HBV Forum: Stopping NUCs in Drug Development Webinar

Wednesday, July 14, 2021
Introduction & HBV Forum Update

Jessica Weber
Forum for Collaborative Research
# Agenda

**HBV Forum - Stopping NUCs in Drug Development webinar**

**Wednesday, July 14**

**12:00 PM** **Meeting Open**

**Moderators:** Harry Janseen, University of Toronto & Nezam Afdhal, Beth Israel Deaconess Medical Center

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Speaker(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>12:00 PM</td>
<td>Introduction</td>
<td>Gnailema Hirode, University of Toronto</td>
</tr>
<tr>
<td>12:10 PM</td>
<td>Overview of Stopping NUCs in Current Clinical Practice</td>
<td>Maria Bermon-Mauwel, Janssen</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Leisa Stamm, Assembly Biosciences</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Maria Maria Gerelli, Roche</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Susanna Tan, Gilead Sciences, Inc.</td>
</tr>
<tr>
<td>12:25 PM</td>
<td>Overview of Recommendations and Current Industry Strategies for Stopping NUCs: Lessons Learned</td>
<td>Poonam Mishra, U.S. Food and Drug Administration (FDA)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Stephanie Buchholz, Federal Institute for Drugs and Medical Devices (BIMM)</td>
</tr>
<tr>
<td>12:45 PM</td>
<td>Trial Design (flares and mitigating risk)</td>
<td>Kosh Agarwal, King’s College London</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Marion Peters, Northwestern University</td>
</tr>
<tr>
<td>1:05 PM</td>
<td>How to move forward? -When to stop? -When to retreat?</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1:25 PM</td>
<td>Overall Discussion and Audience Q&amp;A</td>
<td>Harry Janseen, University of Toronto &amp; Nezam Afdhal, Beth Israel Deaconess Medical Center</td>
</tr>
<tr>
<td>2:00 PM</td>
<td><strong>Meeting Close</strong></td>
<td></td>
</tr>
</tbody>
</table>
HBV Forum- Stopping NUCs 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.
**HBV Forum- Stopping NUCs in Drug Development Webinar**

- This webinar will feature an overview of stopping NUCs in current clinical practice, presentations on industry strategies, regulatory perspectives on trial design, a discussion of how to move forward and an audience q&a.

- This is the first in a series of three HBV Forum webinars in 2021. We will also have webinars focused on therapeutic vaccines and treatment indications based on the science.

- The Forum will also be hosting a webinar on Translating Real World Data into Real World Evidence.
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

## Co-Chairs
- **Oliver Lenz**
  - Janssen Pharmaceuticals
- **Harry Janssen**
  - University Health Network
  - Toronto Centre for Liver Disease
- **Veronica Miller**
  - Forum for Collaborative Research

## Patient Advocates
- **Chari Cohen**
  - Hepatitis B Foundation
- **Michael Ninburg**
  - Hepatitis Education Project
- **Su Wang**
  - Saint Barnabas Medical Center & World Hepatitis Alliance

## Societies
- **Markus Cornberg**
  - EASL
- **Anna Lok**
  - AASLD

## Foundations
- **Tim Block**
  - Hepatitis B Foundation
- **John Tavis**
  - ICE-HBV

## Regulators
- **Stephanie Buchholz**
  - Federal Institute of Drugs and Medical Devices
- **Eric Donaldson**
  - U.S. Food & Drug Administration
- **Poonam Mishra**
  - U.S. Food & Drug Administration
- **Gabriel Westman**
  - Swedish Medical Products Agency
HBV Forum Steering Committee

**Academics**

- **Kosh Agarwal**
  King’s College Hospital

- **Carol L. Brosgart**
  University of California, San Francisco

- **Henry L.Y. 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**
  Loma Linda University Health

- **Seng Gee Lim**
  National University of Singapore

- **Marion Peters**
  Northwestern University

- **Norah Terrault**
  Keck Medicine at University of Southern California

- **Fabien Zoulim**
  INSERM

**Industry**

- **Maria Beumont-Mauviel**
  Janssen

- **Gavin Cloherty**
  Abbott Diagnostics

- **Wolfgang Jessner**
  F. Hoffmann-La Roche AG

- **Hema Kapoor**
  Quest Diagnostics

- **Patricia Mendez**
  Immunocore

- **Christos Petropoulos**
  Monogram Biosciences

- **Terry Wright**
  GlaxoSmithKline
HBV Forum Sponsors

- Abbott
- ALIGOS THERAPEUTICS
- assemblybio
- ENANTA Pharmaceuticals
- ENYO PHARMA
- GILEAD
- gsk
- Hepatitis B Foundation
- IMMUNOCORE
HBV Forum- Stopping NUCs in Drug Development Webinar

- Today we will focus on how “stopping NUCs” fits into the drug development path for curative HBV treatments.
  - Stopping treatment is a necessary step in assessing efficacy of finite HBV treatments
    - Safety concerns
    - Need for some standardization for interpretation and cross-trial comparisons
- We bring the perspectives of multiple stakeholders to the discussion of *When to stop NUCs?* and *When to retreat?*
  - The idea is to learn together, facilitate evolving consensus and encourage standardization where possible
- We look forward to active participation from all during today’s session and ongoing discussion of this important topic