

**HEP DART 2009**  
**Frontiers in Drug Development for Viral Hepatitis**  
**Scientific Program**

**SUNDAY, DECEMBER 6, 2009**

**HEP DART 2009 Opening Session**

15:00 Opening Remarks  
Raymond F. Schinazi *Emory University/VA Medical Center, USA*

**Global Burden of Hepatitis Viruses, Natural History and Management**

Chairs: Raymond F. Schinazi *Emory University/VA Medical Center, USA*  
Robert Murphy *Northwestern University, USA*

15:20 **State of the Art Presentation**

The Future Burden of Chronic Liver Disease and Global Opportunities for Therapeutic Interventions  
Brian McMahon *Alaska Native Medical Center and Alaska Native Tribal Health Consortium, USA*

16:00 Magnitude of Hepatitis Infection in Egypt and Africa  
Mostafa Mohamed *Ain Shams University, Egypt*

16:20 Review of the HCC Epidemic  
Hashem El-Serag *Baylor College of Medicine/Michael E. DeBakey VA Medical Center, USA*

16:40 Hepatitis E: One Virus, Many Faces  
Kenneth Sherman *University of Cincinnati College of Medicine, USA*

17:00 Panel Discussion

18:00 **Welcome Reception**

**MONDAY, DECEMBER 7, 2009**

**Discoveries and Advances in HCV Basic Research**

Chairs: Robert Murphy *Northwestern University, USA*  
Harvey Alter *National Institutes of Health, USA*

8:00 Presentation of William H. Prusoff HEP DART Lifetime Achievement Award  
Harvey Alter *National Institutes of Health, USA*

8:10 **State of the Art Presentation**

The Long and Winding Road Leading to the Discovery of HCV  
Michael Houghton *Epiphany Biosciences, USA*

8:50 Modeling Drug Resistance to STAT-C Agents  
Alan Perelson *Los Alamos National Laboratory, USA*

9:10 Insights into NS5A: A New Emerging Drug Target  
Timothy Tellinghuisen *The Scripps Research Institute, USA*

9:30 **State of the Art Presentation**

HCV-host Interactions - Entry and New Tools  
Charles Rice *The Rockefeller University, USA*

10:00 Panel Discussion

10:20 **Break**

## **New Targets I: Cellular Systems and Infectious Models**

Chairs: Daria Hazuda *Merck & Co., Inc., USA*  
Charles Rice *The Rockefeller University, USA*

### **10:50 State of the Art Presentation**

Understanding Stat-C by Using Cell Culture Models  
Ralf Bartenschlager *University of Heidelberg, Germany*

11:20 Prospects for a Small Animal Model for HCV  
Alexander Ploss *The Rockefeller University, USA*

11:40 Modulation of Hepatitis C Virus RNA Abundance by Liver-specific MicroRNA miR-122  
Peter Sarnow *Stanford University, USA*

12:00 Panel Discussion

### **12:30 Lunch and Free Afternoon**

## **HCV Management: Looking into the Crystal Ball**

Chairs: Douglas Dieterich *Mount Sinai School of Medicine, USA*  
Michael Fried *University of North Carolina at Chapel Hill, USA*

16:00 HCV Treatment, Screening and Monitoring: 2009-2012  
Jean-Michel Pawlotsky *Henri Mondor University Hospital, France*

16:20 HCV Treatment, Screening and Monitoring: 2012-2015  
David Nelson *University of Florida, USA*

16:40 HCV Treatment, Screening and Monitoring: 2015 and Beyond  
Adrian Di Bisceglie *Saint Louis University School of Medicine, USA*

17:00 Panel Discussion

### **17:20 Break**

## **The Business of Antiviral Agents: 2010 and Beyond**

Chairs: Abel De La Rosa *Pharmasset, USA*  
Geoffrey Meacham *JP Morgan Securities, Inc., USA*

17:40 Adam Cutler *Canaccord Adams, USA*  
Vivek Ramaswamy *QVT Financial LP, USA*  
David Witzke *PioneerPath Capital, USA*  
Frank Zavrl *Adage Capital, USA*

## **TUESDAY, DECEMBER 8, 2009**

### **Emergence and Prevention of Viral Resistance**

Chairs: Mark Sulkowski *Johns Hopkins University, USA*  
Christoph Seeger *Fox Chase Cancer Center, USA*

### **8:00 State of the Art Presentation**

HBV Antiviral Drug Resistance: Prevention and Monitoring  
Anna Lok *University of Michigan Medical Center, USA*

8:30 An Update on HBV Resistance: The View From the Hepatocyte  
Stephen Locarnini *VIDRL, Australia*

