INTERNATIONAL WORKSHOP ON

HBV CURE 2021

VIRTUAL PROGRAM
9 - 10 NOVEMBER 2021

Program

virology education

AcademicMedicalEducation.com

Welcome from the Chairs

Dear Delegate,

We are delighted to welcome you to the 8th edition of the **International Workshop on HBV Cure**.

This year's workshop will provide a unique setting for international interchange in order to define the pathway forward for achieving a cure of hepatitis B. The workshop will gather the world's leading basic, translational and clinical experts to discuss the challenges they face, as well as research outcomes.

By participating in this workshop, you will have access to the latest developments relating to a cure, a thorough understanding of new research and ongoing clinical trials, and the well-received and highly popular discussions with the world's leading experts.

This workshop has been designed for clinicians and researchers with an interest in the development of a cure for the HBV infection.

We look forward to seeing you online for the two virtual days of this international workshop.

Sincerely,
The Workshop Chairs

Harry Janssen MD, PhD
Toronto Centre for Liver Disease,
Canada

Workshop Chair

Adam Gehring PhD
Toronto Centre for Liver Disease,
Canada

Workshop Chair

Needs Statement

Viral hepatitis is a major global health burden that has been largely neglected until recently. More than 250 million people are chronically infected with Hepatitis B (HBV) around the globe with a disproportionally high prevalence in South-East Asia. Chronic infection may lead to liver cirrhosis, cancer, and other complications. Effective vaccine programs have reduced the incidence of new infections in the younger population. In line with this, available nucleoside and nucleotide-based drugs decreases the progress towards liver disease in HBV infected people.

However, a cure for HBV does not exist. Furthermore, there are major, universally recognized concerns towards a cure such as the persistence of episomal covalently closed circular DNA (cccDNA), integrated viral genome, and the large antigen load.

Nevertheless, the field of HBV treatment is undergoing major changes and is on the verge of a paradigm shift. A plethora of innovative investigational therapeutic strategies are emerging that may overcome existing concerns.

Their mechanisms of action and biological targets are diverse and include inhibitors of viral targets along with activators of innate and adaptive immunity against HBV. Altogether, this sets the scene to improve treatment and ultimately cure HBV. The rapid development both in academic and industry settings urgently requires a scientific platform to disseminate advances and discuss ways to move forward towards the cure and elimination of HBV.

The International HBV Cure Workshop brings together experts in basic, translational, and clinical HBV research from academia and industry to exchange their advances towards a cure for HBV. Extensive discussion will be dedicated to questions pertaining to the optimization of biomarkers and end points in therapeutic trials, and how to combine different agents targeting the virus and/or immune system. Besides sharing the latest breakthroughs in research, participants will get the chance to network and foster new collaborations and thus combine their efforts to cure HBV.

Meeting Objectives

- Discuss how to reach an HBV functional cure with newly developed agents targeting the immune system or the viral replication cycle;
- Develop endpoints and better biomarkers for these studies; and
- Discuss how new agents should be combined to reach the goal of a functional cure.

Learning Objectives

After participating in this activity, the participants will:

- Critically evaluate biomarkers used in clinical HBV studies;
- Outline advances made to cure HBV; and
- Critically assess current approaches taken to achieve the development of a functional cure.

Certificate of Attendance
Certificates of attendance will be sent by e-mail in the week following the workshop after completion of the post-workshop survey.

Feedback
Your feedback is very valuable to us and enables us to further improve this conference. After each session a short questionnaire will pop-up and we would like ask you to take a minute to complete it. After the workshop, a survey will be send to you via email, with other questions to improve this workshop.

Group Picture
We ask you all to take a photo of yourself and send it to the HBV Cure secretariat at Rikke.Rode@amededu.com. We will stitch it all together and send out the finished virtual group photo at the end of the workshop.

Meeting Hub
The Meeting Hub allows you to connect and communicate with other attendees. Once you have located an attendee you want to connect with, click the Connect button. Once the other attendee accepts your request, you can choose to interact by starting a live chat or live video call. You can also schedule a meeting at a later time, send messages and take notes. Contact information for all attendees you have connected with will be included when you export contacts

Notes
You will be able to take notes during the virutal workshop. Any notes that you take throughout the event can be exported by selecting the Export icon in the top right of the screen near your Profile image.

Virtual Workshop Portal
OnAIR is the virtual workshop platform being used for HBV Cure 2021. A video tutorial on how to use the workshop portal can be found here.

Social Media
We encourage you to post news and tweet about HBV Cure to your social media accounts as often as you like during the workshop. You can either post your own tweets to your followers using the hashtag #HBVCure or retweet a message through the official @Academic_MedEdu account.

Technical Team
Should you encounter any technical problems, please contact us at federica@amededu.com or through the live support on the virtual workshop portal.

Time Zones
Times are in Eastern Standard Time (EST). If you need to convert the times to your timezone, this website might be of interest to you: www.worldtimebuddy.com.

Presentations and Webcasts
All recordings of presentations and discussions will remain available on the virtual workshop platform for 3 weeks after the workshop date.
After these 3 weeks, webcasts of the presentations along with the PDF presentations will be available on www.AcademicMedicalEducation.com.

