

# RSV VACCINES FOR THE WORLD

18-20 November 2015, The Salk Institute, La Jolla, California, USA

# FINAL ORAL PROGRAMME & POSTER PROGRAMME

# RSVVV 2015

## SCIENTIFIC ADVISORY PANEL

Gregory Glenn (*Novavax, Gaithersburg, Maryland, USA*)

Deborah Higgins (*PATH, Seattle, Washington, USA*)

Pedro Piedra (*Baylor College of Medicine, Houston, Texas, USA*)

Gale Smith (*Novavax, Gaithersburg, Maryland, USA*)

Louis Bont (*University Medical Center Utrecht, Utrecht, The Netherlands*)

Geeta Swamy (*Duke College of Medicine, Durham, North Carolina, USA*)

Edward Belongia (*Center for Clinical Epidemiology and Population Health, Marshfield Clinic, Marshfield, Wisconsin, USA*)

Larry Anderson (*Emory University – Children's Center, Atlanta, Georgia, USA*)

Harish Nair (*Usher Institute of Population Health Sciences and Informatics, University of Edinburgh, Edinburgh, UK*)

Steven Varga (*University of Iowa, Iowa City, Iowa, USA*)

Rob Lambkin-Williams (*hVIVO Ltd, London, UK*)



08.30-9.30

Arrival/Registration/Poster Set-Up/Coffee

## OPENING PLENARY SESSION

Moderator: Deborah Higgins (*PATH, Seattle, Washington, USA*)

09.30-10.00

### 'Down Memory Lane with RSV'

Pedro Piedra (*Baylor College of Medicine, Houston, Texas, USA*)

10.00-10.30

### 'Catalyzing RSV Vaccine Development'

Niteen Wairagkar (*Bill & Melinda Gates Foundation, Seattle, Washington, USA*)

10.30-11.00

Coffee Break

## SESSION 1: VIRUS STRUCTURE AND VACCINE DESIGN

Moderator: Gale Smith (*Novavax, Gaithersburg, Maryland, USA*)

11.00-11.30

### 'CryoEM Structures of Envelope Glycoproteins'

Andrew Ward (*Scripps Research Institute, La Jolla, California, USA*)

11.30-12.00

### 'Viral Fusion Proteins: Structures and Vaccines'

Qinghua Wang (*Baylor College of Medicine, Houston, Texas, USA*)

12.00-12.30

### 'Biophysical Characterization of an RSV F Nanoparticle Vaccine'

Oleg Borisov (*Novavax, Gaithersburg, Maryland, USA*)

12.30-13.00

### 'RSV F Protein Stabilized in the Prefusion Conformation via Unique Mutational Elicits Full Protection Against RSV Challenge in Cotton Rats'

Tobias Kamphuis (*Janssen Vaccines, Leiden, The Netherlands*)

13.00-14.00

Lunch Break

## SESSION 2:

### VIRAL EPIDEMIOLOGY AND CLINICAL RELEVANCE

Moderator: Pedro Piedra (*Baylor College of Medicine, Houston, Texas, USA*)

14.00-14.10

### 'RSV Fusion Gene Sequence Variability of Major Antigenic Sites'

Pedro Piedra (*Baylor College of Medicine, Houston, Texas, USA*)

14.10-14.35

### 'Genetic and Antigenic Variability in the Surface Proteins of Respiratory Syncytial Virus (RSV): Evidence from a 20 Years Period Analysis in Santiago de Chile and Houston, Texas'

Lorena Tapia (*Programa de Virología, Instituto de Ciencias Biomédicas, Facultad de Medicina, Universidad de Chile, Santiago, Chile*)

14.35-15.00

### 'Within-Host Deep Sequencing and Diversity Analysis of RSV Infection Reveals Dynamics of Genomic Diversity'

Yonatan H. Grad (*Brigham and Women's Hospital, Harvard Medical School, Boston, Massachusetts, USA*)

15.00-15.25

### 'Molecular Epidemiology and Evolutionary Dynamics of RSV: Clinical Relevance and the Impact of Immune Pressure'

Justin Bahl (*University of Texas School of Public Health, Houston, Texas, USA*)

