Maximizing Immunogenicity, Improving Scalable Manufacturing and Overcoming Regulatory Hurdles of Neoantigen Based Cancer Therapies

Expert Speakers Including:

Andrew Allen  
Chief Executive Officer  
Gritstone Oncology

Richard Gaynor  
President of R&D  
Neon Therapeutics

Elisa Scarselli  
Chief Scientific Officer  
Nouscom AG

Laronna Colbert  
Medical Officer, CBER  
FDA

Hideho Okada  
Professor & Director of Brain Tumor Immunotherapy Program  
University of California, San Francisco

Fred Ramsdell  
Vice President, Research  
Parker Institute for Cancer Immunotherapy

Mette Husbyn  
Chief Technical Officer  
Vaccibody

Jessica Flechtner  
Chief Scientific Officer  
Genocea Biosciences

Drew Pardoll  
Director, Bloomberg-Kimmel Institute for Cancer Immunotherapy  
Johns Hopkins Medicine

Tel: +1 617 455 4188  Mail: info@hansonwade.com  Neoantigens in Immunotherapy
Join the Exploding Neoantigen Community

The 3rd NeoAg Summit is the leading end-to-end industry-focused meeting dedicated to advancing neoantigen-based cancer vaccines and cell therapies.

The NeoAg Summit brings together pioneers personalizing immunotherapies to showcase the most up-to-date advances in neoantigen prediction & validation.

Boost the success of neoantigen targeting by truly understanding complexities of the immune response.

Gain clarity from the FDA & EMA on regulatory requirements in clinical development and CMC.

Move freely between 2 parallel tracks focusing on prediction & discovery; clinical development & manufacturing to choose the talks most valuable for you and maximize your time out of the office.

Join leaders from Neon Therapeutics, Gritstone Oncology, Moderna, Genentech & Parker Institute for Cancer Immunotherapy as they share their approaches to overcoming key challenges and accelerating safe, effective and commercially viable neoantigen-based immunotherapies.

Your Checklist to Advancing Neoantigen-Based Immunotherapies

1. Evaluate neoantigen prediction approaches to fine tune clinical relevance. Learn from computational methods of Gritstone and the TESLA consortium as well as the ATLAS bioassay method from Genocea.

2. Obtain a complete picture of the immune response to improve the efficacy of your therapy. Let the leading immunology experts from Immunicum and the Mayo Clinic guide you through how to induce the right response.

3. Learn from case studies of past clinical trials to avoid any potential pitfalls. Absorb the most advanced data from Neon and Genentech.

4. Navigate the regulatory landscape for faster approval. Representative from the FDA will give perspectives on clinical development personalized immunotherapy.

5. Streamline personalized manufacturing to minimize time and cost maximizing market access opportunities. Get in depth knowledge on DNA and mRNA process development from Vaccibody and Moderna.
Your Expert Speakers

Mark Klinger
Head of TCR Discovery
Adaptive Biotechnologies

Mark Findeis
Senior Director Research Biochemistry
Agenus

Dennis Underwood
Vice President of Molecular & Information Systems
Agenus

Geoffrey Lynn
Chief Executive Officer
Avidia Technologies

Wei Li
Professor & Dan L Duncan Chair in Cancer Research
Baylor College of Medicine

Stephen Johnston
Chief Executive Officer
Calviri

Eustache Paramithiotis
Vice President, Discovery
Caprion Biosciences

William Watt
Chief Executive Officer
EpiThany

Laronna Colbert
Medical Officer, Office of Tissues & Advanced Therapies, CBER FDA

Mahesh Yadav
Research & Early Development Scientist
Genentech

Niranjan Y. Sardesai
Chief Executive Officer & President
Geneos Therapeutics

Jessica Flechtner
Chief Scientific Officer
Genocea Biosciences

Erin Jones
Global Head of Regulatory Affairs and Quality Assurance
Gritstone Oncology

Roman Yelensky
Chief Technology Officer
Gritstone Oncology

Andrew Allen
Chief Executive Officer
Gritstone Oncology

Rongfu Wang
Professor & Director of Center for Inflammation & Epigenetics
Houston Methodist

Julia Kodysh
Computational Researcher
Icahn School of Medicine at Mount Sinai

Alex Karlsson-Parra
Co-Founder & Chief Scientific Officer
Immunicum AB

Sune Justesen
Chief Scientific Officer
Immunitrack

Drew Pardoll
Director of Bloomberg-Kimmel Institute for Cancer Immunotherapy
Johns Hopkins Medicine

Keith Knutson
Professor of Immunology
Mayo Clinic

David Pajerowski
Director, Process Development & CMC, Personalized Vaccines Unit
Moderna Therapeutics

Marc Wolfgang
Vice President of Technical Operations
Neon Therapeutics

Richard Gaynor
President of R&D
Neon Therapeutics

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www.neo-antigen.com   Neoantigens in Immunotherapy
This was my first Hanson Wade Summit and I really enjoyed it. I was quite impressed by the quality of speakers. The meeting being focused on a single topic it was small enough in size to allow for good networking opportunities. It also offered a good representation of the state of the industry.

