

December 5-7 2017
MIAMI, FL

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ONCOLYTIC VIROTHERAPY

Summit 2017



The leading end-to-end industry forum dedicated to accelerating the clinical development of the next generation of immuno-oncolytic virotherapies for use in combinations

Expert Speakers Include:



Matt Mulvey
CEO
Benevir Biopharm



Angelica Loskog
CEO
Lokon Pharma



Charles Morris
CDO
PsiOxus Therapeutics



Stephen Russell
CEO
Vyriad



Stephen Thorne
CEO
Western Oncolytics



Rob Coffin
CEO
Replimune



Frank Tufaro
CEO
DNAtrix



Matt Coffey
CEO
Oncolytics Biotech

Partners



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Tel: +1 212 537 5898 | E: info@hansonwade.com | [in](#) Oncolytic Viruses

Researched &
Developed By:



Welcome to the 3rd Annual Oncolytic Virotherapy Summit

Enhancing the clinical efficacy of oncolytic virotherapies through genetic engineering, combination strategies and streamlining delivery of therapeutics to patients in need.

After two years of Imlygic being on the market, fresh new phase 2 data in combination with checkpoint modulating drugs has yielded promising results leading to a surge of interest from immuno-oncology developers looking to collaborate with the leaders in Oncolytic Virotherapy.

The Oncolytic Virotherapy Summit will gather the leaders in immuno-oncolytic virus development to discuss the most up-to-date clinical advances alongside novel innovations being made through the genetic modification of viruses.

Map out the route to market focusing on the strategic advancements needed to improve viral manufacturing yield and scale along with the operational and logistical aspects of delivering oncolytic virotherapies to patients in need.

This year's **Oncolytic Virotherapy Summit** sets the stage for oncolytic viruses to be the combination therapeutic of choice through enhanced tumor microenvironment and immune modulating activity.

Hear What Previous Attendees Have To Say:

“Extraordinary and valuable niche meeting to follow the exciting growth of oncolytic virotherapies.”

Unleash Immuno Oncolytics

“Very well organized, relaxed setting conducive to interactions among attendees and speakers”

MedImmune

Effectively Navigating Oncolytic Virus Development

- 1 Prime the immune system response to disease through effective oncolytic viruses combination immunotherapies
- 2 Overcome the inhibitory effects of the tumor microenvironment with novel mechanisms to target cytokines or through genetic manipulation
- 3 Improve the delivery method of viruses so they are less invasive and operationally easier to administer
- 4 Achieve the right viral volumes and dosages effectively whilst decreasing costs for large scale manufacture of oncolytic virotherapies
- 5 Overcome operational handling hurdles of Oncolytic Viruses to ensure healthcare facilities are geared up for “live” oncolytic virotherapies

“The meeting included very useful networking sessions which is great to meet new people that are experts in the OV field.”

Merck



Expert Speaker Faculty



Matt Mulvey
CEO
Benevir Biopharm



Matteo Di Piazza
Principal Scientist
**Boehringer
Ingelheim**



Frank Tufaro
CEO
DNAtrix



Samuel Rabkin
Professor of
Neurosciences,
Neurosurgery
**Harvard Medical
School**



Robert Andtbacka
Co-Director Melanoma
Program & Melanoma
Clinical Research
Program
**Huntsman Cancer
Institute**



Angelica Loskog
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Matt Coffey
CEO
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Charles Morris
CDO
PsiOxus Therapeutics



Rob Coffin
CEO
Replimune



Douglas Jolly
EVP, Research &
Pharmaceutical
Development
Tocagen



Monika Lusky
Director
Transgene



Noriyuki Kasahara
Professor,
Departments of
Cell Biology and
Pathology
University of Miami



Sari Pesonen
VP, Scientific &
Clinical Development
Valo Therapeutics



Joe Connor
CSO
Virtu Biologics



Stephen Russell
CEO
Vyriad



Stephen Thorne
CEO
Western Oncolytics

“Extremely useful conference to meet other players in the modern OV development, which will make a change in how we are going to treat diseases like cancer.”