Our Team

Rikke Puggaard-Rode
Project Manager
Rikke.Rode@amededu.com

Federica Ressa
Project Manager
federica@amededu.com

Organizing Committee

Charles Boucher, MD, PhD
Erasmus Medical Center,
The Netherlands

In Memoriam

Adam Gehring PhD
Toronto Centre for Liver Disease,
Canada

Harry Janssen MD, PhD
Toronto Centre for Liver Disease,
Canada

Pietro Lampertico MD, PhD
University of Milan,
Italy

Mala Maini MD, PhD
University College London,
United Kingdom

Marion Peters MD
University of California at San Francisco (UCSF),
United States

Raymond Schinazi PhD, DSc
Emory University Center for AIDS Research (CFAR),
United States

Fabien Zoulim MD, PhD
Lyon I University / Hospices Civils de Lyon / INSERM,
France

Tuesday, 9 November 2021

Times are in Eastern Standard Time (EST)

	Opening of the Workshop
09:00 AM EST	**Welcome** **Harry Janssen, MD, PhD** Toronto Centre for Liver Disease, Canada
Session 1	**Therapeutic Advancements for Viral Hepatitis** *Chairs: Jordan Feld & Veronica Miller*
09:10 AM EST	**Patient Selection for Clinical Trials Based on Drug Class** **Fabien Zoulim, MD, PhD** Lyon I University / Hospices Civils de Lyon / INSERM, France
09:25 AM EST	**New Data From Combination Trials for Chronic Hepatitis B** **Pietro Lampertico, MD, PhD** University of Milan, Italy
09:40 AM EST	**New Combination Therapies in Hepatitis Delta Therapy** **Jeffrey S. Glenn, M.D., Ph.D.** Stanford University, United States
09:55 AM EST	**Discussion**
10:25 AM EST	Break
Session 2	**Clinical Immunology and Immunotherapy Updates** *Chairs: Mala Maini & Adam Gehring*
10:35 AM EST	**What Can We Learn by Deploying Immunological Analysis in Phase II Clinical Trials?** **Adam Gehring, PhD** Toronto Centre for Liver Disease, Canada
10:50 AM EST	**TLR-8 Agonist** **Simon Fletcher, PhD** Gilead Sciences, Inc, United States
11:00 AM EST	**Anti-HBs Antibody** **Carey Hwang, MD, PhD** Vir Biotechnology, Inc., United States
11:10 AM EST	**Immunotherapeutics in the Treatment of Chronic Hepatitis B** **Sarah Browne, MD** Altimmune, Inc., United States
11:20 AM EST	**VBI-2601: Immunotherapeutic HBV Vaccine Candidate Overview** **Francisco Diaz-Mitoma, MD, PhD** VBI Vaccines, Canada
11:30 AM EST	**HBV Immunotherapeutic Vaccines (Lessons from HCV)** **Eleanor Barnes, PhD, FRCP, F Med Sci** Vaccitech; University of Oxford, United Kingdom
11:40 AM EST	**A Novel Approach At Targeting the PD-1/PD-l1 Pathway: PD-l1 Lna** **Anna Maria Geretti, MD, PhD, FRCPath** Roche Pharma Research & Early Development, Switzerland; University of Rome, Italy; King's College London, United Kingdom
11:50 AM EST	**Discussion**
	Closure
12:20 PM EST	**Overview of Day 1** **Adam Gehring, PhD** Toronto Centre for Liver Disease, Canada
12:25 PM EST	End of Day 1

Wednesday, 10 November 2021

Times are in Eastern Standard Time (EST)

	Opening
09:00 AM EST	**Welcome to Day 2** **Adam Gehring, PhD** Toronto Centre for Liver Disease, Canada
Session 3	**Patient Selection, Stopping Treatment and Biomarkers** *Chairs: Marion Peters & Scott Fung*
09:05 AM EST	**HBsAg Loss as a Predictor for Long-Term Clinical Outcomes** **Marion Peters, MD** University of California at San Francisco (UCSF), United States
09:20 AM EST	**Outcomes After Therapy Discontinuation** **Markus Cornberg, MD** Hanover Medical School; Centre for Individualised Infection Medicine, Germany
09:35 AM EST	**How to Handle Flares in HBV Trials With Novel Agents** **Harry Janssen, MD, PhD** Toronto Centre for Liver Disease, Canada
09:50 AM EST	**Safety Monitoring during HBV Clinical Trials and after Antiviral Discontinuation** **Poonam Mishra, MD, MPH, FAASLD** US Food and Drug Administration, United States
10:05 AM EST	**Discussion**
10:35 AM EST	Break
Session 4	**Update on Viral Targets for HBV/HDV Therapy** *Chairs: Fabien Zoulim & Raymond Schinazi*
10:45 AM EST	**Biological Insights Taught by Clinical Responses to Novel HBV/HDV Drugs** **Stephan Urban, PhD** Heidelberg University Hospital, Germany
11:00 AM EST	**Core Inhibitors (Capsid Assembly Modulators)** **Luisa Stamm, MD, PhD** Assembly Biosciences, United States
11:10 AM EST	**Antisense Oligos** **Leigh Felton, BSc, PhD** GlaxoSmithKline, United Kingdom
11:20 AM EST	**STOP Agents** **Matthew McClure, MD** Aligos, United States
11:30 AM EST	**Active Site Polymerase Inhibitor Nucleotides (APSINs)** **Douglas Mayers, MD** Antios Therapeutics, United States
11:40 AM EST	**Hepcludex** **Dmitry Manuilov, MD** Gilead Sciences, Germany
11:50 AM EST	Debate/Discussion of Drug Progress
	Closure
12:20 PM EST	**Closing Remarks** **Adam Gehring, PhD** Toronto Centre for Liver Disease, Canada **Harry Janssen, MD, PhD** Toronto Centre for Liver Disease, Canada
12:35 PM EST	End of the Workshop

