HBV Forum: Therapeutic Vaccines Webinar

Tuesday, January 18th, 2022
Introduction

Emily Gainor
Forum for Collaborative Research
# Agenda

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
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<tbody>
<tr>
<td>10:30am ET</td>
<td>Welcoming Remarks</td>
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<tr>
<td>10:40am ET</td>
<td>Overview of Therapeutic Vaccines for HBV</td>
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<tr>
<td>10:45am ET</td>
<td>a. Overview of Therapeutic Vaccines Moving Goals of Therapeutic Vaccines Moving Forward (including a brief discussion on previous strategies)</td>
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<tr>
<td>10:55am ET</td>
<td>Company Presentations:</td>
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<tr>
<td></td>
<td>a. Vir (Michael Schmid)</td>
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<td>b. Virion (Hildegund Erdt)</td>
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<td>c. VBI (Francisco Diaz-Mitoma)</td>
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<td>d. GSK (Ventsi Vassilev)</td>
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<td>e. Alimmune (Sarah Browne)</td>
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<td>12:15pm ET</td>
<td>Discussion &amp; Audience Questions:</td>
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<tr>
<td></td>
<td>a. Optimal combinations</td>
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<td>b. Monitoring response [peripheral, intrasplastic, etc]</td>
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<td></td>
<td>c. Stratification/ patient groups</td>
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<td>d. Endpoints</td>
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<td>12:55pm ET</td>
<td>Conclusions/ Next Steps</td>
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**Moderator:** Adam Gehring, University of Toronto

**Veronica Miller, Forum for Collaborative Research**

**John Tavis, Saint Louis University**

**Ulla Protzer, Technical University of Munich**

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Previous Presenters: Regulators, Patient Representatives

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Adjourn Webinar

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3  | FORUM FOR COLLABORATIVE RESEARCH  | CATALYZING CLINICAL RESEARCH TO IMPROVE GLOBAL HEALTH

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HBV Forum- Therapeutic Vaccines Webinar

- You will be muted on entry
- Clarifying questions may be answered by the presenter
- Discussion will take place after the presentations
- To ask questions or make a comment:
  - If generally applicable to the session, please use the Zoom chat function and send to everyone
  - Or use the raise your hand function
Rules of the [Zoom] Room

- Presentations, discussions, comments, and questions are not for attribution
  - Participants speak as individuals and express views that may not represent those of their organizations
  - Recording by participants is not permitted. Slides will be available on our website pending speaker permission.

- Participation Reminder (Forum Operating Principles)
  - We restrict participation to experts with the necessary scientific knowledge from organizations or entities with a clear commitment to advancing the diagnostic and therapeutic field of the disease area of the project they participate in, whether they be from government, academia, industry or community. Only in this way can we achieve the effectiveness and productivity needed to add value to the field. The Forum is not a venue for marketing and/or investment experts.
Introduction and HBV Forum Updates

Veronica Miller
Forum for Collaborative Research
HBV Forum- Therapeutic Vaccines Webinar

- This webinar will feature an overview of therapeutic vaccines for HBV, presentations on industry strategies, and an audience q&a with a panel representing academia, industry, regulators, and patient advocates.
Overview of the HBV Forum

- **What:** a platform for ongoing multi-stakeholder dialogue to identify barriers, prioritize research and identify solutions to accelerate therapeutic development for HBV

- **How:** provide a neutral, independent, safe space for discussion and deliberation across stakeholder groups
  - Focus on developing consensus, increasing synergy and collaboration, and reducing duplication and uncertainty
  - Ongoing working group activity throughout the year anchored by larger project events
  - Active & engaged participation
HBV Forum Steering Committee Members

Co-Chairs
- Veronica Miller, Forum for Collaborative Research
- Marion Peters, UCSF
- Oliver Lenz, Janssen