Parker Institute for Cancer Immunotherapy
Conference Day One | Thursday November 15 2018

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<thead>
<tr>
<th>Time</th>
<th>Session Title</th>
<th>Presenter/Institution</th>
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<tbody>
<tr>
<td>8.00</td>
<td>Registration &amp; Morning Refreshments</td>
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<tr>
<td>8.45</td>
<td>Chair’s Opening Remarks</td>
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<tr>
<td>9.00</td>
<td>Public vs Private Neoantigens – Can Both Be Used Therapeutically?</td>
<td>Fred Ramsdell, Vice President of Research, Parker Institute for Cancer Immunotherapy</td>
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<tr>
<td></td>
<td>• Therapeutics targeting public neoantigens can be “off-the-shelf” but patient selection is key – likely only a subset of solid tumors display these targets</td>
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<td>• Most solid tumor patients could benefit from personalized immunotherapy against private neoantigens – neoantigen identification and product manufacturing are critical</td>
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<td>• An ability to elicit profound T cell responses in humans is a likely obligate requirement of both approaches</td>
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<td>9.30</td>
<td>Improved induction of neoantigen-specific T cells with self-assembling nanoparticles</td>
<td>Geoffrey Lynn, CEO, Avidea Technologies</td>
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<td>• Properties of peptide-based vaccines that impact CD8 T cell induction</td>
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<tr>
<td></td>
<td>• Self-assembling nanoparticles allow rapid, reliable manufacturing and enhanced CD8 T cell induction</td>
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<td></td>
<td>• Validation of epitope prediction algorithms in mice</td>
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<td>• Primate models for translation</td>
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<td>10.00</td>
<td>An Integrated Machine-Learning Approach to Improve the Prediction of Clinically Relevant Neoantigens</td>
<td>Trevor Clancy, Co-Founder &amp; CSO, Oncolmmunity</td>
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<td></td>
<td>• Here, we outline a high-performing machine learning approach, trained on mass spectrometry data, that predicts naturally processed and presented antigens</td>
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<td>• The predictor is integrated with several immune parameters, such as HLA binding, in a deep learning layer to predict bone fide neoantigens</td>
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<td>• We illustrate its application to significantly improve the identification of neoantigen targets for personalized cancer immunotherapy</td>
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<tr>
<td>10.30</td>
<td>Speed Networking &amp; Morning Refreshments</td>
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Prediction & Discovery

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<tbody>
<tr>
<td>11.30</td>
<td>TESLA Consortium: Update on Neoantigen Predictions</td>
<td>Fred Ramsdell, Vice President of Research, Parker Institute for Cancer Immunotherapy</td>
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<tr>
<td></td>
<td>• Over two dozen distinct computational pipelines exist for neoantigen prediction</td>
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<td>• These pipelines utilize over a dozen different parameters to select peptides for vaccines</td>
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<td>• The identity of the key factors in the selection of validated peptides are not clear</td>
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<td>• Using 4 different bioassays, including patient-derived cells, the consortium is characterizing the key factors in peptide prediction</td>
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Clinical Development & Manufacturing

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<tr>
<td>11.30</td>
<td>Neoantigen-targeting T Cell Therapy for Brain Cancer</td>
<td>Hideho Okada, Professor &amp; Director of UCSF Brain Tumor Immunotherapy Program, University of California, San Francisco</td>
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<td></td>
<td>• Overview of the neoantigen landscape for malignant gliomas</td>
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<td>• Development of vaccine and T cell therapies targeting the novel H3.3K27M-derived neoantigen</td>
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<td>• Unique challenges related to antigen heterogeneity of malignant gliomas</td>
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<tr>
<td>12.00</td>
<td>Neoantigen Prediction: Approach and Validation</td>
<td>Roman Yelensky, Chief Technology Officer, Gritstone Oncology</td>
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<td>• Neoantigen identification for cancer immunotherapy remains a significant challenge</td>
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<td>• Tumor immunopeptidomics combined with deep learning provides a powerful approach for neoantigen prediction</td>
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<td>• Gritstone’s EDGETM prediction model identifies therapeutically relevant neoantigens</td>
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<td>12.00 Neoantigen Targeted CD8 T Cell Responses Via Optimized DNA Immunotherapy</td>
<td>Niranjan Y. Sardesai, CEO &amp; President, Geneos Therapeutics</td>
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<td>• Tumor neoantigen targeting has emerged as a viable approach for treating cancer</td>
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<td>• Beyond prediction and selection algorithms, neoantigen delivery platforms and platform potency are important considerations to drive neoantigen targeted immune responses in vivo</td>
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<td>• Plasmid DNA based ASPIRE® platform for development of neoantigen targeted personalized cancer immunotherapy</td>
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### 12.30 Immunitrack: a Unique Platform for Supporting Immuno-Oncology Projects