Faculty

SPEAKER

Eleanor Barnes, PhD, FRCP, F Med Sci

Vaccitech / University of Oxford,
United Kingdom

Eleanor Barnes is Professor of Hepatology and Experimental Medicine, leading a research group in applied immunology relevant to liver disease. She has a long standing interest in hepatotrophic viruses, viral pathogenesis, immunology and vaccine development.

She has led early human experimental medicine studies with the aims of developing a prophylactic HCV vaccine, including 2nd generation HCV vaccines based on conserved viral genomes, and constructs that encode genetic adjuvants with the potential for wide applicability in cancer and infectious disease.

She is also developing a program in HBV using adenoviral vectored vaccines for HBV immunotherapy for use in combination with check point modulators. She will present new human HBV vaccine data and highlight some lessons learnt from previous HCV studies that are relevant to HBV vaccine development.

Potential conflict of interest:
Vaccitech

SPEAKER

Sarah Browne, MD

Altimmune, Inc.,
United States

Sarah K. Browne, M.D., practices in the areas of internal medicine and infectious diseases in the Washington, DC area, affiliated with the VA Medical Center and MedStar Washington Hospital Center, and is Senior Director, Vaccine Development at Altimmune.

Prior to joining Altimmune, she served as Senior Advisor, Clinical at the Food and Drug Administration (FDA) in the Division of Vaccines and Related Product Applications, Office of Vaccines Research and Review (OVRR), part of the Center for Biologics Evaluation and Research (CBER). In this role she engaged in clinical, regulatory, and policy decisions intended to facilitate development of investigational vaccine candidates. She also served as a clinical reviewer on numerous original biologics license applications and investigational new drug applications.

Before joining the FDA, Dr. Browne was an Assistant Clinical Investigator in the Laboratory of Clinical Infectious Diseases, National Institute of Allergy and Infectious Diseases, part of the National Institutes of Health (NIH).

No potential conflict of interest.

Speaker

Markus Cornberg, MD

Hanover Medical School / Centre for Individualised Infection Medicine, Germany

Markus Cornberg is Professor Infectious Diseases with a focus on Hepatology and Deputy Director of the Department of Gastroenterology, Hepatology and Endocrinology at Hannover Medical School, Germany. Since 2019, he is Clinical Director Helmholtz Centre for Infection Research and Director of the Centre for Individualized Infection Medicine (CIIM). Prof. Cornberg is Medical Executive Director of the German Liver Foundation.

Since 2007, Prof. Cornberg has coordinated the German guideline on the management of hepatitis B virus infection. From 2017 to 2020, he served on the Scientific Committee and Governing Board of the European Association for the Study of the Liver (EASL). He has been Associate Editor of the Journal of Hepatology since 2019. His basic science research focus is the investigation of cellular immune responses for disease progression and treatment response in patients with viral hepatitis.

Prof. Cornberg has published >250 original scientific papers as well as review articles.

Potential conflict of interest:
AbbVie Deutschland GmbH & Co. KG, Falk Foundation e.V., Gilead Sciences GmbH, MSD Sharp & Dahme GmbH, GSK Service Unlimited, Janssen-Cilag GmbH, Novartis AG, F. Hoffmann-La Roche AG, Spring Bank Pharmaceuticals, Swedish Orphan Biovitrum AB (SOBI)

Speaker

Francisco Diaz-Mitoma, MD, PhD

VBI Vaccines, Canada

Dr. Diaz-Mitoma is a renowned medical scientist and professor who most recently served as a professor of the Northern Ontario School of Medicine ("NOSM"). While in this position, Dr. Diaz-Mitoma was Vice President of Research at Health Sciences North and founder of the Advanced Medical Research Institute of Canada ("AMRIC") and served as its Chief Executive Officer and Chief Scientist. AMRIC is focused on translational medical and vaccine development research.

Prior to joining the faculty at the NOSM, Dr. Diaz-Mitoma was a professor of Pediatrics, Pathology, Laboratory Medicine, and Microbiology at the University of Ottawa. While in this position, he founded the Vaccine and Infectious Disease Centre at the Children's Hospital of Eastern Ontario ("CHEO"), a pediatric health and research center.