15.25-16.00

Tea Break & Posters

## SESSION 3: RSV AND ASTHMA

Moderator: Louis Bont (*University Medical Center Utrecht, The Netherlands*)

16.00-16.30

### 'The Epidemiological Link Between RSV and Asthma'

Tina Hartert (*Center for Asthma and Environmental Sciences Research, Vanderbilt University, USA*)

16.30-17.00

### 'We Have Learned from Immunoprophylaxis RCTs'

Eric Simoes (*University of Colorado Denver, Aurora, Colorado, USA*)

17.00-17.30

### 'Asthma Follow-up in RSV Vaccine Trials: How Long is Enough?'

Fernando Martinez (*Arizona Respiratory Center, University of Arizona Health Sciences Center, Tucson, Arizona, USA*)

\* This final programme is correct at the time of printing. However the organizers reserve the right to make any alterations that may be required in the interests and integrity of the final conference programme.

**SESSION 4:  
GENERAL SESSION**

Moderator: Geeta Swamy (*Duke College of Medicine, Durham, North Carolina, USA*)

09.00-09.30

**'Placental Antibody Transfer in Health and Disease: Considerations for an RSV Vaccine in Maternal Immunization'**

Geeta Swamy (*Duke College of Medicine, Durham, North Carolina, USA*)

09.30-10.00

**'Host Response to RSV Infection in Aged Mice'**

Steven Varga (*University of Iowa, Iowa City, Iowa, USA*)

10.00-10.30

**'RSV Vaccines: An unhappy past, an ever brighter future?'**

Rob Lambkin-Williams

(*hVIVO/Retroscreen, Queen Mary University of London, London, UK*)

10.30-11.00

Coffee Break & Posters

**SESSION 5:  
RSV NONCLINICAL STUDIES**

Moderator: Steven Varga (*University of Iowa, Iowa City, Iowa, USA*)

11.00-11.15

**'Proof-of-Principle Studies: RSV Immunoprophylaxis via Antibody Gene Transfer'**

Rebecca J. Loomis<sup>1</sup>, Hua-Ren Cherng<sup>1,2</sup>, Azad Kumar<sup>3</sup>, Barney S. Graham<sup>3</sup> and Philip R. Johnson<sup>1,2</sup> (*1 Children's Hospital of Philadelphia, Philadelphia, USA; 2 University of Pennsylvania, Philadelphia, Pennsylvania, USA; 3 Vaccine Research Center, NIAID/NIH, Bethesda, Maryland, USA*)

11.15-11.30

**'A Non-Glycosylated G Protein Vaccine Protects against Homologous and Heterologous Respiratory Syncytial Virus Challenge'**

Sandra Fuentes, Elizabeth Coyle, Hana Golding and Surender Khurana (*Center for Biologics Evaluation and Research (CBER) / FDA, Silver Spring, Maryland, USA*)

11.30-11.45

**'Addition of CpG with Inulin-Derived Adjuvant Skews Towards Th1-Phenotype in Vaccination Against Respiratory Syncytial Virus'**

T.M. Wong, N. Petrovsky and T.M. Ross (*University of Georgia, Athens, Georgia, USA*)

11.45-12.00

**'Recombinant Low-Seroprevalent Adenoviral Vectors Ad26 and Ad35 Expressing the RSV F Protein Induce Potent Th1 Skewed Immune Responses and are Protective Against RSV Challenge in Rodents'**

Leslie van der Fits, Myra Widjojoatmodjo, Lies Bogaert, Dominika Czapska, Renske Bolder, Marjolein van der Meer, Jort Vellinga, Jerome Custers, Hanneke Schuitemaker and Roland Zahn (*Janssen Infectious Diseases and Vaccines, Leiden, The Netherlands*)

12.00-12.15

**'An Oral Adenovirus Vaccine Platform for RSV'**

S. Tucker, C.D. Scallan, E. Dora, K. Hodgson and J. Lindbloom (*Vaxart Inc., San Francisco, California, USA*)

12.15-12.30

**'Protective Immunogenicity of RSV-Vaccine Candidates Based on the Modified Vaccinia Virus Ankara (MVA) Platform Technology in Mice and Cotton Rats'**