- NPPrDx: a best-in-class peptide:MHC stability predictor, trained on proprietary peptide:MHC I & II stability assay data. The PrDx software can generate up to 80% less false-positives (compared to netMHC) with the identification of larger subsets of T-cell epitopes.
- Best-in-class peptide/MHC stability and affinity assays (US and European client contracts).
- Addresses the unmet client production need for customized MHC/epitope complexes and reagents

**Sune Justesen**, Chief Scientific Officer, **Immunitrack**

### 14.30 Better Predictive Algorithms for Neoantigens and T cell Clonal Recognition: AI-MHC, Deepseq, and MANAFEST

- MANAFEST - a new platform for assessing antigen recognition, identifies broad recognition of mutation-associated neoantigens, including those derived from driver oncogenic mutations.
- Allele independent MHC (AI-MHC) - a new convolutional network strategy to improve prediction of T cell epitopes.
- Prediction of clinical response to immunotherapy based on T cell clonal dynamics within the tumor.

**Drew Pardoll**, Director of Bloomberg-Kimmel Institute for Cancer Immunotherapy, **Johns Hopkins Medicine**

### 15.00 Beyond Algorithms: The ATLAS Bioassay Method for Neoantigen Identification and Characterization

- HLA agnostic assay identifies CD4 and CD8 T cell neoantigens
- Uniquely distinguishes mutations that elicit stimulatory and inhibitory T cell responses
- Personalized neoantigen vaccine using ATLAS entering clinical development.

**Jessica Flechtner**, Chief Scientific Officer, **Genocea Biosciences**


- Mass cytometry and highly-multiplexed combinatorial peptide-MHC tetramer staining was used to longitudinally monitor neoantigen-specific CD8+ T cells in PBMC from 14 NSCL cancer patients treated with atezolizumab
- 782 candidate tumor neoantigens as well as 73 control peptides (mostly virus-derived epitopes) were screened across all patient samples
- T cell reactive for 13 different neoantigens were identified by unbiased analysis across all patients
- 9 out of 13 Neoantigen specific T cell responses were detected in patients with objective response (n=8) compared to only 4 hits in patients with progressive disease

**Mahesh Yadav**, Research & Early Development Scientist, **Genentech**

### 15.00 Personalized Adoptive NeoE-specific TCR-T Cell Therapies for Cancer

- Validation beyond Predictions: imPACTTM technology for the identification and isolation of neoE-specific T cells that constitute the intrinsic immune response in cancer patients
- Expanding the neoE specific T cell repertoire beyond HLA-A2
- Precision genome engineering of primary human T cells
- PACT’s non-viral technology for personalized neoE TCR engineering
- Functional characterization of personalized adoptive neoE-specific TCR-T cells – the path to clinical development

**Alex Franzussoff**, Chief Executive Officer, **PACT Pharma**

### 16.00 From Sample to Neoantigens for Vaccines: Key Challenges and Solutions

- Improving neoantigen identification
- Elaborating TME, immuno-modulators and vaccine response biomarkers
- Overcoming poor sample quality and quantity for NGS sequencing
- Overcoming sequencing gaps that can harbor neoantigens
- cfDNA neoantigens: dealing with tumor heterogeneity
- Validation and regulatory issues on the way to commercialization

### 16.30 Clinical Considerations for Neoantigen-based Cancer Therapy - A Regulatory Perspective

- Current landscape of Neoantigen-based cancer therapies
- Challenges in clinical trial design
  - Study population
  - Target identification and selection
  - Safety and Efficacy Endpoints
- Opportunities to further advance the field