Dr. Diaz-Mitoma received his medical degree from the University of Guadalajara, completed fellowship training in Infectious Diseases at the University of Manitoba, and earned a Ph.D. in Virology from the University of Alberta.

Potential conflict of interest:
VBI Vaccines, Inc.

Session Chair

Jordan Feld, MD, MPH

Toronto Centre for Liver Disease,
Canada

Dr. Feld trained in GI and Hepatology at the University of Toronto and did post-doctoral training in the Liver Diseases Branch at the National Institutes of Health in laboratory and clinical research in viral hepatitis.

After completing a Masters in Public Health at the Johns Hopkins Bloomberg School of Public Health, he returned to Toronto where holds the R. Phelan Chair in Translational Liver Research as a clinician-scientist at the Toronto Centre for Liver Disease in the Toronto General Hospital where he now leads a large clinical and translational research program focused primarily on viral hepatitis.

Potential conflict of interest:
Abbvie, Antios, Eiger, Enanta, Finch, Gilead, GSK

Speaker

Leigh Felton, BSc, PhD

GlaxoSmithKline,
United Kingdom

Leigh Felton B.Sc. Ph.D. is a Clinical Development Director at GlaxoSmithKline (GSK, Stevenage, UK) working within the late-stage Clinical Sciences Hepatology group.

He received his B.Sc. in Physiology and Pharmacology and Ph.D. in Psychoneuroimmunology from the University of Southampton, United Kingdom. He then went on to complete a postdoctoral research fellowship on the role of perturbations of the blood-brain-barrier in the immunopathology of Multiple Sclerosis.

Since joining GSK in 2006, Leigh has accrued 15 years' experience of drug development over a broad range of therapeutic platforms, including small molecule inhibitors, biopharms, oligonucleotides and cell-based therapies. During this period he has worked extensively on Ph1-2b studies across multiple disease areas, including respiratory, autoimmune, oncology and infectious diseases. He has a strong background in clinical immunology and biomarker research, being recognised as a subject matter expert both within and outside of GSK, advising projects in preclinical development, early and late stage clinical development, and specialising in human challenge models and immune biomarker development. Leigh has been working on GSK's Bepirovirsen (HBV ASO) project for functional cure of CHB infection for the past 3 years, and is currently clinical lead for sequenced therapy studies, including the B-Together Ph2b study (Bepirovirsen + Pegylated-IFN), and pediatric development activities.

Potential conflict of interest:
GlaxoSmithKline UK

SPEAKER

Simon Fletcher, PhD

Gilead Sciences,
United States

Simon Fletcher is an Executive Director at Gilead Sciences. He received his undergraduate and Ph.D. degrees from the University of Cambridge (UK) and performed post-doctoral studies at Roche. He then moved to Anadys Pharmaceuticals where he worked on developing immunomodulatory therapies to treat chronic hepatitis C virus (HCV) infection.

In 2009, he moved to Roche where he led drug discovery and translational research teams working towards the development of a functional cure for chronic hepatitis B virus (HBV) infection.

Since 2012, he has worked at Gilead Sciences, where he leads a group focused on developing novel therapies for HBV and other chronic viral infections.

Potential conflict of interest:
Gilead Sciences

SESSION CHAIR

Scott Fung, MD, FRCPC

Toronto General Hospital,
Canada

Dr. Scott Fung completed his undergraduate and postgraduate medical training at the University of Toronto. After completing a fellowship in Gastroenterology, he received further training in Hepatology research at the University of Michigan in Ann Arbor. He is currently appointed as Associate Professor of Medicine at the University of Toronto and is staff hepatologist at University Health Network and Sinai Health System. He is the site director for Gastroenterology education and General Internal Medicine educational coordinator for GI at Toronto General Hospital. In addition, Dr. Fung is a member of the University of Toronto Gastroenterology Residency Training Committee.

Dr. Fung co-directs the Hepatology Fellowship program at University of Toronto and is the education director for the Toronto Center for Liver Disease. He serves on committees for the Canadian Association for the Study of the Liver and volunteers for the Royal College of Physicians and Surgeons of Canada.

He has published several articles on the epidemiology and treatment of chronic hepatitis B and C and non-alcoholic fatty liver disease. Dr. Fung recently co-authored the Canadian national guidelines for the management of chronic HBV infection.

Potential conflict of interest:
Gilead, AbbVie, Novo Nordisk, Merck

Workshop Chair

Adam Gehring, PhD

Toronto Centre for Liver Disease,
Canada

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.

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.

Potential conflict of interest:
Janssen Pharmaceuticals, GSK, Gilead Sciences, Roche, Vir Biotech, Finch Therapeutics, SQZ Biotech

Speaker

Anna Maria Geretti, MD, PhD, FRCPath

Roche Pharma Research & Early Development, University of Rome; King's College London, Switzerland, Italy, UK

Professor Anna Maria Geretti – MD, PhD – is an academic clinician who specializes in virology, with a focus on antiviral therapy and drug resistance. She is based in the United Kingdom and in Italy and is affiliated with the Departments of Infectious Diseases of King's College London and the University of Rome Tor Vergata.

