ICE-HBV
International Coalition to Eliminate HBV

PROMOTING GLOBAL COLLABORATION IN HBV CURE RESEARCH

HBV Cure: The Mechanisms Behind Combination Therapies

30 SEPTEMBER 2021

9:15 - 13:00 Eastern Daylight Time (Toronto)

CORRESPONDING TIMES:

MELBOURNE	23:15 PM	AEDT	UTC+11 hours
BEIJING	21:15 PM	CST	UTC+8 hours
JOHANNESBURG	15:15 PM	SAST	UTC+2 hours
PARIS	15:15 PM	CEST	UTC+2 hours
NEW YORK	09:15 AM	EDT	UTC-4 hours
SAN FRANCISCO	06:15 AM	PDT	UTC-7 hours

Please register via the link below:
https://www.hbvmeeting.org/program/ice-hbv-symposium/

This event is endorsed by the HBV International Meeting.

HBV
INTERNATIONAL MEETING

BACKGROUND & OJBECTIVES

30 SEPTEMBER 2021

Functional cure for chronic HBV infections, defined as stable post-therapy loss of HBV surface antigen, is the major goal of current HBV cure strategies using direct acting antivirals and/or anti-HBV immune-stimulating responses.

The new drugs that are currently being developed and tested will most likely be used as components of combination therapies. It is essential to understand the mechanisms behind the anticipated therapeutic combinations in the pipeline to prepare for future clinical trials.

The ICE-HBV symposium will address the following questions:

- Which combinations make mechanistic sense, and why? What are the logical points of synergy?
- What pre-clinical evidence is needed to justify advancing a combination into clini cal tirals? What is the pre-clinical evidence for combination of antiviral and immune strategies?
- What is the best way to design combination trials to advance the most promising drugs efficiently and rapidly?
- Flares: how to distinguish virally induced, immune induced, and toxic flares?
- HDV and HBV cross-utility: How the drugs in development for Delta could be useful for HBV, and vice-versa?
- Round-table discussion: What are industry perspective on combination therapy?

In this workshop, a range of academic and industry experts will discuss the latest advances and identify knowledge gaps in our understanding of combination mechanisms. They will discuss challenges that need to be overcome to ensure the efficacy and safety of combination therapies.

Presentations will be complemented by an in-depth discussion panel with the pharmaceutical and diagnostic industries that will debate these challenges and propose a way forward.

PROGRAM

30 SEPTEMBER 2021

09:15 - 13:00 All times in Eastern Daylight Time (Toronto)

09:15 - 09:20	Opening Remarks	
09:20 - 09:35	Combinations of direct acting antivirials to decrease the cccDNA pool	Haitao Guo
09:35 - 09:50	Combinations of compounds that stimulate and enhance function of HBV-specific B/T cells	Adam Gehring
09:50 - 10:05	Pre-clinical evidence for combination strategies	Maura Dandri
10:05 - 10:20	Q & A	
10:40 - 10:55	Clinical trial design for combination therapies	Norah Terrault
10:55 - 11:10	Use of novel biomarkers to assist combination trials	Massimo Levrero
11:10 - 11:25	Flares in clinical trials: Who is good? Who is bad?	Grace Wong
11:25 - 11:40	HBV and HDV cross utility for drug development	Heiner Wedemeyer
11:40 - 12:00	Q & A	
12:00 - 12:45	Round-table: The Industry Perspective on Combination Therapy	*Moderator:* Harry Janssen *Panelists:* Oliver Lenz (Janssen) Doug Mayers (Antios Therapeutics) Tse-I Lin (Aligos Therapeutics) William Delaney (Assembly Bio) Michael Sofia (Arbutus)

BIOS

PROGRAM CHAIRS:

Fabien Zoulim obtained his M.D. in Gastroenterology and Hepatology in Lyon Medical School in 1991. He has also obtained a PhD in Molecular and Cellular Biology and was trained as a post-doctoral researcher at Fox Chase Cancer Center in Philadelphia. He is Professor of Medicine at Lyon I University since 1997. He is currently Medical Director of the Hepatology Department at the Hospices Civils de Lyon, and Scientific Director of the Department of Immunology and Virology of INSERM Unit 1052 where he is leading the team on 'Antiviral therapy of viral hepatitis'. Dr Zoulim has served as an Associate Editor for Journal of Hepatology and is currently Associate Editor for Gut. He also served as an expert in the microbiology study section of the INSERM and is currently head of the clinical viral hepatitis study section at ANRS. He served as a Governing Board member of the European Association for the Study of the Liver (EASL). Dr Zoulim received the William Prusoff award of the International Society for Antiviral Research. Furthermore, he has been the scientific coordinator of a European community-funded Network of Excellence on the management of antiviral drug resistance, and is currently head of the ANRS "HBV cure" program in France. Fabien Zoulim is a recognised expert in the field of viral hepatitis and antiviral therapy. He has published more than 350 articles (H index 63, Web of Science)