### 17.00 Chair’s Closing remarks
**Conference Day Two | Friday November 16 2018**

### 8.45 Chair’s Opening Remarks

**Richard Gaynor**  
President of R&D  
Neon Therapeutics

### 9.00 Neoantigen Approaches as Personal and Precision Cancer Therapeutics

**Eustache Paramithiotis**, Vice President, Discovery, Caprion Biosciences

- Neon Therapeutics is a clinical-stage immuno-oncology company that utilizes multiple therapeutic modalities, and both personal and precision approaches, to target neoantigens in a variety of human tumors.
- Neon’s approach in the personalized vaccine setting currently includes utilizing a personal neoantigen vaccine in combination with a checkpoint inhibitor and, in certain cases, chemotherapy, to treat patients with high mutational burden tumors in the metastatic setting.
- As part of Neon’s personalized T cell approach, Neon is investigating ex vivo immunization of multiple T cell populations that are generated to target each individual patient’s unique set of neoantigens.
- Finally, as part of Neon’s precision approach, Neon is working to identify neoantigens that are conserved in specific tumors across a broader spectrum of patients and can be adapted for treatment through either vaccine or T cell based therapies.

### 9.30 Optimization of cancer vaccine development by using Multiplexed Identification of T-cell Receptor Antigen Specificity (MIRA)

**Mark Klinger**  
Director of TCR Discovery  
Adaptive Biotechnologies

- Generating immunogenicity data to antigens of interest at scale informs antigen selection for improved vaccine design and development.
- Adaptive Biotechnologies has developed a novel, highly sensitive approach known as Multiplexed Identification of T cell Receptor Antigen specificity (MIRA).
- MIRA combines high-throughput T-cell receptor (TCR) repertoire sequencing with conventional immune techniques to assess T cell specificity to hundreds query antigens at a time with a sensitivity of one in 10 million naïve human T cells.
- To validate this approach, we assessed biologically relevant T-cell immune responses against more than 350 neoepitopes using T cells sourced from the naïve repertoire of 50 healthy donors to leverage the massive diversity of the naïve TCR repertoire and identify ultra-low frequency antigen-specific T cell responses.

### 10.00 A CMO Approach to Supporting Personalized Peptide Vaccines

**Trishul Shah**  
Director of Business Development  
PolyPeptide Group

- What PolyPeptide has set-up
- Our approach to regulatory aspects of personalized peptide vaccines
- Challenges and how they were overcome

### 10.30 Morning Refreshments & Networking

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| **11.00** Identification and Characterization of Presented Tumour Neo- Epitopes from Metastatic Colon Cancer  
- Primary cancer data  
- Metastatic cancer  
- Normal tissue expression  
- Functional characterisation  
**Eustache Paramithiotis**, Vice President, Discovery, Caprion Biosciences | **11.00** TG01 - A Neo-antigen Specific Peptide Vaccine Targeting RAS Mutations in Solid Tumors  
- RAS mutations, a well characterised neo-antigen and therefore a most attractive target  
- TG01, a 7 peptide vaccine able to cover 98% of RAS mutations in pancreas cancer  
- Encouraging phase II clinical data using  
- TG01 in combination with adjuvant chemotherapy in resected pancreas cancer  
**Magnus Jaderberg**, Chief Medical Officer, Targovax |

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**Tel:** +1 617 455 4188  
**Mail:** info@hansonwade.com  
**www.neo-antigen.com**  
**Neoantigens in Immunotherapy**
11.30 Presentation of MHC Bound Phosphopeptides from Primary Patient Tissue Enables the Identification of Prevalent Molecular Targets for Vaccines and Cell Therapy

- Post-translational modification is central to the control of cellular pathways and are critical to a transformed cancerous state.
- The presentation of phosphopeptides on MHCs follows distinct allele preferences that reflect both the anchors required for strong MHC binding and motifs that mirror dysregulated kinases pathways. We will describe these.
- Identification of clear immune responses to phosphopeptides and not to unmodified peptides reflects the role of phosphorylation in breaking tolerance. Experiments showing immune responses in mouse experiments post vaccination will be described. In addition, highly specific TcRs to phosphopeptide MHC complexes will be described.