Her research, primarily for translation of science into clinical care applications, has led to over 250 publications spanning laboratory-based, patient-side, and epidemiology projects, which includes fieldwork in sub-Saharan Africa, collaborations with the World Health Organization, and drug and biomarker development within the industry.

Anna Maria is Editor in Chief of the BMJ journal Sexually Transmitted Infections. Her ambition is to deliver an impact that promotes the progress of medicine and science and is globally beneficial to patient care.

Potential conflict of interest:
Roche

Speaker

Jeffrey Glenn, MD, PhD

Stanford University, United States

Jeffrey Glenn is a Professor of Medicine (Division of Gastroenterology & Hepatology) and Microbiology & Immunology at Stanford University School of Medicine, and the Director of the Center for Hepatitis and Liver Tissue Engineering. He also heads a research laboratory focused on studying molecular virology and the translation of that knowledge into novel antiviral strategies, as well as the development of new treatments for liver diseases and cancer. He is the founder of Eiger BioPharmaceuticals, Inc. (NASDAQ:EIGR), co-founder of Riboscience LLC, and founder of I-Cubed Therapeutics, local biotechnology companies developing several new classes of antiviral and anti-cancer drugs.

Glenn was born in Los Angeles, and grew up in Switzerland. He received his B.A. degree in Biochemistry and French Civilization from U.C. Berkeley from where he graduated summa cum laude. He received his M.D. and Ph.D. in Biochemistry and Biophysics from U.C.S.F.. He trained in internal medicine at Stanford University where he completed specialty training in gastroenterology and hepatology, and joined the faculty in 2000.

He is the principal investigator on multiple NIH grants, an inventor on numerous patents, an elected member of the American Society for Clinical Investigation, and a member of the FDA Antiviral Drugs Advisory Committee.

Potential conflict of interest:
Eiger BioPharmaceuticals, Inc.

Speaker

Carey Hwang, MD, PhD

Vir Biotechnology, Inc., United States

Dr. Hwang serves as Senior Vice President, Clinical Research for Vir Biotechnology, where he is responsible for the Company's chronic infection clinical development portfolio. Since joining Vir in January 2021, Dr. Hwang oversees the development of the Company's lead hepatitis B candidates, VIR-2218 and VIR-3434, as well as its lead HIV vaccine candidate, VIR-1111.

Dr. Hwang has focused his career on the study and development of treatments for serious infectious diseases, including HIV, hepatitis B and hepatitis C. His industry career began at Bristol-Myers Squibb, conducting exploratory clinical and translational research focused on early phase clinical development of HIV and hepatitis C treatments. He joined Merck & Co. in 2016, where he served as Executive Director and Product Development Lead in Global Clinical Development – Infectious Diseases and led the worldwide development and global approval of two treatments for HIV.

Dr. Hwang received his bachelor's degree in molecular biology from Princeton University and his MD, PhD from West Virginia University with a dissertation focused on retroviral recombination. He completed his internal medicine residency and infectious disease fellowship at Vanderbilt University with research focused on the latent reservoir of HIV.

Potential conflict of interest:
Vir Biotechnology

Workshop Chair

Harry Janssen, MD, PhD

Toronto Centre for Liver Disease,
Canada

Harry L.A. Janssen, MD, PhD is a Professor of Medicine at the University of Toronto, Chief of Hepatology and Director of the Toronto Centre of Liver Disease at University Health Network, Toronto General Hospital. He obtained his PhD at the Erasmus University in Rotterdam, The Netherlands on the role of immune modulating therapy in chronic hepatitis B and worked as Research Fellow in Hepatology at the Center of Basic Research in Digestive Diseases in the Mayo Clinic. Dr. Janssen has coordinated numerous international multicenter clinical and translational studies on the natural history and treatment for chronic viral hepatitis and other liver diseases. His clinical and translational research aiming for immunological control and cure of hepatitis B and C has led to several novel treatment concepts. Based on publications and citations he is currently ranked as the global top-rated expert in chronic hepatitis B (Expertscape). His research contributions include sustained federal funding (greater than 20 years), over 520 peer reviewed publications, an H-index of 101, and over 50,000 citations (Google Scholar).

In addition to his longstanding expertise in antiviral therapy of chronic viral hepatitis, he is a leading scientist in the field of vascular disorders of the liver. Dr. Janssen is a member of the EASL Guideline Committees for both Hepatitis B and for Vascular Liver Disease. He is also the Chair of the AASLD Special Interest Group (SIG) for Hepatitis B, Chair of the Global Hepatitis Summit, and the Chair of HBV Forum providing scientific guidance to industry, regulatory bodies (FDA and EMA) and the academic communities in the areas of liver drug and diagnostic development. He has acquired over $50 million USD in research funding from many different organizations among which NIH, European Commission, CIHR, NWO and ZonMW. He has received several prestigious international awards and has mentored over 50 PhD students, many of whom have taken leadership positions in the field of Hepatology or Virology.