Regulatory
- Stephanie Buchholz, Federal Institute of Drugs and Medical Devices
- Eric Donaldson, US FDA
- Poonam Mishra, US FDA
- Gabriel Westman, Swedish Medical Products Agency

Patient Advocates
- Chari Cohen, Hepatitis B Foundation
- Michael Ninburg, Hepatitis Education Project

Academia
- Kosh Agarwal, King’s College Hospital
- Timothy Block, Hepatitis B Foundation, Baruch S. Blumberg Institute
- Carol Brosgart, UCSF
- Henry Chan, The Chinese University of Hong Kong
- Jordan Feld, Toronto Western Hospital Liver Center
- Robert Fontana, University of Michigan
- Adam Gehring, University of Toronto
- Robert Gish, Professor of Medicine, Loma Linda
- Seng Gee Lim, National University of Singapore
- Harry Janssen, University Health Network Toronto Centre for Liver Disease

Academia
- John Tavis, Saint Louis University
- Norah Terrault, Keck Medicine at USC
- Su Wang, Center for Asian Health, Saint Barnabas Medical Center, Hepatitis B Foundation, World Hepatitis Alliance
- Fabien Zoulim, INSERM – French National Institute of Health
- Anna Lok, AASLD
- Markus Cornberg, EASL
- Gavin Cloherty, Abbott Diagnostics
- Wolfgang Jessner, F. Hoffmann-La Roche AG
- Hema Kapoor, Quest Diagnostics
- Patricia Mendez, Gilead
- Christos Petropoulos, Monogram Biosciences
- Teresa Wright, GlaxoSmithKline

Society
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- Wolfgang Jessner, F. Hoffmann-La Roche AG
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Industry
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- Patricia Mendez, Gilead
- Christos Petropoulos, Monogram Biosciences
- Teresa Wright, GlaxoSmithKline
Last but not least!

- **Forum Staff**
  - Emily Gainor – Research Associate
  - Brenda Rodriguez – Deputy Director
  - Jessica Weber – Senior Research Associate
  - Joseph Lau – Research Associate
  - Victoria Mason – Research Associate
  - Nicholas Murdock – Research Associate
HBV Forum Updates

- Steering Committee Leadership Update
  - Steering Committee Co-Leads: Oliver Lenz and Marion Peters
    - Thank you to Harry Janssen and Anuj Gaggar

- Recent Past Webinars
  - Stopping NUCs in Drug Development
  - Intrahepatic Panel Webinar
  - Webinar Series Safety Panel

- Upcoming Webinars
  - Liver Forum: Histology Webinar Series (January 28th)
HBV Forum Updates

- Immune Monitoring Working Group: manuscript accepted to the *Journal of Hepatology*

- New working group on treatment discontinuation to evaluate finite treatment

- Additional new working groups to be announced shortly!

Immunological Biomarker Discovery in Cure Regimens for Chronic Hepatitis B Virus Infection

Key Points:

- Current evidence suggests that some level of immune reconstitution will be required for functional cure of chronic hepatitis B with both novel immune-targeting and direct acting antiviral therapies.

- Phenotypic and functional assays to characterize changes in the HBV-specific immune responses during and off treatment will be necessary to understand the relationship between viral antigen reduction and immune responses, predict clinical outcomes after discontinuation of therapy, inform combination strategies and improve our understanding of liver damage.

- The extent of immunological analyses should be carefully assessed with new experimental therapies that may not have logically predicted impacts on HBV-directed immunity and tested in ancillary studies in late Phase 1 or early Phase 2 clinical studies.

- In addition to validating the mechanism of action (MoA) for immunotherapies, the behavior of the immune response and immunological biomarkers during and off treatment will provide meaningful information to inform patient selection for clinical trials and safety monitoring related to combination therapy and liver inflammation.

- Standardization of assays across diverse laboratories is a challenge and subsequent validation for their use in clinical research will require collaboration among laboratory experts, immunologists, drug developers, regulators and the HBV research community.