16.00

COFFEE/TEA BREAK

16.00 - 17.00

### SESSION 9:

#### ROUNDTABLE DISCUSSION - Clinical Trial and Regulatory Issues

Moderator: **Michael Ison**, Northwestern University, Chicago, IL, USA

**Debra Birnkrant**, FDA, Silver Spring, MD, USA

**Jason Chien**, Janssen BioPharma, San Francisco, CA, USA

**Jeffrey Murray**, FDA, Silver Spring, MD, USA

**Tim Uyeki**, CDC, Atlanta, GA, USA

17.15 - 18.30

### VIEWING OF POSTERS AND RECEPTION

8.30 – 10.15

## PROGRAMME

### SESSION 10:

#### ORAL ABSTRACTS Session 4 – Antiviral Resistance

Chairs: **Maria Zambon**, Public Health England, London, UK &  
**Larisa Gubareva**, CDC, Atlanta, GA, USA

##### Introductory Talk: Antiviral Resistance Monitoring Strategies

**Aeron Hurt**, WHO Collaborating Centre, Melbourne, Australia

##### Osetamivir Resistance: Correlating In Vitro IC50 with In Vivo Clinical Effectiveness Using a Ferret Model

**Rubaiyea Farrukee**, WHO Collaborating Centre for Reference and Research on Influenza, VIDRL; University of Melbourne, Australia

##### A Single Amino Acid Substitution (I38T) in the PA Endonuclease Domain Mediates Resistance to Next-Generation Polymerase Inhibitors

**Jeremy Jones**, St. Jude Children's Research Hospital, Memphis, TN, USA

##### Susceptibility of Influenza Viruses to the Novel Cap-Dependent Endonuclease Inhibitor Baloxavir Marboxil

**Emi Takashita**, National Institute of Infectious Diseases, Tokyo, Japan

##### Methods for Testing Influenza Virus Susceptibility to Novel Polymerase Inhibitors

**Larisa Gubareva**, CDC, Atlanta, GA, USA

##### Panel Discussion: Future Challenges of Resistance Monitoring

Moderator: **Maria Zambon**, Public Health England, London, UK

10.15 – 10.45  
COFFEE/TEA BREAK

10.45 – 12.50

### SESSION 11:

#### HOT TOPICS AND LATE-BREAKERS

Chairs: **Ralph Baric**, University of North Carolina, Chapel Hill, NC, USA &  
**Barbara Rath**, Vienna Vaccine Safety Initiative, New Orleans, LA, USA

##### Antiviral Design Against Emerging and Pre-Epidemic Coronaviruses

**Ralph Baric**, University of North Carolina, Chapel Hill, NC, USA

##### Remdesivir Provides Superior Therapeutic Efficacy to Lopinavir, Ritonavir, and Interferon Beta Against MERS-CoV

**Amy Sims**, University of North Carolina, Chapel Hill, NC, USA

##### EDP-938, a Novel Non-Fusion Replication Inhibitor of RSV with High Barrier to Resistance

**Kai Lin**, Enanta Pharmaceuticals, Inc., Watertown, MA, USA

##### Replicative fitness of seasonal influenza A viruses displaying decreased susceptibility to polymerase inhibitor Baloxavir

**Larisa Gubareva**, CDC, Atlanta, GA, USA

##### INSIGHT FLU-IVIG: A Randomised, Placebo Controlled Trial of Influenza Immunoglobulin in the Treatment of Adults Hospitalized with Influenza

**Richard Davey**, NIAID/NIH, Bethesda, MD, USA

##### High-Titer Versus Low-Titer Anti-Influenza Immune Plasma for the Treatment of Severe Influenza A

**John Beigel**, NIAID, Bethesda, MD, USA

##### Examining Clinical Data on Potential Adjunctive Therapies in Influenza

**Nelson Lee**, University of Alberta, Edmonton, Canada

12.50 – 13.10

### SUMMARY AND CLOSE

Lunch and Depart