Potential conflict of interest:
AbbVie, Aligos, Arena, Arbutus, Bristol Myers Squibb, Eiger, Enyo, Gilead Sciences, GlaxoSmithKline, Janssen, Merck, Regulus, Roche, VBI Vaccines (Variation Biotechnologies), Vir Biotechnology Inc., Viroclinics

Organizing Committee

Pietro Lampertico, MD, PhD

University of Milan,
Italy

Professor Pietro Lampertico is Assistant Professor in the 1st Gastroenterology Unit at the Fondazione IRCCS Ca' Granda, Ospedale Maggiore Policlinico, University of Milan, Milan, Italy, under the direction of Professor Massimo Colombo.

A 1986 graduate of the State University of Milan with degrees in medicine and surgery, Professor Lampertico completed his postdoctoral research in the Department of Experimental Pathology at Tulane University in New Orleans, USA. Upon his return to Milan, he completed specialisations in liver diseases and internal medicine. He received his PhD in clinical methodology from the University of Milan in 1998. In the Gastroenterology Unit, Professor Lampertico is primarily involved in the clinical management of chronic viral hepatitis outpatients, particularly those with CHB. His research interests include the treatment of patients with chronic hepatitis/cirrhosis due to HBV, the long-term outcome of cirrhotic patients undergoing antiviral treatment, and the diagnosis and management of antiviral resistance to oral nucleos(t)ide analogues.

Professor Lampertico is currently a reviewer for *Gastroenterology, Hepatology, Journal of Hepatology,* and other top ranked journals, and a member of AASLD, EASL and AISF.

He has spoken internationally about liver disease, specifically the natural history of HBV and antiviral treatment, and has published several articles and book chapters. He is currently involved in national and international HBV clinical trials.

Potential conflict of interest:
Bms, Roche, Gilead Sciences, GSK, AbbVie, MSD, Arrowhead, Alnylam, Janssen, Sbring Bank, MYR, Eiger

Organizing Committee

Mala Maini, MD, PhD

University College London, United Kingdom

Mala Maini is a Professor of Viral Immunology in the Division of Infection and Immunity at UCL, London, Deputy Head of Department and also works as a Consultant Physician in the viral hepatitis clinic.

After completing her specialist medical accreditation in 1995 she obtained an MRC Clinical Training Fellowship, leading to a PhD on T cell clonality and senescence in 1998. In 2002 she was awarded an MRC/Academy of Medical Sciences Tenure-track Clinician Scientist Fellowship, and built up her own group working on the immunopathogenesis of hepatitis B.

In 2009 she was promoted to a Personal Chair; she was awarded a Wellcome Trust Senior Investigator Award in 2013 and Fellowship of the Academy of Medical Sciences in 2016. Her lab is at the forefront internationally of research on Hepatitis B immunity and immunopathology, focusing on cellular interactions in the liver. Their goal is to dissect mechanisms informing the development of immunotherapy for hepatitis B and hepatocellular carcinoma.

Potential conflict of interest:
Gilead Sciences, Roche, Immunocore, GSK, Vir Biosciences

Speaker

Dmitry Manuilov, MD

Gilead Sciences, Germany

After graduating from the State Medical University in Moscow, Dmitry started his career in Clinical Research in pharmaceutical industry where he contributed to the development of a novel therapy for breast cancer and branded generics as well as took leadership roles in some of the corporate initiatives. Dmitry then moved on to biotech / venture capital environment where he helped manage the clinical development program of an innovative gastrointestinal product and successfully contributed to other programs and projects.

In 2017 Dmitry joined MYR GmbH to lead the clinical development of bulevirtide – a novel breakthrough entry inhibitor for the treatment of chronic HDV infection. During this time, the team completed phase 2b studies, launched an international phase 3 program, and ensured granting the Conditional Marketing Authorization of bulevirtide in the EU. Following the acquisition of MYR GmbH by Gilead Sciences in 2021, he moved to Gilead to continue contributing to the development of bulevirtide and help addressing the unmet medical need worldwide.

Dmitry's area of scientific interest is focused on viral hepatitis, especially HBV/HDV co-infection. He is also interested in various aspects of drug development and clinical research, such as streamlining drug development, implementation of innovative study designs, ethical considerations, and harmonization of international regulations.

Potential conflict of interest:
Gilead Sciences, MYR GmbH

Speaker

Douglas Mayers, MD

Antios Therapeutics,
United States

Dr. 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. 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.

Dr. Mayers has authored numerous publications and is the editor for the two-volume textbook, Antimicrobial Drug Resistance, and is a Fellow of the American College of Physicians and the Infectious Disease Society of America.

He received the Jay P. Sanford Award for lifetime professional achievement from the Armed Forces Infectious Disease Society. He holds a Bachelor's Degree in Electrical Engineering from Penn State University, and an M.D. from the University of Pennsylvania.

Potential conflict of interest:
Antios Therapeutics

Speaker

Matthew McClure, MD

Aligos,
United States

Matthew W. McClure, M.D., is the Chief Medical Officer of Aligos, a clinical stage biopharmaceutical company focused on developing novel therapeutics to address unmet medical needs in viral and liver diseases.

Dr. McClure has more than 20 years of clinical and drug development experience with significant expertise in the design, execution and interpretation of Phase 1-3 clinical trials across a range of therapeutic areas, particularly in chronic viral hepatitis and NASH.