Frank-Peter Wachs<sup>1</sup>, Ultan Power<sup>2</sup>, Caroline Quinn<sup>2</sup>, Gail Leeming<sup>3</sup>, Hanni'ah Abdullah<sup>2</sup>, Kevin C Yim<sup>4</sup>, Jorge Blanco<sup>4</sup>, James W Jackson<sup>1</sup> and Sonja Leyrer<sup>1</sup> (*1 Emergent BioSolutions Inc., Rockville, Maryland, USA; 2 Centre for Infection and Immunity, Queen's University, Belfast, Northern Ireland; 3 School of Veterinary Science and Department of Infection Biology, University of Liverpool, Liverpool, UK; 4 Sigmovir Biosystems, Rockville, Maryland, USA*)

12.30-12.45

**'The development of a prefusion F-type RSV subunit vaccine'**

Kees Leenhouts (*Mucosis BV, Groningen, The Netherlands*)

12.45-14.00

Lunch Break & Posters

**SESSION 6:  
RSV CLINICAL TRIALS**

Moderator: Deborah Higgins (*PATH, Seattle, Washington, USA*)

14.00-14.30

**'Randomized Phase 2 Trial of an RSV F nanoparticle vaccine in the elderly: Epidemiology and Efficacy'**

Edward Belongia (*Center for Clinical Epidemiology & Population Health, Marshfield Clinic Research Foundation, Marshfield, Wisconsin, USA*)

14.30-15.00

**'Phase 2 Trial of an RSV F Nanoparticle Vaccine in Pregnant women towards maternal immunization'**

Allison August (*Novavax, Gaithersburg, Maryland, USA*)

15.00-15.30

**'A Phase 1b Randomized Study of MEDI7510, an Adjuvanted RSV Vaccine for Older Adults'**

Judith Falloon (*MedImmune, Gaithersburg, Maryland, USA*)

15.30-16.00

**'A Passive Vaccine Approach to RSV Prophylaxis for All Infants: Results of a Phase 1 Study in Healthy Adult Volunteers'**

M. Pamela Griffin (*MedImmune, Gaithersburg, Maryland, USA*)

16.00-16.30

Tea Break & Posters

**SESSION 7:  
LATEBREAKERS SESSION**

Moderator: Rob Lambkin-Williams (*hVIVO, London, UK*)

16.00-16.15

**'Lung administration of an RSV vaccine with an M protein deletion induces high titers of neutralizing antibody in the infant baboon model'**

Robert C. Welliver Sr<sup>1</sup>, A. Oomens<sup>2</sup>, R. Wolf<sup>1</sup>, J. Papin<sup>1</sup>, V. Ivanov<sup>1</sup>, A. Preno<sup>1</sup>, S Henry<sup>1</sup> and P. Piedra<sup>3</sup> (*1 University of Oklahoma Baboon Reserve, 2 Oklahoma State University, Oklahoma City, Oklahoma, USA; 3 Baylor College of Medicine, Houston, Texas, USA*)

16.15-16.30

**'A paradigm shift: A next generation anti-RSV F monoclonal antibody as a passive immunization for prevention of RSV disease in all infants'**

N. Ulbrandt<sup>1</sup>, N. Kallewaard<sup>1</sup>, S. Palaszynski<sup>1</sup>, J. Zhang<sup>1</sup>, C. Svabek<sup>1</sup>, J. McAuliffe<sup>1</sup>, B. Moldt<sup>1</sup>, A. Yuan<sup>1</sup>, K. Cook<sup>1</sup>, B. Richter<sup>1</sup>, G. Robbie<sup>1</sup>, M. Kwakkenbos<sup>2</sup>, E. Yusada<sup>2</sup>, T. Beaumont<sup>2</sup> and J. Suzich<sup>1</sup> (*1 MedImmune, Gaithersburg, Maryland, USA; 2 AIMM Therapeutics, Amsterdam, The Netherlands*)

16.30-16.45

**'Intradermal delivery of a single-dose of a non-replicating DNA-based vaccine provides immunity against respiratory syncytial virus'**

Trevor Smith (*INOVIIO Inc., San Diego, California, USA*)