**Dennis Underwood**, Vice President of Molecular & Information Systems, Agenus

11.30 Heat Shock Protein Chaperoned Synthetic Peptide Cancer Vaccines

- Vaccine format: Heat shock protein noncovalently complexed peptides
- Use of the protein chaperone is dose sparing, reduces amount of antigenic peptide required
- Vaccine is adjuvanted with clinically validated QS-21

**Mark Findels**, Senior Director Research Biochemistry, Agenus

12.00 Identification of Tumor-resident and Circulating Neoantigen-specific Lymphocytes

- Identification of neoantigen-specific lymphocytes from the tumor and peripheral blood
- Identification of neoantigens in patients with low mutation burden
- Comparison of techniques available for identification of personalized neoantigens

**Alena Gros**, Group Leader, Tumor Immunology & Immunotherapy

12.00 Th1 Epitopes for Versatile Tumor- and Patient-tailored Vaccine Combination Therapies (VCT)

- EpiThany develops multiantigen cancer vaccines from a neo-repertoire of Th1-selective epitopes arising from overexpressed tumor antigens
- Multiple Phase 1 patient studies of our vaccines have demonstrated antigen-specific IFNg T cell titers comparable or superior to neo-epitope platforms, epitope spreading, and enhanced survival
- Retrospective analyses of archived epitopes for immune phenotype (Th1 or Th2) and a spectrum of genomic features suggests sequence homology to bacterial/fungal species may confer immunogenic properties

**William Watt**, Chief Executive Officer, EpiThany

12.30 Lunch & Networking

13.30 Development and Testing of Cancer-type Specific Vaccines based on Frameshift Neoantigens

- Recurrent frameshift neoantigens are produced in tumors in RNA processing
- Immune reactions to the FS neoantigens can be detected by a simple blood assay
- Vaccines focused on particular cancer types can be pre-made from common FS neoantigens

**Stephen Johnston**, Chief Executive Officer, Calviri

13.30 Adjuvants for Peptide Based Cancer Vaccines – Are We There Yet?

- What are vaccine adjuvants – a general overview
- Why are adjuvants crucial for Neoantigen-based Cancer Vaccines
- What does the cancer vaccine field use and are they good enough?

**Dennis Christensen**, Head of Vaccine Adjuvant Research, Statens Serum Institute

14.00 Sources of variability in neoantigen prediction

- Status update on neoantigen trials at Mount Sinai
- Description of the genomics/neoantigen prediction pipeline used for those trials
- Exploration of how much our predictions change as we change the tools used in this pipeline

**Julia Kodysh**, Computational Researcher, Icahn School of Medicine at Mount Sinai

14.00 Interrogating the Right Signals to Induce the Right Immune Response

- "Danger" signals, not "stranger" signals, as the main promoters of DC-mediated cross-priming of MHC class I restricted CD8+ T cells
- Allogeneic, off-the-shelf, "stranger"-stimulated DCs (alloDCs) promote efficient "danger"-mediated cross-priming of CD8+ T cells by endogenous "bystander" DCs
- The adenovector Ad5PTDf35 efficiently transduce alloDCs with with genes coding for tumor-specific antigens

**Alex Karlsson-Parra**, Co-Founder & Chief Scientific Officer, Immunicum AB
**14.30 High Tumor Burden Mandates a Cancer Vaccine Targeting many Neoantigens**

- Great Apes Ad (GAd) vaccination is highly effective as stand-alone treatment in an early therapeutic setting
- Large established tumors are resistant to cancer vaccination
- Resistance can be overcome by a vaccine targeting many neoantigens combined with immunomodulators

*Elisa Scarselli,* Chief Scientific Officer, *Nouscom AG*

**14.30 Meeting the Neoantigen Vaccine Challenge with Virotherapeutics**

- The place of neoantigen vaccines in the immunotherapeutic landscape
- Engineering improvements of viral vaccines for enhanced immunogenicity and efficacy
- Rethinking manufacturing paradigms to reduce lead time, cost and environmental impact of bespoke vaccines.

*Kaïdre Bendjama,* Project Leader, Personalized Vaccines, *Transgene SA*

**15.00 Vaccinating Against Neoantigens Induced in Concurrent and Future Tumors**

- Experiments in advanced murine tumor models have shown that the approach was devoid of measurable toxicity, and was superior to vaccinating against “personalized” neoantigens
- Vaccinating against induced neoantigens overcomes the main limitations of targeting endogenous tumor neoantigens, generating clonal neoantigens, preventing immune evasion, and applicable to all patients (including the majority of patients that do not expressing endogenous neoantigens)

*Elia Gilboa,* Professor & Director of Dodson Interdisciplinary Immunotherapy Institute at Miller School of Medicine, *University of Miami*

**15.00 Manufacturing, Regulatory and Logistics Challenges in the Rapidly Evolving Area of Individualized Therapeutic Cancer Vaccines: The Road to FASTDNA at a low cost One-Stop-Shop**

