Forum for
Collaborative HIV Research

HCV DrAG MEETING #9:
ISSUES IN HCV DRUG DEVELOPMENT

NOVEMBER 8, 2012

The Fenway Institute, Fenway Health
1340 Boylston Street
Boston, MA 02215

School of
Public Health
UNIVERSITY OF CALIFORNIA, BERKELEY

enhancing and facilitating HIV research

Save the Date

November 26–28, 2012
Washington DC

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2012 National Summit
on HIV and Viral Hepatitis Diagnosis, Prevention and Access to Care

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AGENDA

2:30 PM **Opening Reception** — The Fenway Institute, Fenway Health

3:00 PM **Welcome & Introductions**

Veronica Miller, PhD
Forum for Collaborative HIV Research

Robert Kauffman, MD, PhD; Co-chair
Vertex Pharmaceuticals

Kenneth Mayer, MD
Fenway Health

Jean-Michel Pawlotsky, MD, PhD; Co-chair
Hôpital Henri Mondor

3:10 PM **HCV RNA Measurement**
Discussion:
• Value in clinical trials and in clinical practice
• Ideal time points for decision-making

Moderators:
Heiner Wedemeyer, MD
Hannover Medical School

Nina Mani, PhD, MPH
Forum for Collaborative HIV Research

Discussants:
Patrick Harrington, PhD
Division of Antiviral Products, FDA/CDER

Gaston Picchio, PhD
Janssen R&D, Infectious Disease Therapeutic Area

Filip Josephson, MD, PhD
Swedish MPA

Christoph Sarrazin, MD, PhD
University of Frankfurt

Jean-Michel Pawlotsky, MD, PhD
Hôpital Henri Mondor

3:30 PM **HCV Drug Resistance- Should It Be Used in the Decision to Treat?**
Discussion:
• Documenting sequence information on patients who fail DAA therapy:
  • Fate of resistant mutants
  • Response to DAA re-treatment
• Is there a role for baseline drug resistance in deciding HCV treatment options for patients who are naïve to DAA treatment?
• Is there a role for baseline drug resistance in deciding HCV treatment options for patients for whom DAA therapy has failed?

Moderators:
Heiner Wedemeyer, MD
Hannover Medical School

Isabel Najera, PhD
Hoffmann LaRoche-Genentech

Discussants:
Richard Barnard, PhD
Merck & Co, Inc.

Filip Josephson, MD, PhD
Swedish MPA

Douglas Dieterich, MD
Mount Sinai School of Medicine

Jean-Michel Pawlotsky, MD, PhD
Hôpital Henri Mondor

Jordan Feld, MD, MPH
University of Toronto

Lorren Sandt
Caring Ambassadors Program

Patrick Harrington, PhD
Division of Antiviral Products, FDA/CDER

4:00 PM **HCV Treatment in HIV-HCV Co-Infected Patients: Community and Clinician Perspectives**
Discussion:
• Risk tolerance with respect to drug-drug interactions:
  • Perspectives from clinical trials
  • Perspectives from post-approval cohorts e.g. CUPIC and TARGET

Moderators:
Russ Fleischer, PA-C, MPH
FDA

Kenneth Sherman, MD, PhD
University of Cincinnati

Discussants:
Curtis Cooper, MD, FRCPC
University of Ottawa

Tracy Swan
TAG

Jules Levin, BA
NATAP

Heiner Wedemeyer, MD
Hannover Medical School

Kenneth Mayer, MD
Fenway Health

4:30 PM **BREAK**

5:00 PM **Clinical Trial Design: IDUs and HCV Clinical Trials**

Moderators:
Veronica Miller, PhD
Forum for Collaborative HIV Research

Ira Jacobson, MD
Weill Cornell Medical College

ACTIVATE: An International Network for HCV Therapeutic Evaluation Among People Who Inject Drugs
Greg Dore, MBBS, PhD, MPH
Kirby Institute

NIH's National and International Research Portfolio
Jag Khalsa, PhD, MS
OASH, NIDA/NIH

Panel Discussion
- Drug-drug interaction issues with methadone and buprenorphine, and other drugs
- Investigating expanding the remit of current care and treatment facilities to accommodate IDU trials
- Trial design and stage of clinical development

Discussants:
Ronald D'Amico, DO, MSc
Abbott Labs

Daniel Raymond
Harm Reduction Coalition

Jason Grebely, BSc, PhD
University of New South Wales

Tracy Swan
TAG

Alain Litwin, MD, MPH
Albert Einstein College of Medicine

Bill Symonds, PharmD
Gilead Sciences, Inc.

Robert Lubran, MS, MPA (phone)
SAMHSA

Lynn Taylor, MD
Brown University

6:00 PM **Clinical Trial Design: Interferon-free Trials Using SVR 12 As Primary Endpoint**
- Current status
- Duration of follow up
- Determinants of late relapse and tracking relapse

Moderators:
Veronica Miller, PhD
Forum for Collaborative HIV Research

Ira Jacobson, MD
Weill Cornell Medical College

Discussants:
Patrick Harrington, PhD
Division of Antiviral Products, FDA/CDER

Filip Josephson, MD, PhD
Swedish MPA

Donald Jensen, MD
University of Chicago

Daniel Raymond
Harm Reduction Coalition

6:15 PM **Clinical Trial Design: Control Regimens for Interferon-Free Trials**
- Current status

Moderators:
Veronica Miller, PhD
Forum for Collaborative HIV Research

Ira Jacobson, MD
Weill Cornell Medical College

Discussants:
Russ Fleischer, PA-C, MPH
FDA

Filip Josephson, MD, PhD
Swedish MPA

Donald Jensen, MD
University of Chicago

Daniel Raymond
Harm Reduction Coalition

6:35 PM **Clinical Trial Design: Considerations When Combining DAAs in People Who Urgently Need Interferon-Free Regimens**

This refers to DAAs that are not being co-developed through a formal phase 3 program but which have been studied in phase 2 programs and have adequate data on individual safety, PK in people with hepatic impairment, and some evidence of safety and efficacy when used in combination.
- Issues pre-vs. post-approval
- Use of drugs in expanded access protocols
- Regulatory issues for labeling
- Issues with reimbursement

Moderators:
Veronica Miller, PhD
Forum for Collaborative HIV Research

Ira Jacobson, MD
Weill Cornell Medical College

Discussants:
Lynda Dee, JD
AIDS Action Baltimore

Robert Kauffman, MD, PhD
Vertex Pharmaceuticals

Douglas Dieterich, MD
Mount Sinai School of Medicine

Jules Levin, BA
NATAP

Filip Josephson, MD, PhD
Swedish MPA

Poonam Mishra, MD
FDA

7:05 PM **Real Life Efficacy with PI Triple Therapy**

Moderator: Veronica Miller, PhD
Forum for Collaborative HIV Research

CHeCS Update — Scott Holmberg, MD, MPH
Centers for Disease Control and Prevention

TARGET Update — Ira Jacobson, MD
Weill Cornell Medical College

- Introduction
- Data being collected
- Possible data analysis

7:20 PM **Closing Remarks**

Veronica Miller, PhD
Forum for Collaborative HIV Research

Robert Kauffman, MD, PhD; Co-chair
Vertex Pharmaceuticals

Kenneth Mayer, MD
Fenway Health

7:30 PM **Closing Reception** — The Fenway Institute, Fenway Health