Dr. McClure received his degree in medicine from Duke University and graduated (summa cum laude) with a Bachelor of Science in biochemistry and cell biology from the University of California, San Diego.

Potential conflict of interest:
Aligos Therapeutics

Session Chair

Veronica Miller, PhD

Forum for Collaborative Research, UC Berkeley School of Public Health, United States

Veronica Miller is the Executive Director of the Forum for Collaborative Research (the Forum), a public/private partnership addressing cutting-edge science and policy issues through a process of stakeholder engagement and deliberation.

Dr. Miller has extensive experience in working with all major global and U.S. organizations and agencies involved in HIV research and policy. She is a leading expert in the process of engaging stakeholders from both sides of the Atlantic to resolve significant health policy and public health issues.

Additionally, Dr. Miller is a Senior Researcher and Lecturer at the UC Berkeley School of Public Health. She developed and teaches a course on FDA and Drug Development based on case studies from the Forum's rich history in facilitating drug development to Berkeley and Bay Area graduate students and post-docs. She mentors interns and fellows pursuing regulatory, biotech, and translational medicine careers.

Dr. Miller has served on numerous industry and government advisory boards. She has published over 90 peer-reviewed publications on HIV treatment strategies and regulatory strategies for HIV and HCV.
She joined the Forum in 2001 after having directed the interdisciplinary HIV Research Group at the HIV Outpatient Clinic of the JW Goethe University in Frankfurt, Germany. Together with Joep Lange, she co-founded and chaired the Euro-Guidelines Group on HIV Drug Resistance, the first pan-European group established for the purpose of assuring a common standard of care for patients in all European states.

Dr. Miller obtained a Bachelor of Science in Microbiology from the University of Manitoba, and a Doctor of Philosophy in Immunology from the University of Manitoba.

Potential conflict of interest:
Dr. Veronica Miller is an employee of UC Berkeley and her position is funded by the Forum for Collaborative Research (Forum). The Forum has received unrestricted educational or research support from multiple sources.

Speaker

Poonam Mishra, MD, MPH, FAASLD

US Food and Drug Administration, United States

Dr. Poonam Mishra is the Deputy Director for Safety in the Division of Antivirals, in the Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration (FDA). She shares the responsibility for overseeing the safety of antiviral drug products to ensure that the benefits of approved drugs outweigh their known risks. Dr. Mishra joined FDA in 2008 as a Medical Officer in the Division of Antiviral Products where she has been involved in the regulatory review of multiple antiviral products, including direct-acting antivirals for the treatment of chronic hepatitis C.

She is actively involved in the drug development of novel therapies for treatment of chronic hepatitis B and chronic hepatitis D virus infection. Dr. Mishra also has a strong interest in the evaluation of drug-induced liver injury particularly in patients with pre-existing chronic liver disease.

No potential conflict of interest.

Organizing Committe

Marion Peters, MD

University of California at San Francisco (UCSF), United States

Marion Peters, MD is a Professor of Medicine and Chief of Hepatology Research at the University of California at San Francisco, where she currently holds the John V. Carbone, MD, Endowed Chair in Medicine.

She received her Bachelor of Medicine/Bachelor of Surgery degree and her Doctorate of Medicine from Melbourne University Medical School in Melbourne, Australia.

Her research focuses on viral hepatitis in complicated clinical settings, patients with co-morbid conditions including alcoholism and HIV infection. In these complex situations, her group focuses on the role of host responses to hepatitis virus infection, and examines the effect of alcohol or HIV on the progression of viral hepatitis and the response to anti-viral therapy. She studies the factors associated with the progression of hepatitis C and HIV, including race/ethnicity, immune status, and the role of reproductive aging.

She has been a major scientific leader in the AIDS Clinical Trial Group (ACTG), and leads the ACTG Hepatitis Transformative Science Group and the Women's Interagency HIV Study (WIHS) Hepatitis Working group where she is studying new serum markers to evaluate liver fibrosis in women, outcomes in Hepatitis B and new HCV drugs for patients with HCV, with and without HIV. She has published numerous peer-reviewed articles.

Potential conflict of interest:
Aligos, Antios, Hoffman La Roche

Organizing Committee

Raymond Schinazi, PhD, DSc

Emory University Center for AIDS Research (CFAR), United States

Raymond F. Schinazi, PhD, DSc is Frances Winship Walters Professor of Pediatrics at Emory and director of the Laboratory of Biochemical Pharmacology. His is a senior research career scientist at the Atlanta Veterans Affairs Medical Center and Director of the Scientific Working Group on Viral Eradication for the Emory University Center for AIDS Research (CFAR).

Schinazi received his BSc (1972) and PhD (1976) in chemistry from the University of Bath, England. A world leader in the area of nucleoside chemistry, Schinazi is the founder of five biotechnology companies including Pharmasset Inc. He has authored over 470 peer-reviewed papers, 7 books and has received many honors. He holds 92 issued US patents which have resulted in 11 New Drug Applications (NDA).

More than 94 percent of HIV-infected individuals take at least one of the drugs he invented.

Potential conflict of interest:
Aligos Therapeutics, Precision Biosciences, Petrichor Healthcare, Gliknik, Pythia Labs, Inc., Cocrystal Pharma, Inc., Brace Pharma Capital, Reviral, Gilead Sciences, Ely Lilly, GSK, Pfizer, BMS

SPEAKER

Luisa Stamm, MD, PhD

Assembly Biosciences, United States

Luisa Stamm, MD, PhD, is an infectious disease physician and Chief Medical Officer at Assembly Biosciences. She is currently focused on the development of a cure for chronic hepatitis B infection with core inhibitors and other candidates with complementary mechanisms. Prior to her current role, Dr. Stamm worked at Gilead Sciences on the clinical development of sofosbuvir-based therapies for chronic hepatitis C infection and of broadly neutralizing antibodies for HIV cure. Dr. Stamm received her MD and PhD from University of San Francisco, California, and completed her clinical training at Brigham and Women's Hospital and Massachusetts General Hospital.

Potential conflict of interest:
Assembly Biosciences

SPEAKER

Stephan Urban, PhD

Heidelberg University Hospital, Germany

Professor Stephan Urban is head of the Translational Virology unit at the Department of Infectious Diseases, Molecular Virology at Heidelberg University Hospital. He is also Project Coordinator in the DZIF TTU Hepatitis. He completed his Diploma in Biochemistry at the University of Tübingen in 1991 and was awarded a Ph.D. in 1995 under Prof. Dr. P.H. Hofschneider at the Max-Planck-Institut für Biochemie, Martinsried and undertook Postdoctoral research at the Centre for Molecular Biology (ZMBH), Heidelberg University with Prof. Dr. H. Schaller.

Between 2008 and 2012 he was Project coordinator of the BMBF-network "Innovative Therapies" and from 2011 Project coordinator in the DZIF TTU hepatitis. In 2014 he was awarded with the 1. DZIF Research Award. He is the recipient of the Pettenkofer Price of the Pettenkofer Foundation 2011.

Professor Urban's research interests include Molecular mechanisms of Hepatitis B- and Hepatitis D Virus/host interactions with a focus on the early and late events of viral infection; Identification of hepadnaviral receptors and structural analyses of virus receptor interactions; Development of novel cell culture systems and animal models for HBV and HDV; Clinical development of entry inhibitors for HBV and HDV infection; Development of hepatotropic drugs for the therapy of liver diseases.

Between 2008 and 2016 Professor Urban has published in numerous peer reviewed journals on Hepatitis B, C, and D.

Potential conflict of interest:
MYT GmbH / Gilead Sciences

Organizing Committee

Fabien Zoulim, MD, PhD

Lyon I University / Hospices Civils de Lyon / INSERM, France

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 Head of the Hepatology Department at the Hospices Civils de Lyon, and Head of the Viral Hepatitis Research Laboratory of INSERM Unit 1052.

Dr Zoulim is currently Associate Editor for Gut. He also 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. He is currently coordinating the ANRS “HBV cure” Task Force in France and the “IP-cure-B” project within the EU H2020 workprogram. He co-founded and is currently the chair of the International Coalition to Eliminate HBV (ICE-HBV: http//:www.ice-hbv.org). He has published more than 500 articles (Web of Science H index 83).

Potential conflict of interest:
Aligos, Antios, Assembly, Beam Therapeutics, Enochian, Gilead, GSK

Acknowledgement

SILVER LEVEL SPONSOR

GILEAD

BRONZE LEVEL SPONSOR

ENYO PHARMA

janssen Infectious Diseases & Vaccines
PHARMACEUTICAL COMPANIES OF Johnson & Johnson

Roche

SUPPORT LEVEL SPONSOR

ANTIOS THERAPEUTICS

assemblybio

EIGER BIOPHARMACEUTICALS

VIR

CONTRIBUTOR LEVEL SPONSOR

Arbutus BIOPHARMA

IMMUNOCORE

VBI VACCINES

FRIEND LEVEL SPONSOR

altimmune

Acknowledgement

WORKSHOP PARTNER

TORONTO CENTRE FOR LIVER DISEASE

MEDIA PARTNERS

hep YOUR GUIDE TO HEPATITIS

SAGE Publishing

ENDORSERS

African Association of Gastroenterologists

AFEW International

AHI Africa Hepatitis Initiative

BVHG British Viral Hepatitis Group

EATAN European African Treatment Advocates Network

ELPA European Liver Patients' Association

Erasmus MC Universitair Medisch Centrum Rotterdam

GLI Global Liver Institute

HEP Hepatitis Education Project

hepatitis australia

Hepatitis B Foundation

IAPAC International Association of Providers of AIDS Care

ICE-HBV International Coalition to Eliminate HBV

ILCA International Liver Cancer Association

NATAP National AIDS Treatment Advocacy Project www.natap.org

The National Organisation for People Living with Hepatitis B NOPLHB

NVHR National Viral Hepatitis Roundtable

Pan-African Organization for Health Education & Research POHER

The Task Force for Global Health

Coalition for Global Hepatitis Elimination

academic
medical education

AcademicMedicalEducation.com