16.45-17.00

**'Protective efficacy of native respiratory syncytial virus-like particles (RSV VLPs) in cotton rat model of RSV disease'**

Pramila Walpita, Lisa Johns and Ravi Tandon (*University of Hawaii School of Medicine, Honolulu, Hawaii*)

17.00-17.15

**'RSV infection and vaccines: Antigenic fingerprinting following RSV vaccination and infection identify novel vaccine targets'**

Surender Khurana, Sandra Fuentes and Hana Golding (*Center for Biologics Evaluation and Research (CBER) / FDA, Silver Spring, Maryland, USA*)

**SESSION 8:**

**RSV IN OLDER ADULTS: EPIDEMIOLOGY, IMMUNOLOGY AND LESSONS LEARNED FROM INFLUENZA**

Moderator: Edward Belongia (*Center for Clinical Epidemiology and Population Health, Marshfield Clinic, Marshfield, Wisconsin, USA*)

09.00-09.30

**'RSV Epidemiology and Burden in the Elderly'**

Ann Falsey (*University of Rochester Medical Center, Rochester, New York, USA*)

09.30-10.00

**'The Human Viral Challenge Model and Development of RSV vaccines for the Elderly'**

Anthony Gilbert (*hVIVO/RetroScreen, Queen Mary University of London, London, UK*)

10.00-10.30

**'Planning for an RSV Vaccine in Older Adults: Lessons Learned from Influenza'**

Lisa Jackson (*Group Health Research Institute, Seattle, Washington, USA*)

10.30-11.00

Coffee Break & Posters

**SESSION 9:**

**CONSIDERATIONS FOR RSV IMMUNE MEASURES**

Moderator: Larry Anderson

(*Emory University – Children's Center, Atlanta, Georgia, USA*)

11.00-11.25

**'Measuring Immunity in Young Children'**

Eric Simoes (*University of Colorado Denver, Aurora, Colorado, USA*)

11.25-11.50

**'Measuring Immunity in Adults'**

Ann Falsey (*University of Rochester Medical Center, Rochester, New York, USA*)

11.50-12.15

**'Other Immune Measures'**

Larry Anderson (*Emory University – Children's Center, Atlanta, Georgia, USA*)

12.15-12.30

**'Survey of Diverse RSV Neutralization Assays Using a Common Sample Panel'**

Nancy Hosken (*PATH, Seattle, Washington, USA*)

12.30-14.00

Lunch Break & Posters

**SESSION 10:**

**GLOBAL RSV BURDEN AND HEALTH ECONOMICS**

Moderator: Harish Nair (*Usher Institute of Population Health Sciences and Informatics, University of Edinburgh, Edinburgh, UK*)

14.00-14.35

**'Global burden of RSV in young children'**

Harish Nair (*Usher Institute of Population Health Sciences and Informatics, University of Edinburgh, Edinburgh, UK*)

14.35-14.55

**'RSV burden in preterm infants'**

Louis Bont (*University Medical Center Utrecht, Utrecht, The Netherlands*)

14.55-15.15

**'Gaps in RSV data and proposed designs for future burden studies'**

Harry Campbell (*Usher Institute of Population Health Sciences and Informatics, University of Edinburgh, Edinburgh, UK*)

15.15-15.35

**'The cost of hospitalisation associated with RSV in young children'**

Shanshan Zhang (*Usher Institute of Population Health Sciences and Informatics, University of Edinburgh, Edinburgh, UK*)

15.35-16.00

**'The global impact of an RSV vaccine: Methods and initial estimates of vaccine impact'**

Nathaniel Hendrix (*PATH, Seattle, Washington, USA*)

16.00-16.10

**Closing Remarks**

Greg Glenn (*Novavax, Gaithersburg, Maryland, USA*)

16.10

Departure

**POSTER SESSION**

Poster 101

**'Towards a reliable intranasal immunization procedure for RSV vaccines in non-human primates'**

Michael Citron, Mona Purcell, Paul McQuade, Daniel Rubins, Marie Holahan, Mark Knowler, Ioan Petrescu, Cynthia Spencer-Bauer, Walter Knapp, Tony Cabal, Jeff Sachs, Chinedu Orekie, Sai Chamarthy, Cheryl Callahan, Manishkumar Patel, Lin Shu-An, Andrew Bett, Daniel DiStefano and Amy Espeseth (*Merck & Co., Inc., Kenilworth, New Jersey, USA*)