John Tavis, Ph.D., is a Professor of Molecular Virology and the Director of the Saint Louis University Institute for Drug and Biotherapeutic Innovation at Saint Louis University, Saint Louis, Missouri, USA. He has studied the HBV replication mechanism of HBV and the biochemistry of the viral reverse transcriptase since 1992. He serves on the Editorial Boards of the Journal of Virology and Antiviral Research and is Guest Editor of the Antiviral Research symposium "Wide-ranging immune and direct-acting antiviral approaches to curing HBV and HDV infections". He is the Chairman of the Scientific Advisory Council for the annual International HBV Meeting and Incoming Chair for the International Coalition to Eliminate HBV (ICE-HBV), and serves on the Medical and Scientific Advisory Committee of the Hepatitis B Foundation and on the Governing Board of the HBV Forum. Dr. Tavis received the American Cancer Society's Mission Hero award in 2018 for his efforts through the Society to suppress virally mediated cancers His current work focuses on the biochemistry and biology of the HBV ribonuclease H enzyme and on developing novel drugs to suppress HBV replication that target the ribonuclease H.

BIOS

SPEAKERS:

Haitao Guo is currently a professor of microbiology and molecular genetics in University of Pittsburgh and the co-leader of cancer virology program of UPMC Hillman Cancer Center. His major research interests are HBV molecular biology, HBV-induced liver cancer, and antiviral development.

My research aims at understanding the molecular mechanisms of HBV DNA replication and morphogenesis, with special focus on the biosynthesis and regulation of HBV covalently closed circular (ccc) DNA, which is the persistent form of HBV infection, and is the culprit for the failure of current antiviral therapies. It also focuses on studying the innate immunity and oncogenic signaling pathways that regulate HBV replication, as well as identification and characterization of host restriction factors that inhibit HBV infection and propagation in human hepatocytes.

Adam Gehring received his Ph.D. at Case Western Reserve University in Cleveland, Ohio. His training included a Postdoctoral Fellowship in the Institute of Hepatology at University College London and a position of Senior Research Fellow, and subsequently Assistant Principal Investigator, at the Singapore Institute for Clinical Sciences with Antonio Bertoletti. During his postdoctoral training Dr. Gehring was instrumental in developing TCR gene therapy for chronic HBV. His foundational work resulted in human application of engineered T cells for HBV-related HCC tumors expressing viral antigen. Dr. Gehring moved to Saint Louis University as an Assistant Professor in the Molecular Microbiology and Immunology department in March 2013 before joining the Toronto Center for Liver Disease as Biology Lead in February 2016.

Dr. Gehring runs a translational HBV immunology research lab focused on liver pathogenesis and sex-based differences in disease progression. His primary interest lies in defining the mechanisms driving liver inflammation during HBV-related flares using functional and transcriptomic approaches in liver biopsies. He has established an internal immune monitoring core within his lab to process and analyze immune responses in Phase 1/2 clinical studies for HBV.

Dr. Gehring is currently Co-Chair for the Immune Monitoring Workgroup of the HBV Forum and on the Governing Board of the International Coalition to Eliminate HBV (ICE-HBV). He is Co-Chair for the International HBV Meeting being organized in Toronto in September, 2021.

Maura Dandri is a full Professor at the University Medical Center Hamburg-Eppendorf, in Germany, where she leads the research group Viral Hepatitis. She received her PhD in Microbiology and Immunology at the University of Trieste, Italy. Her training included a Postdoctoral Fellowship at Albert Einstein College of Medicine, New York, and at Heinrich-Pette-Institute, Hamburg, Germany (EMBO Fellowship). Since 2009 she is principal investigator at University Medical Center Hamburg-Eppendorf and was awarded in 2013 by the German Research Foundation with a Heisenberg Professorship. She is currently member of the executive board of the German Center for Infection Research (DZIF) and of the Governing Board of the International Coalition to Eliminate HBV (ICE-HBV). She has performed pioneering work by developing humanized mouse models of viral hepatitis infection. Her research interest mainly focuses on investigating cccDNA metabolism, virus-host interplay and the potential of novel therapeutic strategies, in particular against HBV and HDV. Her lab is also experienced in monitoring viral and host parameters in liver biopsy samples.

