6th isirv-AVG Conference
Advances in Respiratory Virus Therapeutics

Tuesday 13th - Thursday 15th November 2018
Hilton Washington DC/ Rockville Hotel, Washington DC, USA

Preliminary Programme

Tuesday 13 November	
08:30-08:45	**Welcome** Chairs: Alan Hay, Francis Crick Institute, London, UK & Frederick Hayden, University of Virginia School of Medicine, Charlottesville, VA, USA
08:45-09:30	**Session 1:** Opening Lecture Chairs: Frederick Hayden, University of Virginia School of Medicine, Charlottesville, VA, USA & Alan Hay, Francis Crick Institute, London, UK BARDA Perspectives on Advancing Respiratory Virus Therapeutics *Rick Bright, BARDA, Washington, D.C., USA*
09:30-11:00	**Session 2 :** Symposium - Preclinical Topics Chairs: Amy Krafft, NIAID/NIH, Rockville, MD, USA & TBC 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 Break**
11:30-13:00	**Session 3:** Oral Abstract Session 1- Preclinical Development Chairs: Robert Krug, University of Texas at Austin, Austin, TX, USA & TBC Preclinical characterization of CC-42344, a broad spectrum, potent influenza A PB2 inhibitor for potential triple route (oral, inhalation, and IV) treatment - *Sam Lee* The therapeutic potential of reducing neutrophil activation and migration using different strategies in models of murine influenza A infection - *Cristiana Garcia* Chemical Intervention of Influenza Virus RNA Nuclear Export - *Matthew Esparza*

	VH244: a novel broad spectrum antiviral for respiratory virus infections with a wide therapeutic window in vivo - *Isabel Najera* Small molecules targeting HRSV M2-1 - *Ralf Altmeyer* Targeting Host-Cell Metabolism To Address Respiratory Viruses - *Eain Murphy*
13:00-14:15	**Sponsored Lunchtime Seminar – Janssen** Clinical Outcome Endpoints in Trials of Respiratory Viral Illness: Needs & Novel Ideas 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, Illinois, USA* Hospital Recovery Scale – The Pimodivir experience with an Ordinal Scale Endpoint *Lorant Leopold, Janssen Pharma R&D, Titusville, NJ, USA*
14:15-15:00	**Session 4:** Symposium- Clinical Trial Design Issues Chairs: Wendy Carter, FDA, Silver Spring, MD, USA & TBC 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*
15:00-15:30	**Coffee Break**
15:30-17:00	**Session 5:** Oral Abstracts Session 2- Antivirals and Monoclonal Antibodies Chairs: Martin Friede, WHO, Geneva, Switzerland & TBC Orally Available Broad-Spectrum Anti-Influenza Ribonucleoside Analog Inhibitor with Potent Efficacy in Ferrets and Differentiated Human Airway Epithelia - *Richard Plemper* Pharmacodynamic effect of different dosage regimes of oseltamivir in severe influenza patients requiring mechanical ventilation - *Wai-Tat Wong* Combination effects of baloxavir acid with neuraminidase inhibitors against influenza B virus in vitro - *Keiko Baba* Antiviral therapy against influenza B virus infection in immunocompromised murine model - *Philippe Noriel Pascua* In Vitro Antiviral Assessments of VIS410, a Monoclonal Antibody to Influenza A Virus, in Combination with Baloxavir and Neuraminidase Inhibitors - *Kristin Narayan* Composite Peptide Conjugate Vaccines Induced Broadly Reactive Serum and Monoclonal Antibodies to Influenza – *Clara j Sei*
17:00-18:00	**Welcome Buffet Reception**