- Plasmid DNA vaccine
- Game changing regulatory environment
- Logistics

*Mette Husbyn,* Chief Technical Officer, *Vaccibody*

**15.30 Afternoon Break and Networking**

**16.00 A Novel Small-molecule Approach to Induce De-novo Neoantigen Creation**

- NeoPhore is creating drug inhibitors of DNA mismatch repair for cancer immunotherapy
- Mismatch repair is a highly validated target: genetic MMR deficiency generates neoantigens and checkpoint blockade sensitivity in both lab and clinical settings
- Mismatch repair inhibitors should exhibit efficacy across many cancer types, in combination with both checkpoint blockade and other immunostimulatory strategies

*Jeff Roix,* Chief Executive Officer, *NeoPhore*

**16.00 Strategic Management of COGs and Manufacturing Turnaround for Personalized Cancer Vaccine Development**

- Setting targets
- Identifying and asses sing opportunities
- Prioritizing improvement projects

*Marc Wolfgang,* Vice President of Technical Operations, *Neon Therapeutics*

**16.30 Mechanisms of Immune Suppression in the Tumor Microenvironment**

- Understand the multiple mechanisms of immune suppression that are utilized by cancers to evade immune-mediate destruction
- Understand mechanisms underpinning the therapeutic efficacy of inhibitors of the PD-1/PD-L1 immune regulatory axis
- Understand emerging strategies to reverse local immune suppression in the tumor microenvironment

**17.00 Chair's Closing Remarks**

**17.15 Close of Summit**
Workshop A

Maximizing the Chances of Immunogenicity of Neoantigen-Based Treatments to Improve Success Rates

9.00 - 12.00

Bioinformatics and mass spectroscopic predictions for epitope binding to MHC Class I has improved greatly. However, the immune response to selected neoantigens is still not well understood and cannot be determined easily.

In this workshop we discuss principles for the induction of effective neoantigen T cell responses.

Attendees will learn about:
- Why some epitopes are recognized and some are not?
- Is selecting for driver mutations the way to go?
- Reasoned approach to the selection of neoantigens
- The need to characterize the pre-existing T cell response to neoantigens in patients to be treated
- Are cross-reactive responses deleterious?

Workshop Leader
Antonella Vitiello  
Founder & CEO  
PersImmune

Dr. Antonella Vitiello founded PersImmune in 2010. Presently, PersImmune is conducting a clinical trial (NCT03258359) of personalized adoptive T cell therapy targeting MDS stem cell neoantigens (PACTN).

Workshop B

Neoantigen Selection, Prediction and Validation to Improve Target Efficacy

13.00 - 16.00

Identification of tumor antigens and neoantigens is critical to the success of immune targeting in next generation cancer vaccines and cell immunotherapies. A variety of methods are being employed to approach neoantigen calling.

In this workshop we explore the landscape of techniques and technologies in the development of neoantigen-based therapies.

Attendees will learn about:
- Optimal process for neoantigen selection
- Case studies for various methods for identification and validation of neoantigen
- Approaches that are less costly and time consuming
- Immune dominance of neoantigens and dual recognition of neoantigens by a single T cell receptor

Workshop Leader
Rongfu Wang  
Professor & Director of Center for Inflammation & Epigenetics  
Houston Methodist

Professor Rongfu Wang currently serves as the Director of the Center for Inflammation and Epigenetics and Professor of Microbiology and Immunology, Weill Cornell Medicine, Cornell University.

Workshop Leader
Michal Bassani-Sternberg  
Director, Immunopeptidomics Unit, Lausanne Branch, Ludwig Institute for Cancer Research  
University of Lausanne

Michal Bassani-Sternberg integrates mass spectrometry based immunopeptidomics into the innovative translational clinical strategy of personalized immunotherapy.
Neoantigen based vaccines and cell therapies have made significant progress and as commercialization draws closer, limitations in personalised manufacturing process is causing the effective therapies to be expensive and time consuming to produce. This bootcamp brings together quality, regulatory and process development perspectives to give you a comprehensive boost in your CMC approaches.

Attendees will learn about:
- Understanding Regulatory Requirements and Cutting Time and Cost of Manufacturing
- Experiences and perspectives in working with FDA & EMA
- Regulatory and Compliance Considerations in the Manufacture of Individualized Medicines
- Approaches to release tests that cut time and cost
- Optimizing process development

Workshop Leader
Erin Jones
Senior Vice President and Global Head of Regulatory Affairs and Quality Assurance
Gritstone Oncology

Erin Jones is senior vice president and global head of regulatory affairs and quality assurance at Gritstone Oncology. Previously, he oversaw BLA submissions and ODAC preparations for Nerlynx™, Kadcyla™ and Perjeta™ in HER2-positive breast cancer, and approvals for Herceptin™ in breast and gastric cancers. He has directed regulatory development of dozens of small molecules, monoclonal antibodies, antibody-drug conjugates, plasmids, adenoviral gene therapies, and companion diagnostics in oncology and hematology at Genentech, BioMarin, Cephalon and Centocor. He received his M.S. in computer systems at Pennsylvania State University.