BIOS

SPEAKERS:

Norah Terrault is Professor of Medicine and Chief of Gastroenterology and LiverDiseases at the Keck School of Medicine at University of Southern California. She received her MD from the University of Alberta and completed fellowships in Internal Medicine and Gastroenterology at the University of Toronto and a Masters in Public Health at the University of California at Berkeley. Dr. Terrault has focused her clinical and research activities on viral hepatitis and non-alcoholic fatty liver disease, especially in special populations including those with cirrhosis and those with transplants. In addition to multiple clinical trials related to preventing and treating chronic hepatitis viral hepatitis and fatty liver, Dr. Terrault has been PI on multiple NIH-funded studies, including the current NIH-supported HBV clinical research network (HBRN) and nonalcoholic steatohepatitis clinical research network (NASH CRN). She has authored 330 peer-reviewed manuscripts, editorials, invited reviews as well as US national guidelines for treatment of chronic hepatitis B and C. She is past associate editor for Hepatology and deputy editor for Liver Transplantation and co-edited Zakim and Boyer's textbook in hepatology. She is the founder of ECHO-Plus, a multifaceted program to train and support primary care physicians in California to care for patients with hepatitis. She has a long history of mentoring fellows and junior faculty in clinical research and is passionate about creating research support and opportunities for the next generation of GI/Hepatology investigators. Dr. Terrault was recently elected as Councilor to the AASLD governing board and will serve as president in 2023.

Massimo Levrero is Professor of Medicine at the University Claude Bernard Lyon 1 (UCLB1), Lyon, France and Praticien Hospitalier in the Service d'Hepatologie et Gastroenterologie – Hopital de la Croix Rousse – Hospices Civils de Lyon. He leads a Research Unit on "Epigenetics and Epigenomics of Hepatocellular Carcinoma", at the Centre de Recherche en Cancérologie de Lyon (CRCL) – INSERM U1052 in Lyon, France. He also serves as Associate Member at the IIT – Sapienza Center for Life NanoScience (CLNS) in Rome and he is on leave of absence from the Department of Internal Medicine (DMISM) at the Sapienza University of Rome, where he had his research activity and academic practice in hepatology until 2014. Professor Levrero trained and completed his residency at Sapienza before holding posts at the University Paris VI and the Institut Gustave Roussy in Paris. He has acted as Scientific Secretary of EASL (European Association for the Study of the Liver) and he currently presides the CSS12 study session on basic and translational research on viral hepatitis at the French National Agency for Research on AIDS and Viral Hepatitis (ANRS). He is a founding member and seats in the Governing Board of ICE (International Coalition to Eliminate HBV). He is actively involved in clinical research and treatment of HBV and HCV chronic hepatitis and he served as Network Coordinator and/or Primary Investigator in a number of research projects and clinical studies. HBV research focuses on the epigenetic regulation of cccDNA function and HBV replication, the identification of new targets for anti-¬-viral therapy and on liver oncogenesis in HBV related hepatocellular carcinoma. Additional research interests include: signal transduction and transcription in the liver; IFN transcriptome; chromatin modifiers in solid tumours development and progression. Professor Levrero is the author of over 200 publications in peer-reviewed journals, including Nature, Nature Medicine, Nat Cell Biol, Nature Communications, Science, J Clin Invest, J Exp Med, Mol Cell, PNAS USA, Cancer Res, Oncogene, EMBO J, J Biol Chem, Sci Rep, Gastroenterology, J of Hepatology, GUT, Hepatology, J of Virology, Virology, J Gen Virol, J Infect Dis, Blood.