Wednesday 14 November	
08:30-10:35	**Session 6:** Symposium - Updates on Clinical Trials Chairs: Kimberly Armstrong, Biomedical Advanced Research and Development Authority (BARDA), Washington DC, USA & Tim Uyeki, CDC, Atlanta, GA, USA Evaluation of Anti-HA Stem Monoclonal Antibody FluA in Two Phase 2 Influenza Studies *Melicent Peck, Genentech, South San Francisco, California, 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, New Jersey, 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 Break**
11:00-13:00	**Session 7:** Symposium- Clinical Trial and Regulatory Issues Chairs: Wendy Carter, FDA, Silver Spring, MD, USA & Karl Erlandson, Biomedical Advanced Research and Development Authority (BARDA), Washington DC, USA FDA Considerations for Influenza Drug Development ○ Trial Designs for Serious Influenza ○ Therapeutic Combinations (Antivirals, Adjunctive Therapies) ○ Pediatric Considerations *Wendy Carter, FDA, Silver Spring, MD, USA* Statistical Considerations/Endpoints *LaRee Tracy, FDA, Silver Spring, MD, USA* EMA Perspective *Radu Botgros, EMA, London, UK* Investigator Perspective (Influenza) *Michael Ison, Northwestern University, Chicago, Illinois, USA* FDA Perspective of RSV Drug Development *Prabha Viswanathan, FDA, Silver Spring, MD, USA* Investigator Perspective (RSV) *John DeVincenzo, University of Tennessee, Memphis, Tennessee, USA*
13:00-14:00	**Lunchtime Seminar** 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 – Meet-the-Professor *Yaseen Arabi, King Saud Bin Abdulaziz University for Health Sciences, Riyadh, Kingdom of Saudi Arabia*

14:00-15:30	**Session 8:** Oral Abstract Session 3- Clinical Trials Chairs: Norio Sugaya, Keiyu Hospital, Yokohama, Japan & TBC Phase 3 Trial of Baloxavir Marboxil in High Risk Influenza Patients (CAPSTONE-2 Study) - *Simon Portsmouth* 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* Preliminary results of an adaptive study of the pharmacokinetics of favipiravir in patients with severe influenza – *Bin Cao* Clinical efficacy of Ziresovir (AK0529) with respect to signs and symptoms in infants hospitalised with RSV infection - *Stephen Toovey* Umifenovir therapy improves outcomes from secondary bacterial pneumonia following influenza - *Irina Leneva*
15:30-16:00	**Coffee/Tea Break**
16:00-17:00	**Session 9:** Roundtable Discussion- Clinical Trial and Regulatory Issues *Academic, Regulatory and Industry representatives* Moderator: Michael Ison, Northwestern University, Chicago, Illinois, USA *Debra Birnkrant, FDA, Silver Spring, MD, USA* *Jeffrey Murray, FDA, Silver Spring, MD, USA* *Tim Uyeki, CDC, Atlanta, GA, USA* *Jason Chien, Janssen BioPharma, San Francisco, CA, USA*
17:00-18:00	**Poster Session**
Thursday 15 November	
08:30-10:00	**Session 10:** Oral Abstracts Session 4- Antiviral Resistance Chairs: Maria Zambon, Public Health England, London, UK & TBC Introductory Talk: Antiviral Resistance Monitoring Strategies *Aeron Hurt, WHO Collaborating Centre, Melbourne, Australia* Oseltamivir resistance: Correlating in vitro IC50 with in vivo clinical effectiveness using a ferret model - *Rubaiyea Farrukee* A single amino acid substitution (I38T) in the PA endonuclease domain mediates resistance to next-generation polymerase inhibitors - *Jeremy Jones* Susceptibility of influenza viruses to the novel cap-dependent endonuclease inhibitor baloxavir marboxil - *Emi Takashita* Methods for testing influenza virus susceptibility to novel polymerase inhibitors - *Larisa Gubareva*
10:00-10:30	**Coffee Break**
10:30-12:30	**Session 11:** Hot Topics and Late-Breakers Chairs: Ralph Baric, University of North Carolina, Chapel Hill, NC, USA & TBC Antiviral Design Against Emerging and Pre-Epidemic Coronaviruses *Ralph Baric, University of North Carolina, Chapel Hill, NC, USA* Examining Clinical Data on Potential Adjunctive Therapies in Influenza *Nelson Lee, University of Alberta, Edmonton, Canada*
12:30-13:00	Summary and Close of Conference
	Lunch and Depart