Workshop Leader
David Pajerowski
Director, Process Development & CMC, Personalized Vaccines Unit
Moderna Therapeutics

David Pajerowski is Director of Process Development and CMC for Moderna’s Personalized Vaccines Unit. Previously, he was Associate Director of PD and Tech Transfer at WuXi AppTec in Philadelphia, where he focused on the manufacturing readiness of cell therapy and AAV processes. Prior to 2014, Dave held multiple roles within MS&T and PD at Merck and Company in West Point, PA. His experience spans from early development to commercial support of licensed vaccine products, and crosses cell culture and purification of mRNA, VLP and live virus vaccines, gene therapy vectors, and cell therapies. Dave holds a Doctorate in Biological Engineering from the University of Pennsylvania, and obtained his Bachelors of Chemical Engineering from the University of Delaware.

The Neoantigen Summit is the focal point for updates in the cancer neoantigen vaccine field and should be attending by everybody with a keen interest in the field.
OncoImmunity is a bioinformatics company offering proprietary machine-learning based software to address the key knowledge gaps in the prediction of bone fide immunogenic neoantigens for personalized cancer immunotherapy. OncoImmunity is dedicated to develop software solutions that facilitate effective patient selection for cancer immunotherapy, and identify optimal neoantigen targets for truly personalised cancer vaccines & cell therapies in clinically actionable time-frame.

www.oncoimmunity.com

Adaptive Biotechnologies is a pioneer in combining high-throughput sequencing and expert bioinformatics to profile T-cell and B-cell receptors. Adaptive Therapeutics' platform allows the discovery of potent, ultra-low frequency TCRs with differentiated therapeutic potential. This TruTCR® engine combines Adaptive's foundational immunosequencing platform with a multiplex approach to map TCRs to antigens at high specificity plus pairSEQ® to accurately pair TCR alpha/beta chains. Adaptive has discovered and is validating candidate TCRs with superior cytolytic activity in oncology.

www.adaptivebiotech.com

Avidea Technologies (Baltimore, MD) is using self-assembling nanoparticles to improve the manufacturing, safety, and efficacy of immunotherapies. Avidea's lead program is a personalized cancer vaccine (PCV) based on peptide neoantigen-TLR-7/8a conjugates that self-assemble into nanoparticles (“SNP-7/8a”). Avidea has validated a process for manufacturing SNP-7/8a as a PCV under cGMP and demonstrated that SNP-7/8a safely induces robust neoantigen-specific T cell responses in mice and primates. Clinical testing of SNP-7/8a is planned for early 2019.

www.avideatechnologies.com

Personalis, Inc. provides genomic solutions to support the development of personalized cancer vaccines and other next-generation cancer immunotherapies. Our patented ACE Technology improves every step in the sequencing process, from nucleic acid extraction, to sequencing, to data analytics. This delivers augmented coverage of difficult-to-sequence genomic regions that are missed with conventional sequencing techniques. This comprehensive approach provides data of the highest quality to enable the rational design and development of effective cancer immunotherapies.

www.personalis.com

Geneos Therapeutics is harnessing the power of advances in genomics, artificial intelligence and cancer immunotherapy to develop patient specific, tumor neoantigen targeted immunotherapies against cancer. The company, created as a spinout of Inovio Pharmaceuticals, has exclusively licensed Inovio’s DNA based ASPIRE® (Antigen Specific Immune Responses) immunotherapy platform for individualized treatments. The versatile platform has demonstrated clinically the induction of antigen specific CD8 T cells and CTL and TIL activity across a variety of therapeutic settings. Geneos’ neoantigen approach is established to deliver large neoantigenic payloads and benefits significantly from the safety profile, potency, and rapid manufacturing turnaround times of plasmid DNA products.

www.geneosbiomarkers.com

The PolyPeptide Group employs approximately 750 staff at sites in Belgium, France, India, Sweden and the USA. The PolyPeptide Group is the world’s largest independent contract manufacturer of therapeutic peptides. The privately-held organization manufactures over one third of all approved peptide drug substances and accounts for over 30% of the sales of outsourced peptide therapeutics worldwide. The Group offers its customers an almost unprecedented long-term security of supply with six GMP facilities worldwide and an exclusive focus on pharmaceutical peptide manufacture.

