# Satellite Symposium of the 2017 International HBV Meeting

# Novel HBV Antiviral or Immune Modulatory Therapies in Late Pre-Clinical/Clinical Development

Organizers: Anna Lok and Marc Ghany

**Symposium Date:** September 7<sup>th</sup>, 2017

**Location**: Thursday, September 7, 8:15 AM – 12:30 PM

Marriott Waldman Hotel 2660 Woodley Rd NW, Washington, DC 20008

**Target Audience:** Hepatologists, Academic Researchers (basic and clinical), Pharmaceutical and Biotechnology Drug Developers and Regulatory agencies

**Description of Symposium:** There has been a resurgence in interest in therapy of chronic hepatitis B with the development of novel inhibitors of HBV life cycle and therapies aimed at restoring host immune response to HBV. This symposium will provide an overview of gaps in knowledge of current and future HBV treatment, as well as discussion on endpoints and designs of clinical trials aimed at HBV cure.

# **Activity Learning Objectives:**

- 1) Attendees will have a greater understanding of the current status of drug development for chronic HBV infection.
- 2) Attendees will have a better understanding of appropriate endpoints to guide early and late phase drug development
- 3) Attendees will be aware of the appropriate populations to study novel agents with different mechanisms of action.

# Symposium Format (4 hours)

8:15-8:20 AM	Introductory remarks T. Jake Liang
8:20-10:00 AM	Session I - Hepatitis B Treatment Overview
	Moderators: Marc G. Ghany, Fabien Zoulim, Poonam Mishra
8:20-8:40 AM	Current HBV treatment: efficacy and limitations Marc G Ghany
8:40-9:00 AM	HBV lifecycle and potential targets for antiviral therapy Fabien Zoulim
9:00-9:20 AM	Immune response to HBV and strategies to restore immune response Adam Gehring

9:20-10:00 AM Definition of HBV cure and pathway to regulatory approval

Anna S. Lok

10:00-10:15 AM Coffee Break

# 10:15 AM-12:30 PM Session II – Abstract presentations

Moderators: Anna S. Lok and Raymond Schinazi

# 10:00 - 10:12 AM Andrew Vaillant

Clearance of serum HBsAg by nucleic acid polymers suggests a critical role for HBsAg loss in establishing functional control of HBV and HDV infection

# 10:12 - 10:24 AM Zhipeng Yan

A novel core protein allosteric modulator reduces HBeAg through induction of its precursor misassembly

#### **10:24 – 10:36 AM** Patrick Arbuthnot

Sustained inhibition of hepatitis B virus replication in vivo after systemic injection of scAAVs that express virus-targeting primary micro RNAs

#### 10:36 – 10:48 AM Simon Fletcher

GS-9688 is a selective agonist of TLR8 that induces sustained efficacy and surface antigen seroconversion in the woodchuck model of chronic hepatitis B

# 10:48 - 11:00 AM Nezam Afdhal

Phase IIa Achieve Clinical Trial of SB 9200: Results from the Tenofovir switch segment of the 25 mg cohort.

# 11:00 - 11:12 AM Edward Clark

Recombinant HBcAg-anti-CD180 Immunotherapeutic Induces Strong Antibody Polyfunctional CD4 and CD8 T Cell Responses in Macaques

# 11:12 – 11:24 AM Thomas Michler

Hepatitis B virus-specific T cell receptors with high functional redirect T cells to eliminate HBV

#### 11:24 - 11:36 AM David Whitacre

A therapeutic vaccine that circumvents immune tolerance and clears serum HBV in infected human-liver chimeric mice

# 11:36 – 11:48 AM Safiehkhatoon Moshkani

A highly attenuated VSV-based vaccine platform controls HBV replication in an immunocompetent mouse model of persistent infection

Janine Kah 11:48 - 12:00 PM

Antiviral activity of T cells transiently expressing TCRs against HBV in HDV/HBV co-infected humanized mice

12:00-12:30 PM Panel discussion

Future of HBV treatment