Poster 102

**'Influenza virus and respiratory syncytial virus infections in immunocompetent and immunocompromised patients and ferrets'**

K.J. Stittelaar<sup>1</sup>, L. de Waal<sup>1</sup>, E. Van der Vries<sup>2</sup>, G. van Amerongen<sup>1</sup>, W. Huisman<sup>1</sup>, E.J.B. Veldhuis Kroeze<sup>1</sup>, C.A. van Baalen<sup>1</sup>, P.L.A. Fraaij<sup>2</sup>, J.J. van Kampen<sup>2</sup>, M. Schutten<sup>1</sup>, R.L. de Swart<sup>2</sup> and A.D.M.E. Osterhaus<sup>1</sup> (*1 Viroclinics Biosciences B.V., Rotterdam, The Netherlands; 2 Erasmus Medical Centre, Rotterdam, The Netherlands*)

Poster 103

**'RSV F subunit vaccine adjuvanted with GLA-SE: Pre-clinical evaluation of immunogenicity, efficacy and enhanced disease in the cotton rat model'**

Kirsten Schneider-Ohrum<sup>1</sup>, Corinne Cayatte<sup>1</sup>, Angie Snell<sup>1</sup>, Gaurav Rajani<sup>1</sup>, Krystal Nacel<sup>2</sup>, Leigh Hostetler<sup>2</sup>, Lily Cheng<sup>3</sup> and Michael P. McCarthy<sup>1</sup> (*1 Infectious Disease and Vaccines, 2 Laboratory Animal Resources and 3 Pathology Department, MedImmune, Gaithersburg, Maryland USA*)

Poster 104

**'Delivery of DNA vaccines to RSV by different routes can alter the outcome of infection from enhanced disease to protection'**

E. Kinnear<sup>1</sup>, L. Caproni<sup>2</sup> and J.S. Tregoning<sup>1</sup> (*1 Group of Mucosal Infection and Immunity, Department of Medicine, Imperial College London, London, UK; 2 Touchlight Genetics, Leatherhead, UK*)

Poster 105

**'Preclinical evaluation of a novel epicutaneous vaccine against respiratory syncytial virus'**

Pierre-Louis Herve *et al.* (*DBV Technologies, Bagneaux, France*)

Poster 106

**'Analysis of clinical isolates of Respiratory Syncytial Virus (RSV) for Palivizumab resistant mutants in Korean children'**

Yae-Jean Kim *et al.* (*Sungkyunkwan University, Seoul, Republic of Korea*)

Poster 107

**'Qualification of a fluorescent foci-based RSV microneutralization assay and the effect of complement enhancement on neutralization titers from subjects in a Phase 1a study that were vaccinated with RSV sF or RSV sF plus glucopyranosol lipid A – stable emulsion (GLA-SE) (MED17510)'**

Cindy Shambaugh *et al.* (*MedImmune, Mountain View, California, USA*)

Poster 108

**'Hospitalization and mortality due to respiratory syncytial virus pneumonia in infants in rural Nepal'**

Helen Y. Chu *et al.* (*University of Washington, Seattle, Washington, USA*)

Poster 109

**'Total IgG and RSV-specific transplacental antibody transfer in Seattle, Washington'**

Helen Y. Chu *et al.* (*University of Washington, Seattle, Washington, USA*)

Poster 110

**'RSV fusion gene sequence variability among contemporary and historical genotypes'**

Anne M. Hause, David M. Henke, Vasanthi Avadhanula, Chad A. Shaw and Pedro A. Piedra (*Baylor College of Medicine, Houston, Texas, USA*)

Poster 111

**'Sera derived from immunization with a recombinant RSV F-protein nanoparticle vaccine obtained from cotton rats and women of child-bearing age, contains antibodies competitive with neutralizing monoclonals against multiple epitopes'**

Hanxin Lu *et al.* (*Novavax Inc., Gaithersburg, Maryland, USA*)