Boehringer Ingelheim

Conference Day One | Tuesday December 5th, 2017

8.00 **Breakfast & Registration**

9.00 **Chair's Opening Remarks**

Combination Therapies: Checkpoint Modulation & Beyond



Robert Andtbacka
Co-Director
Melanoma
Program
Co-Director
Melanoma Clinical
Research Program
**Huntsman Cancer
Institute**

9.30 **Development Strategy of HF10, a Spontaneous Mutant Herpes Simplex Virus**

- HF10 is the spontaneous mutant strain of HSV-1 with attenuated virulence and lack of neuroinvasiveness. Because of no exogenous gene (ex. GM-CSF), there is less regulatory hurdles
- Oncolytic viruses are categorized as regenerative medicine products in Japan, and could be approved based on the limited endpoint data, if the product has an effect that is reasonably likely to predict clinical benefit
- The combination of HF10 and Ipilimumab demonstrated a favorable benefit/risk profile and encouraging antitumor activity in patients with stage IIIB, IIIC, or IV unresectable or metastatic melanoma
- Neoadjuvant HF10 and Nivolumab in resectable metastatic melanoma is being investigated, and is likely to yield clinical benefit
- Endoscopic ultrasound guided HF10 injection in pancreatic cancer has also been established



Joe Conner
CSO
Virtu Biologics

10.00 **The Horse Before the CAR-T? Pretreatment With Oncolytic Herpes Simplex I Viroimmunotherapy Augment CAR-T Cell Therapy**

- While CD19-directed CARs demonstrate significant anti-leukemic efficacy, CARs directed against solid tumors have been less successful. Some potential explanations include limited CAR tumor-homing and infiltration, insufficient proliferation, and poor persistence
- These findings are likely attributable to the immunosuppressive microenvironment, oncolytic viroimmunotherapy is an attractive adjunct to cellular therapies, as these attenuated viruses not only cause direct tumor-specific cell death, but also induce pro-inflammatory signals
- We sought to determine whether the use of oHSV might enhance third-generation GD2-directed human CAR-T cell efficacy in GD2-expressing tumors. Using flow cytometry, we confirmed our CARs expressed CXCR-3 and CCR-5, allowing chemotactic signaling through CXCL-10 and CCL-5, respectively. In transwell migration assays, we found increased CAR migration toward oHSV-infected over non-infected tumor cells
- Survival studies using athymic nude mice and cyclophosphamide lymphodepletion prior to CAR therapy demonstrated delayed tumor growth and prolonged survival of mice treated with combination therapy compared to CAR monotherapy
- These results indicate that Seprehvir is a valuable adjunct to CAR T-cell therapy and the combination should be further explored

10.30 **Morning Refreshments & Speed Networking**

OVs and the Tumor Microenvironment



Charles Morris
CDO
**PsiOxus
Therapeutics**

11.30 **An Oncolytic Virus Expressing a FAP-Specific T-Cell Engager to Target Storm-Rich Tumors**

- Enadenotucirev (EnAd) is a chimeric oncolytic group B adenovirus with potent and selective anti-tumor activity against a range of epithelial cancer cells, with a blood stability profile that enables systemic dosing and has been administered intravenously to over 100 cancer patients
- Cancer-associated fibroblasts (CAFs) play a pivotal role in the development of solid carcinomas by facilitating invasion, coordinating angiogenesis and establishing and maintaining an immune suppressive microenvironment in the tumor stromal tissue
- As an approach to immunogene therapy targeting stromal rich tumors, transgene-modified variants of EnAd expressing a bi-specific T-cell engager (BiTE) molecule recognizing human fibroblast activating protein (FAP) on cancer associated fibroblasts (CAFs) and CD3 on T-cells have been produced
- Clinical candidates are in preparation to test whether production of BiTE proteins by virus infected tumor cells could be an effective way of modifying the stromal microenvironment to drive effective anti-tumor immunity and would bypass delivery and safety issues related to systemic dosing of BiTE proteins



Sari Pesonen
VP, Scientific &
Clinical
Development
Valo Therapeutics

12.00 PeptiCRAd™: An Innovative Oncolytic Vaccine Platform to Refocus the Immune Response from Virus to Tumor

- Our results clearly show that PeptiCRAd is superior to oncolytic virus or peptide vaccinations
- With the PeptiCRAd approach, tumour specific peptides were efficiently cross-presented in an MHC-I restricted manner. In addition, both the frequency of dendritic cells cross-presenting the PeptiCRAd peptides and the frequency of peptide-specific CD8+ T-cells were clearly elevated in PeptiCRAd treated animals compared to virus alone or virus with non-complexed peptide
- PeptiCRAd technology combines peptide vaccination and oncolytic virus-based immunotherapy, to deliver a highly synergistic anti-tumor effect
- This strategy can be used to rapidly and cost efficiently target different tumors and antigens without the need to manipulate the viral backbone
- Phase I/II clinical trial is in preparation



Matt Mulvey
CEO
Benevir Biopharm

12.30 T-Stealth™ Technology Promotes Synergy Between Oncolytic Viruses and Immuno-Stimulatory Agents

- The immune system is both friend and foe to OV: OV need the immune system to attack and kill uninfected tumor cells, but the immune system is best at eliminating viruses rather than cancer
- To be successful, regimens combining OV and immune-stimulatory agents must deal with the downsides of anti-viral innate and adaptive immune responses in the tumor microenvironment without affecting anti-tumor immunity
- BeneVir platform OV encode T-Stealth™ Technology, which hides OV from both innate and adaptive immunity in order to mitigate the downsides of anti-viral immunity without negatively affecting anti-tumor immune responses

13.00 Lunch & Networking

OVs to Elicit True Immune Responses



Rob Coffin
CEO
Replimune

14.00 Introducing Replimune's Next Generation "Immulytic™" Oncolytic Immunotherapy Platform

- Oncolytic immunotherapy requires the robust virus-mediated destruction of tumors by immunogenic cell death, with the accompanying release of tumor antigens (including neoantigens), combined with the stimulation of potent anti-tumor immune responses to provide systemic clinical benefit
- Replimune has developed a new oncolytic immunotherapy platform which aims to maximize each of these properties and therefore maximize the clinical benefit which can be achieved
- This is intended to generate a potent and practical tumor neoantigen vaccine in situ within the patient which is potentially appropriate for the treatment of all solid tumor types, particularly in combination with other therapies such as those targeting PD-1/L1
- In addition to providing enhanced tumor cell death and viral spread within the tumor, Replimune's Immulytic platform delivers multiple potent immune activating proteins directly to tumors and draining lymph nodes, focusing on the targeting of pathways which may best be activated or inhibited at the site of immune response initiation, rather than through the use of systemic antibody approaches
- This includes the delivery of optimized versions of the ligands for the immune co-stimulatory pathways and antibody-like molecules targeting CTLA-4, both of which Replimune has found to be very powerful means by which to augment systemic effects and the "Immulytic" delivery of which Replimune believes may supersede other approaches to addressing these targets. Replimune's first product, RP1, has recently initiated a large Phase 1/2 clinical trial in multiple tumor types, including in combination with anti-PD1 therapy



Matteo Di Piazza
Principal Scientist
**Boehringer
Ingelheim**

14.30 Roundtable Discussion: Preclinical Drug Safety

- Species selection
- Biodistribution and shedding
- Translation of preclinical dosing to FIH
- Assessment of immunogenicity

15.30 Chair's Closing Remarks

16.00 End of Day 1

Conference Day Two | Wednesday December 6th, 2017

8.00 **Registration & Coffee**

9.00 **Chair's Opening Remarks**

Improving Delivery of OV's Intravenous vs. Intratumoral



Angelica Loskog
CEO
Lokon Pharma

9.30 **Local L0Ad703 Virus Administration Results in Enhanced Efficacy Compared to Systemic Treatment.**

- In this project, systemic versus local (intratumoral) administration have been compared in vivo with or without neutralizing antibodies (nAbs) to understand if also local delivery is hampered by nAbs
- The treatment effect was better using local delivery likely due to the higher concentration of virus reaching the tumor
- Further, nAbs abolished the effect of systemic L0Ad703 while local delivery could still control the tumor. Local delivery was effective in a wide range of tumor models and could be combined with systemic chemotherapy or checkpoint blockade antibodies
- Local (intratumoral) delivery is effective despite the presence of neutralizing antibodies
- Systemic (intravenous) delivery is hampered by neutralizing antibodies
- L0Ad703 is potent across different tumor models and can be combined with chemotherapy or checkpoint blockade antibodies



Stephen Thorne
CEO
Western Oncolytics

10.00 **Achieving the Right Viral Volumes and Dosages Effectively**

- Increasing yields/decreasing costs for large scale manufacture of oncolytic virotherapies
- Producing viruses at large doses whilst driving down cost of goods
- Outsourcing GMP virus manufacture and ensuring reliable products
- How do we ensure this is a commercially viable product that can be administered globally?

10.30 **Morning Refreshments & Networking**



Rob Coffin
CEO
Replimune



Charles Morris
CDO
PsiOxus Therapeutics



Stephen Russell
CEO
Vyriad



Joe Connor
CEO
Virtu Biologics

11.00 **PANEL: How Can We Improve The Efficacy of Oncolytic Virotherapies?**

- Viral modulation of the tumor microenvironment
- Increasing the viral impact with activated immune responses
- Combination drug therapies to stimulate the immune response and prevent immunosuppression
- Viral delivery for largest impact



Clinical Trial Case Studies

Hear updates on the most advanced clinical programs to discover how the application of oncolytic viruses is being successfully utilised in the clinic.



Monika Lusky
Director
Transgene

12.00 Vaccinia Virus-based Oncolytic Immunotherapy: Ongoing Early and Late Stage Clinical Development

- IPexa-Vec (pexastimogene devacirepvec, JX-594) is an oncolytic and immunotherapeutic vaccinia virus (Wyeth strain) which selectively replicates in and destroys cancer cells.
- A randomized open-label Ph 3 study conducted by Transgene's partner SillaJen is ongoing comparing the efficacy and tolerability of Pexa-Vec plus sorafenib vs sorafenib in advanced first line HCC patients
- An update of Transgene's early stage clinical trials in various indications and in combination with checkpoint blockade will be presented
- Furthermore, operational hurdles encountered in the set-up of clinical trials and educational measures developed for physicians and clinical staff will be discussed
- TG6002 is an oncolytic vaccinia virus (Copenhagen strain) armed with Fcu1, a chimeric enzyme which locally activates the prodrug 5-FU into 5-Fu at the tumor replication site
- Preclinical studies have shown a strong contribution of the immune system in the mechanism of action
- The clinical development of TG6002 is currently starting, with a planned Ph1/2a trial in glioblastoma by the intravenous (IV) route, and possibly gastrointestinal tumors



Stephen Russell
CEO
Vyriad

12.30 VSV-IFN β -NIS and MV-NIS: A Tale of Two Paradigms.

Vyriad is committed to a multiplatform approach to oncolytic immunovirotherapy. The company is currently evaluating VSV and measles oncolytic platforms in early stage clinical trials, and has additional platforms in preclinical development.

- VSV-IFN β -NIS is a low seroprevalence oncolytic virus that drives high level intratumoral IFN β to harness multiple tumor killing mechanisms.
- MV-NIS is a fusogenic measles virus which can persist even in measles-immune subjects, providing a durable stimulus to antitumor immunity.
- The NIS transgene is used for pharmacokinetic imaging of virus spread and to boost efficacy with targeted radioiodine therapy
- Both MV-NIS and VSV-IFN β -NIS have been shown to impact antitumor immunity and induce tumor regression
- Each virus has unique advantages and single agent clinical trials are currently being pursued with combination trials envisaged.



Matt Coffey
CEO
Oncolytics Biotech

13.00 Immune and Genetic Markers in Randomized Clinical Studies using REOLYSIN®

- Clinical research to date in the field of oncolytic virus immunotherapy has yielded promising results. However, as with any novel therapeutic area, it has also presented many challenges
- In order to effectively treat patients, much remains to be discovered regarding the genetic profiles and other characteristics of patients who are most likely to benefit from this type of therapy which are likely specific to each viral vector employed, and the optimal treatment protocols to ensure maximum patient benefit
- Such questions can only be answered definitively in a randomized clinical trial setting
- This presentation will examine the lessons thus far from Oncolytics' randomized studies in head and neck, ovarian, pancreatic, prostate, squamous cell NSCLC, adenocarcinoma of the lung, and colorectal cancer utilizing its oncolytic virus, REOLYSIN®, in an immunotherapeutic context, and explore outstanding areas of enquiry in the field

13.30 Lunch & Networking

Overcoming Operational Handling Hurdles of OV's



Douglas Jolly
EVP, Research &
Pharmaceutical
Development
Tocagen

14.30 Understanding the Risks of Viral Shedding and Ensuring Steps are in Place to Deal with Potential Negative Effects

- How do you measure and account for viral shedding in patients to ensure environmental isolation
- How do you interpret viral shedding data and what are the side effects we need to prevent
- What regulations and controls need to be in place to prevent healthcare incidences of infection spread
- Ensuring the safety and efficacy of "live" viral drugs in patients and the environment
- Overcoming viral latency in the host to prevent reinfection
- Inhibiting genetic integration and viral replication outside of the tumor environment
- Preventing viral recombination in the wider environment and avoiding creation of a new virus



Noriyuki Kasahara
Professor,
Departments of
Cell Biology and
Pathology
**University of
Miami**

15.00 Ensuring Healthcare Facilities are Primed for "live" Oncolytic Virotherapies

- Educating the health care service on viral handling and infection control for safety of frontline carers
- Executing clinical trials effectively to ensure you have buy-in from physicians and healthcare providers
- Preventing spread and viral shedding into the community

15.30 Chair's Closing Remarks: The Future of Oncolytic Virotherapies

16.00 Close of Summit

“The Summit provided great talks including focused and inspiring topics. Hope to see you next year!”

MIT



Workshop A

Novel Approaches for Oncolytic Virus Combination Therapies

Thursday December 7th | Time: 9:00am-12:00pm

The field is in agreement that oncolytic viruses are likely to be most efficacious in combination therapies, alongside recent T-Vec phase 2 combination data and the immuno-oncology revolution there is a huge driver progressing rational oncolytic virus combinations.

Attend this session to discuss:

- Combinations with immuno-oncology therapeutics
- DNA Damage response and repair combinations
- How combinations can modulate the TME for enhanced efficacy

- What are the various different strategies and approaches for combinations
- Preparing combination trials effectively in the clinic with the appropriate end points
- Understanding the combination therapy's mechanism of action

Leave this session with an understanding of the pros and cons of the various combination strategies and how they are playing out in the clinical setting.



Workshop leader

Samuel Rabkin, Professor of Neurosciences, Neurosurgery, **Harvard Medical School**

Samuel D. Rabkin is the Thomas A. Pappas Professor in Neurosciences and Professor of Neurosurgery (Microbiology & Immunobiology) at Harvard Medical School, Boston MA, and Virologist in Neurosurgery at Massachusetts General Hospital, Boston, MA. He is an Associate Editor of Molecular Therapy-Oncolytics. After obtaining his PhD at the University of Chicago, he was an Assistant Member in Molecular Biology at Memorial Sloan-Kettering Cancer Center, New York, NY, and an Associate Professor in Neurosurgery at Georgetown University Medical Center, Washington DC. Dr. Rabkin's research has focused on the development of oncolytic herpes simplex viruses for cancer therapy. He is an inventor on 14 US patents.

Workshop B

Optimizing Oncolytic Viruses: Identifying the Right Viral Platform

Thursday December 7th | Time: 13:00pm-16:00pm

Each and every oncolytic virotherapy program works on a different one of the many viruses that exist from HSV through to the coxsackie virus. But what is the optimum viral platform and do they vary in their efficacies?

Attend this session to discuss:

- How do you choose a viral platform successfully?
- How can we begin to use the multitude of viruses available to target cancer?
- Which is the "right" virus to use?