www.polypeptide.com
Exhibitor

Almac has been supplying peptides to the research community and for clinical trials for over 20 years. The field of personalized cancer vaccines requires a new manufacturing paradigm to ensure high throughput manufacture of multiple neoantigens in an appropriate timescale to the required quality and regulatory standards. Almac has created a unique offering to meet all of those demands, which can be tailored to meet specific client needs.

www.almacgroup.com/api-chemical-development

Exhibitor

Cayman Chemical’s Immunopeptidome Profiling Services enable efficient, cost-effective deep sequence analysis of MHC Class I and II associated peptides by LC-MS/MS, enabling neoantigen identification in cell lines and tumor tissue, and immunogenicity testing of biological therapeutics. Immunopeptidome Profiling is part of Cayman’s diverse suite of discovery services including medicinal chemistry, structure-based drug design, complex multi-step organic synthesis, analytical chemistry, bioanalysis, and custom assay development.

www.caymanchem.com/services

Exhibitor

MedGenome Inc. is a global leader in NGS based biomarker discovery and immunotherapy solutions.

www.medgenome.com

Program Partner

Caprion Biosciences, a CRO laboratory, helps advance biomarker research through scientific partnership and innovative technologies. Our platforms include large-scale proteomic profiling using quantitative mass spectrometry, multi-parametric flow cytometry (peripheral blood and TILs), cytokine testing and ELISpot for monitoring of complex innate and adaptive immune responses. Through a unique approach, we provide discovery and characterization of tumor antigens and neo-epitopes. Our team of expert draws on deep understanding and years of experience in immuno-oncology and immunology.

www.caprion.com

Program Partner

Immunitrack is a spin-out from the academic group that created netMHC. PrdX is a novel peptide MHC stability predictor based on data from our best in class MHC I and II peptide stability assays. Compared to netMHC, PrdX identifies less false positives and is far more specific in identification of potential T cell epitopes. Apart from PrdX we offer in-vitro peptide MHC affinity and stability measurements as well as tetramers. Our platform could support most IO project.

www.immunitrack.com

Exhibitor

Bachem provides a full range of services to the pharma and biotech industries. It specializes in the development of innovative, efficient manufacturing processes and the reliable production of peptide-based active pharmaceutical ingredients. The group has a global reach with more experience and know-how than any other company in the industry. Towards its customers, Bachem shows total commitment to quality, innovation and partnership. Bachem, Pioneering Partner for Peptides.

www.bachem.com

Exhibitor

CPC Scientific is a globally recognized and leading CDMO specializing in synthetic peptide production. We work directly with leaders in the biotechnology and pharmaceutical industries to help bring life-changing therapeutics and diagnostics to market. We boast the largest GMP peptide facility in the world, which successfully has undergone multiple FDA inspections and audits by global pharma organizations. CPC Scientific has the capability of serving customers from early drug discovery stages through clinical trials to commercial manufacturing.

www.cpcscientific.com

Exhibitor

MedGenome Inc. is a global leader in NGS based biomarker discovery and immunotherapy solutions.

www.medgenome.com

Program Partner

Shenzhen Yuce Biotec (Yucebio) is a leading biotech company in China, focusing on neoantigen based tumor immune diagnosis and treatment. We provide a comprehensive solution for clinical unmet need and for potential drug target discovery. Yucebio is a member of TESLA (Tumor Epitope SeLection Alliance), our vision is making cancer immunotherapies more effective!

www.yucebio.com

Exhibitor

Cayman Chemical’s Immunopeptidome Profiling Services enable efficient, cost-effective deep sequence analysis of MHC Class I and II associated peptides by LC-MS/MS, enabling neoantigen identification in cell lines and tumor tissue, and immunogenicity testing of biological therapeutics. Immunopeptidome Profiling is part of Cayman’s diverse suite of discovery services including medicinal chemistry, structure-based drug design, complex multi-step organic synthesis, analytical chemistry, bioanalysis, and custom assay development.

www.caymanchem.com/services

Exhibitor

MedGenome Inc. is a global leader in NGS based biomarker discovery and immunotherapy solutions.

www.medgenome.com
Secure Your Place

3 Easy Ways to Book

1. www.neo-antigen.com/register
2. Tel: +1 212 537 5898
3. Email: register@hansonwade.com

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*Pharma and biotech companies currently and publically developing neoantigen based drugs for therapeutic use.

Team Discounts*

- 10% discount – 3 delegates
- 15% discount – 4 delegates
- 20% discount – 5 or more delegates

Please note that discounts are only valid when three or more delegates from one company book and pay at the same time.

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