BIOS

SPEAKERS:

Grace Lai-Hung Wong MBChB (Hons), MD (CUHK), FRCP(Lond, Edin), FHKCP, FHKAM (Medicine) Director, Medical Data Analytics Centre (MDAC) Deputy Director, Center for Liver Health Assistant Dean (Learning Experience), Faculty of Medicine Professor, Department of Medicine and Therapeutics The Chinese University of Hong Kong Grace Wong is the Professor of The Chinese University of Hong Kong. She graduated from the Chinese University of Hong Kong in 2001 with honors and distinctions in Medicine. In 2010, she received the Doctorial Degree of Medicine of the Chinese University of Hong Kong. Grace Wong's main research interest includes big data research in hepatology, chronic viral hepatitis, and risk prediction and risk reduction of hepatocellular carcinoma, and non-invasive assessment of liver fibrosis. She has published over 340 articles in peer-reviewed journals including Gastroenterology, Journal of Hepatology. Gut and Lancet Gastroenterology and Hepatology. She is currently the editor-in-chief of Hepatology (Hong Kong edition), the associate editor of Alimentary Pharmacology and Therapeutics and Journal of Gastroenterology and Hepatology. She has been awarded for the Young Investigator Award of the Asian Pacific Association for the Study of the Liver in 2009, the Distinguished Research Paper Award for Young Investigators of the Hong Kong College of Physicians in 2010, 2013, 2014 and 2015, the Ten Outstanding Young Persons (TOYP) of Hong Kong in 2014, the Distinguished Young Fellow of Hong Kong Academy of Medicine in 2017, the Emerging Leader Lectureship of the Journal of Gastroenterology and Hepatology Foundation (JGHF), and the Presidential Awards in the Global Hepatitis Summit 2021.

Heiner Wedemeyer MD has been Professor and Chairman of the Department of Gastroenterology, Hepatology and Endocrinology at Hannover Medical School since April 1, 2020. He was Professor and Chairman of the Department of Gastroenterology and Hepatology at the University Clinic Essen between February 2019 and April 2020.

Professor Wedemeyer has a long-term research interest in liver diseases with a main focus on viral hepatitis, liver transplantation and hepatocellular carcinoma. He has been principal investigator in numerous clinical trials, focusing on antiviral therapy and immunotherapy of viral hepatitis B, C, D and E.

BIOS

INDUSTRY PANELISTS:

HarryJanssen (Moderator) is Professor of Medicine at the University of Toronto, Ontario, Canada, where he holds the Francis Family Chair in Hepatology. He currently works at Toronto General Hospital as Chief of Hepatology and Director of the Toronto Centre for Liver Disease.

Dr. Janssen has coordinated numerous clinical and translational studies on treatment for chronic viral hepatitis and other liver diseases. His main research interest is cure of chronic hepatitis B. He has published more than 500 original peer-reviewed papers and many book chapters. His H-index is over 100 and he has been cited 45,000 times (Google Scholar). He has received several prestigious international awards and has mentored over 50 PhD students, of whom many have taken leadership positions in the field of Hepatology or Virology.

Oliver Lenz Ph.D is Scientific Director Clinical Microbiology and Immunology at Janssen Infectious Diseases, part of the Janssen Pharmaceutical Companies of Johnson & Johnson. He is the global virology lead for the development of HBV therapeutics from pre-clinical through clinical development. Prior to his work in HBV he was involved in the discovery of the HCV protease inhibitor simeprevir which he supported subsequently through clinical development until registration. Oliver Lenz completed his PhD at the University of Marburg, Germany, mainly working on hemorrhagic feverviruses and did a postdoctoral fellowship at the European Molecular Biology Laboratory (EMBL) at Grenoble, France, on HIV GP41 structural biology. He is author of 70 peer reviewed papers and co-chair of the HBV Forum surrogate endpoints working group.

Doug Mayers is the Chief Medical Officer and a co-founder of Antios Therapeutics. He was most recently Chief Medical Officer at Cocrystal Pharma (NASDAQ: COCP) developing antiviral drugs against Hepatitis B, Hepatitis C and influenza viruses. Notably, in 2007, Dr. Mayers was named Executive Vice President and Chief Medical Officer at Idenix Pharmaceuticals where he was responsible for drug safety and clinical development for therapies targeting HIV, Hepatitis B and Hepatitis C. After Idenix was acquired by Merck Pharmaceuticals (NYSE: MRK) in 2014, he served for a year as a Principal Investigator at the United States Army Medical Research Institute of Infectious Diseases coordinating efforts to develop drugs against Ebola and MERS coronavirus. Dr. Mayers was commissioned into the United States Navy in 1981 and retired after 38 years of service as a Captain, initially serving as a Staff Internist and rising to Department Head, Division of Retrovirology, where he was responsible for directing HIV natural history studies and clinical trials at Army, Navy and Air Force sites domestically. In 1998, Dr. Mayers left Navy active duty to become the Head of the Division of Infectious Diseases at Henry Ford Hospital. He served as Principal Investigator for the NIH-funded clinical trials unit and conducted NIH-funded clinical trials of antiviral drugs and the clinical implications and management of HIV drug resistance. In 2001, he moved to Boehringer Ingelheim Pharmaceuticals as the International Head/Vice President of the Therapeutic Area Virology where he was responsible for the therapeutic area strategy and global clinical development and support for antiviral drugs including Nevirapine and Tipranavir.