- Does using a different virus result in different effects and what does this mean for the disease indication?
- Are different viruses separate products?
- Do the regulations need to vary when using different viruses?
- Can you use different OV's sequentially to treat multiple tumors?

With so many potential unknowns, explore the landscape of different viral platforms and how each product can potentially be utilized for the best clinical efficacy.



Workshop leader

Stephen Russell, CEO, **Vyriad**

Dr. Russell is a Professor of Molecular Medicine, Consultant Hematologist at Mayo Clinic Rochester and serves on the Board of Trustees of Buena Vista University, Iowa. He was formerly the Dean for Discovery and Experimental Research at Mayo Clinic. He obtained his MD from the University of Edinburgh, Scotland and his PhD from the University of London, England. He trained at University College Hospital and the Royal Marsden Hospital, London, then moved to Cambridge, England, where he led a research team in the MRC Laboratory for Molecular Biology, founded Cambridge Genetics, a biotechnology/drug discovery company that succeeded through a series of mergers, and was a practicing consultant hematologist at Addenbrooke's Hospital. In 1998 he moved to Mayo Clinic where he chaired the Department of Molecular Medicine, built a comprehensive translational gene and virus therapy program, developed innovative technologies for targeting viruses to cancer cells, and orchestrated the first-in-human testing of oncolytic Measles and Vesicular stomatitis viruses.

Partners

Partner



Transgene

Part of Institut Merieux, is a publicly traded French biopharmaceutical company focused on discovering and

developing targeted immunotherapies for the treatment of cancer and infectious diseases. Transgene's programs utilize viral vector technology with the goal of indirectly or directly killing infected or cancerous cells. The Company's two lead clinical stage programs are: TG4010 for non-small cell lung cancer and Pexa-Vec for liver cancer. The Company has several other programs in clinical and pre-clinical development. Transgene is based in Strasbourg, France, and has additional operations in Lyon, as well as satellite offices in China and the U.S.

www.transgene.fr

Exhibitor



Paragon

Working as an outsourcing partner, and with a long-standing tradition of quality and service, Paragon

expands the capabilities of pharmaceutical companies, biotechnology companies and academic laboratories involved in identifying, developing and producing monoclonal antibodies, therapeutic proteins, disease biomarkers, vaccines and reagents for diagnostics. Paragon's focus is the development and manufacturing of biopharmaceutical protein drugs. As a contract development and manufacturing organization (CDMO), Paragon is positioned to capitalize on industry trends—including consolidation in the pharmaceutical industry, all-encompassing "Programmatic Outsourcing", and the looming imperative that is National Preparedness.

www.paragonbioservices.com

Exhibitor



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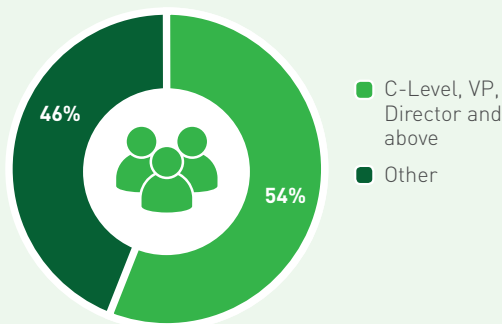
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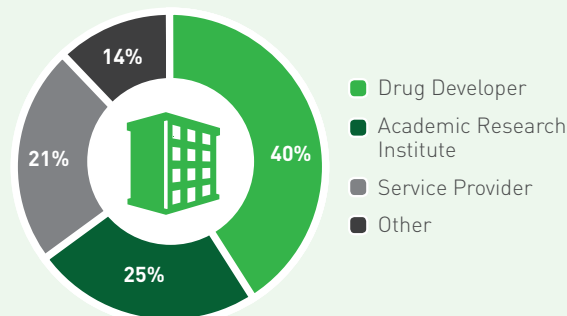
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www.donshulahotel.com



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Full payment is due on registration. Cancellation and Substitution Policy: Cancellations must be received in writing. If the cancellation is received more than 14 days before the conference attendees will receive a full credit to a future conference. Cancellations received 14 days or less (including the fourteenth day) prior to the conference will be liable for the full fee. A substitution from the same organization can be made at any time.

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