8:50 Overview of HCV Resistance to Protease Inhibitors  
Philippe Halfon *Hôpital Ambroise Paré, France*

9:10 HCV Drug Resistance to Nucleoside and Non Nucleoside Polymerase Inhibitors: Potential Impact on HCV Therapies  
Isabel Nájera *Roche Palo Alto, USA*

9:30 A Retrospective Analysis of Tenofovir DF and Entecavir Combination Therapy in Patients with Chronic Hepatitis B (CHB) and Previous Treatment Failure (PTF)  
Robert Gish *CPMC, USA*

9:50 Panel Discussion

10:10 **Break**

### **Clinical Trial Design**

Chairs: Yves Benhamou *Hôpital Pitié-Salpêtrière, France*  
David Nelson *University of Florida, USA*

10:40 Lessons Learned from Failed/Negative Studies in HCV Drug Development  
Paul Pockros *The Scripps Clinic, USA*

11:00 Planning Clinical Trials in Acute Hepatitis C (HCV)  
Douglas Dieterich *Mount Sinai School of Medicine, USA*

### **Oral Abstract Presentations I**

11:20 Selection of Hepatitis C Virus Resistant to Ribavirin  
Dino Feigelstock *CBER, Food and Drug Administration, USA*

11:30 HCV Transmission and Diversification in Infected Subjects Analyzed by Deep Sequencing  
Gary Wang *University of Florida College of Medicine*  
*University of Pennsylvania School of Medicine, USA*

11:40 Longterm Culture of Huh7.5 Cells with Cyclosporine A is Leading to Downregulation of Cyclophilin A and G  
Sandra Ciesek *Hannover Medical School, Germany*

11:50 Evidence that the Duck Hepatitis B Virus Covalently Closed Circular DNA is able to Survive Mitosis during Antiviral Therapy  
Allison Jilbert *University of Adelaide, Australia*

12:00 **Review of Poster Presentations**  
Adrian Di Bisceglie *Saint Louis University School of Medicine, USA*  
Adrian Ray *Gilead Sciences, Inc., USA*

13:00 **Lunch**

15:00 **HCV Education Roundtable: Anticipating a New Clinical Paradigm for Hepatitis C Virus Treatment Overcoming Resistance**  
**[Sponsored by the Forum for Collaborative HIV Research - HCV Drug Resistance Advisory Group (DRAG)]**

Facilitator: Veronica Miller *Forum for Collaborative HIV Research, USA*

### **1) Lessons Learned**

- a. What lessons have we learned from HIV and HBV that would inform the issue of resistance and treatment outcome in HCV patients

Raymond F. Schinazi *Emory University/VA Medical Center, USA*  
Robert Schooley *University of California San Diego, USA*  
Stephen Locarnini *VIDRL, Australia*  
Lei Chou *Treatment Action Group, USA*

### **2) SVR and Cure**

- a. Will durability of SVR observed with pegylated interferon and ribavirin apply to combinations with direct acting antivirals
- b. What roles do direct acting antivirals and pegylated interferon plus RBV play in the achievement of SVR?
- c. What are important messages for people who have been treated with SOC and are considering re-treatment with a 3rd drug?

Kenneth Sherman *University of Cincinnati College of Medicine, USA*  
Mark Sulkowski *Johns Hopkins University, USA*  
Jules Levin *National AIDS Treatment Advocacy Project (NATAP), USA*

### 3) Minimize Resistance by Maximizing SVR

- a. Why is adherence important and how do you explain adherence to your patient?
- b. What can you do to support adherence? What are some evidence-based interventions?
- c. What are pharmacological barriers to resistance?
- d. What are virological barriers to resistance?

Kenneth Sherman  
Jean-Michel Pawlotsky  
Tracy Swan

*University of Cincinnati College of Medicine, USA*  
*Henri Mondor University Hospital, France*  
*Treatment Action Group, USA*

### 4) How Would you Describe/Explain HCV Drug Resistance?

- a. New GI, hepatology or ID residents?
- b. Patients entering a clinical trial with a direct-acting antiviral?
- c. Patients with virologic failure (breakthrough or relapse) on a direct acting antiviral regimen or on pegylated interferon and RBV
- d. Patients with resistance after early discontinuation from a direct acting antiviral regimen

Tracy Swan  
Kenneth Sherman  
Robert Schooley  
Mark Sulkowski

*Treatment Action Group, USA*  
*University of Cincinnati College of Medicine, USA*  
*University of California San Diego, USA*  
*Johns Hopkins University, USA*

### 5) HCV Resistance Education Slide Deck

- 1) Review/discuss draft slide deck
- 2) Discussion- what works, what doesn't, what is missing?

Ann Kwong  
Jean-Michel Pawlotsky  
Tracy Swan

*Vertex Pharmaceuticals, USA*  
*Henri Mondor University Hospital, France*  
*Treatment Action Group, USA*

### 6) Wrap up

Veronica Miller

*Forum for Collaborative HIV Research, USA*

### 16:30 Poster Session

#### New Targets II: Insights into Drug Mechanisms

Chairs: Ralf Bartenschlager  
T. Jake Liang

*University of Heidelberg, Germany*  
*NIDDK National Institutes of Health, USA*

18:30 Ribavirin - Still Needed, but How Does It Work?

Jordan Feld *Toronto Western Hospital Liver Centre, University of Toronto, Canada*

18:50 Anti-HCV Mechanisms of Action of Cyclophilin Inhibitors

Philippe Galle *The Scripps Research Institute, USA*

19:10 Direct Influence of Immunosuppressive Drugs on Hepatitis C Virus Replication and Infection

Thomas Pietschmann *Center for Experimental and Clinical Infection Research, Germany*

19:30 Attacking HBV Assembly: a General Target and a Specific Solution

Adam Zlotnick *Indiana University, USA*

19:50 Panel Discussion

## **WEDNESDAY, DECEMBER 9, 2009**

### **Optimizing Outcome of Therapeutics for Hepatitis Infections**

Chairs: Nezam Afdhal *Beth Israel Deaconess Medical Center, USA*  
Robert Schooley *University of California San Diego, USA*

#### **8:00 State of the Art Presentation**

Optimizing Anti-HCV Regimens: Navigating the Doldrums  
Michael Fried *University of North Carolina at Chapel Hill, USA*

8:30 Can We Cure Hepatitis C without Interferon?  
Yves Benhamou *Hôpital Pitié-Salpêtrière, France*

8:50 Long Term Results of Pegylated Interferon Alfa 2a and Tenofovir for Hepatitis B  
Patrick Marcellin *Hôpital Beaujon, France*

9:20 The Case for Nucleosides as First Line Therapy for HBV Infection  
Jules Dienstag *Massachusetts General Hospital, USA*

9:40 Panel Discussion

#### **9:50 Break**

### **Pharmacology and New Therapies for Hepatitis Infections**

Chairs: Jean-Michel Pawlotsky *Henri Mondor University Hospital, France*  
Frank Chisari *The Scripps Research Institute, USA*

#### **10:20 State of the Art Presentation**

Pharmacology of Anti-HBV and Anti-HCV Drugs  
Adrian Ray *Gilead Sciences, Inc., USA*

10:50 Ending the PEG Interferon/Ribavirin Era in HCV Therapy: The Importance of Multiple Shots on Goal  
Robert Schooley *University of California San Diego, USA*

11:10 Pharmacology of IDX184, a Liver-targeted Nucleotide Prodrug for the Treatment of HCV  
David Standring *Idenix Pharmaceuticals, Inc., USA*

11:20 Panel Discussion

### **Oral Abstract Presentations II**

11:40 The Discovery and Early Development of the HCV NS3 Protease Inhibitor BMS-605339  
Fiona McPhee *Bristol-Myers Squibb, USA*

11:50 Early Clinical Experience with BI201335, a Novel Hepatitis C Virus NS3-NS4A Serine Protease Inhibitor  
Donald Jensen *University of Chicago Medical Center, USA*

12:00 Potent Antiviral Activity Observed with PSI-7851, a Novel Nucleotide Polymerase Inhibitor for HCV, Following Multiple Ascending Oral Doses for 3 Days in Patients with Chronic HCV Infection  
Eric Lawitz *Alamo Medical Research, USA*

12:10 Cyclophilins are Essential Host Factors for HCV Replication: The Required Level Varies with HCV Clone  
Kazuaki Inoue *Showa University Fujigaoka Hospital, Japan*

12:20 Assessment of Serum HCV-RNA at Week 12 Post-treatment is as Relevant as Week 24 to Predict SVR in HCV Patients Receiving Peginterferon plus Ribavirin  
Michelle Martinot-Peignoux *INSERM U-773, Université Paris VII, France*

12:30 Different Kinetics of Serum HBsAg Decline in HBeAg-positive vs HBeAg-negative Patients during 3 Years of Telbivudine Treatment in Chronic Hepatitis B (CHB)  
Karsten Wursthorn *Hannover Medical School, Germany*

12:40 **Lunch and Free Afternoon**

### **Co-infections, Therapeutic Modalities and Regulatory Issues**

- Chairs: Tracy Swan *Treatment Action Group, USA*  
Robert Gish *CPMC, USA*
- 16:00 Public Health Challenges for HIV and Hepatitis C Coinfection  
Gregory Dore *University of New South Wales, Australia*
- 16:20 Treatment for Forgotten Population  
Mark Sulkowski *Johns Hopkins University, USA*
- 16:40 Regulatory Requirements for Combination Studies  
Richard Robson *Christchurch Clinical Studies Trust, New Zealand*
- 17:00 Panel Discussion

### **Immunological Approaches and Vaccines for Hepatitis Infections**

- Chairs: Stephen Locarnini *VIDRL, Australia*  
Eugene Schiff *University of Miami, USA*
- 17:30 Genome-wide Identification of Novel Host Factors Required for Hepatitis C Virus Infection and Propagation  
T. Jake Liang *NIDDK National Institutes of Health, USA*
- 17:50 HCV Persistence and IFN Resistance  
Christoph Seeger *Fox Chase Cancer Center, USA*
- 18:10 Induction and Inhibition of Interferon Effector Functions by HCV  
Frank Chisari *The Scripps Research Institute, USA*
- 18:30 Panel Discussion

### **Oral Abstract Presentations**

- 18:50 Completion of the First Clinical Trial of Therapeutic Vaccination Using Naked DNA Delivered by *In Vivo* Electroporation in Patients with Chronic Hepatitis C: Transient Control of Viremia  
Matti Sallberg *Karolinska Institutet, Sweden*
- 19:00 Efficacy, Safety, and Predictive Value of Early Virologic Response of albinterferon alfa-2b vs peginterferon alfa-2a in Treatment-Naïve Patients With Genotype 1 Chronic Hepatitis C  
Fred Poordad *Cedars-Sinai Medical Center, USA*
- 20:00 **Gala Party**

## **THURSDAY, DECEMBER 10, 2009**

### **Liver Damage, Decompensation Fibrosis and Hepatocellular Carcinoma (Sponsored by Hepatitis B Foundation)**

- Chairs: Timothy Block *Hepatitis B Foundation and Drexel University College of Medicine, USA*  
Philippe Halfon *Hôpital Ambroise Paré, France*
- 8:00 Perspectives from the Hepatitis B Foundation  
Timothy Block *Hepatitis B Foundation and Drexel University College of Medicine, USA*
- 8:10 **State of the Art Presentation**  
Prevention of HCC in Hepatitis B Patients Using Antiviral Agents  
Yun-Fan Liaw *Chang Gung Memorial Hospital, Taiwan*
- 8:40 Cellular Evolution in Patients Chronically Infected with Hepatitis B Virus  
William Mason *Fox Chase Cancer Center, USA*
- 9:00 Management of Liver "Stiffness" and Hepatocellular Carcinoma (HCC)  
Masao Omata *University of Tokyo, Japan*
- 9:20 Hepatic Elastography for Measuring Liver Fibrosis  
Nezam Afdhal *Beth Israel Deaconess Medical Center, USA*

9:40 Biomarkers of Liver Injury for Hepatitis Clinical Trials: An Overview of Longitudinal Studies  
Thierry Poynard *Hôpital Pitié-Salpêtrière, France*

10:00 Can an Aberrant IgG be used as a Biomarker for Disease Progression?  
Timothy Block *Hepatitis B Foundation and Drexel University College of Medicine, USA*

10:10 Panel Discussion

10:30 **Break**

**Oral Abstract Presentations III**

Chairs: Allison Jilbert *University of Adelaide, Australia*  
Raymond F. Schinazi *Emory University/VA Medical Center, USA*

11:00 MicroRNA: New Biomarkers in Chronic Liver Disease  
Hans Peter Dienes *University Hospital Cologne, Germany*

**Late Breaker Oral Abstract Presentations**

11:10 SPC3649 Antagonizes the HCV Host Factor MicroRNA-122 in Chronically Infected Chimpanzees and Suppresses HCV RNA Accumulation  
Robert Lanford *Southwest Foundation for Biomedical Research, USA*

11:20 A Phase Ib Placebo-Controlled, Randomized Study of the Safety, Pharmacokinetics and Antiviral Activity of p7 Inhibitor BIT225 in Patients with Hepatitis C Virus (HCV) Infection  
Carolyn Luscombe *Biotron Limited, USA*

11:30 Telaprevir (TVR) q8h or q12h Combined with Either Peginterferon (PEG-IFN, P) Alfa-2a or Alfa-2b and Ribavirin (RBV, R) in Treatment-naïve Genotype 1 Hepatitis C: Final Results of the Randomized, Open-label, Multicenter Phase 2 Study C208  
Peter Ferenci *Medical University of Vienna, Austria*

11:40 **Framing the Vision**  
Eugene Schiff *University of Miami, USA*

12:30 **Closing Remarks**