BIOS

INDUSTRY PANELISTS:

Tse-I Lin PhD currently holds the position of Vice President, Early Compound Development at Aligos Therapeutics where he is responsible for leading multiple early development teams focusing on developing a combination approach to achieving functional cures for subjects with chronic hepatitis B infection. He is an experienced antiviral drug discovery and development professional, with over 20-year experience in multiple disease areas including HBV, HCV, HIV, HCMV and influenza. He started his professional life as Post-Doc at Bayer Pharmaceutical in Germany. He subsequently joined JNJ/Tibotec BVBA in 2003 and worked for over 12 years at Janssen Pharmaceutical in antiviral drug discovery and development, focusing on HBV and HCV. At Tibotec he discovered and brought several molecules into clinical development, including the HCV protease inhibitor, Simeprevir, which was launched in the US in 2013. In 2010, he took a leadership position in Shanghai for JNJ where he built an antiviral R&D group. During this time, he established and co-chaired the Jointed Research Center for Infectious Diseases with Tsinghua University in Beijing, China. In 2013 Tse-I joined Roche as the Head of Molecular Virology Group to lead discovery groups both in Shanghai and Basel, Switzerland. During this period, he and his group discovered and nominated several NMEs for HBV, which are currently being evaluated in clinical trials. In 2015 He became the Leader of the China Acceleration Strategy for the Roche Infectious Disease group. He led the cross-functional strategic planning effort to accelerate the development of novel medicines in China and the APAC region, especially in HBV. In 2016 he joined Janssen's infectious disease group and continued to work on HBV as the early development project leader for a TLR-7 agonist (in collaboration with CHIATAI TIANQING PHARMA in Nanjing, China) and as the discovery project leader of HBV-TALON and a siRNA Program (in collaboration with Arcturus Pharmaceutical, San Diego, USA). Dr. Lin obtained his B.S. in Public Health from National Taiwan University, Masters and Ph.D. in Biochemistry from Freie Berlin University in Germany.

William Delaney Ph.D joined Assembly as Chief Scientific Officer in 2020. Prior to joining Assembly, he held positions of increasing responsibility over a 20 year period at Gilead Sciences, serving most recently as an Executive Director in the Biology department. While at Gilead, he lead the Viral Hepatitis & Herpes Discovery Biology Group, served as the Research Therapeutic Area Head for HBV, and contributed to the development of several marketed products, including Hepsera®, Viread®, and Vemlidy® for HBV and Sovaldi®, Harvoni®, Epclusa®, and Vosevi® for HCV. He earned a BS in Biotechnology from the University of Delaware and a PhD in Cell and Molecular Biology from the Penn State College of Medicine. In addition, he completed a Postdoctoral Fellowship at the Victorian Infectious Diseases Reference Laboratory (VIDRL), Department of Research & Molecular Development.

BIOS

INDUSTRY PANELISTS:

Michael Sofia Ph.D is Co-founder and Chief Scientific Officer of Arbutus Biopharma, Inc. where he established the programs in HBV-cure and coronaviruse therapeutics. During his career he has introduced numerous drugs into clinical development for both infectious diseases and inflammatorydiseases. He is responsible for the discovery and early development of sofosbuvir, which became the backbone of many HCV curative therapies including Sovaldi®, Harvoni®, Epclusa® and Vosevi®. Mike has held research and research management positions at Gilead Sciences, Pharmasset, Bristol-Myers Squibb, Transcell Technologies and Eli Lilly and Company. He holds a BA in chemistry from Cornell University, a Ph.D. from the University of Illinois and was an NIH postdoctoral fellow at Columbia University.

THANK YOU

SPONSORS:

Gold Sponsor

janssen
PHARMACEUTICAL COMPANIES OF
Johnson & Johnson

Silver Sponsor

ANTIOS
THERAPEUTICS

ALIGOS
THERAPEUTICS

THANK YOU

DONORS: