Forum for
Collaborative HIV Research

HCV DRAG MEETING #7: ISSUES IN HCV CLINICAL TRIALS

NOVEMBER 3, 2011

San Francisco Marriott Marquis
55 Fourth Street
San Francisco, California 94103

School of Public Health
UNIVERSITY OF CALIFORNIA, BERKELEY

enhancing and facilitating HIV research

FORUM FOR COLLABORATIVE HIV RESEARCH

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AGENDA

2:00 PM **Welcome and Introduction of New SC Members**
Veronica Miller, PhD
Forum for Collaborative HIV Research

2:10 PM **Brief Recap of HCV DrAG and Review of Meeting Goals**
Ann Kwong, PhD
Vertex Pharmaceuticals, Inc.
Veronica Miller, PhD
Forum for Collaborative HIV Research

2:20 PM **Summary: HCV Drug Access for People with Bleeding Disorders**
Moderators: Ken Sherman, MD, PhD
University of Cincinnati College of Medicine
Veronica Miller, PhD
Forum for Collaborative HIV Research

2:40 PM **Summary: Control Arm in HCV Trials Meeting**
Moderators: Ira Jacobson, MD
Weill Cornell Medical College
Veronica Miller, PhD
Forum for Collaborative HIV Research

3:00 PM **HCV Reference Strains for *in-vitro* Studies**
Moderators: Patrick Harrington, PhD
FDA/DAVP
Ann Kwong, PhD
Vertex Pharmaceuticals, Inc.

3:30 PM **HCV Viral Load Assays: LOD/LLOQ**

Moderators: Jean-Michel Pawlotsky, MD, PhD
Hôpital Henri Mondor
Veronica Miller, PhD
Forum for Collaborative HIV Research

Discussants: Gavin Cloherty, PhD
Abbott Molecular
Gaston Picchio, PhD
Tibotec, Inc
Patrick Harrington, PhD
FDA/DAVP
Stephen Rossi, PharmD
Gilead Sciences
Gabrielle Heilek, PhD
Roche Molecular Systems
Christoph Sarrazin, MD
University Hospital Frankfurt
Charles Walworth, MD
Monogram Biosciences

Discussions

1. LOD/LLOQ FDA Summary
2. Defining the terms LOD and LLOQ
   a. LOD/LLOQ – how is it derived and how should it be applied?
   b. Discrepancy between manufacturer readout, laboratory report and data analysis during clinical trials
3. Discussion: Can the DrAG come to consensus on a single HCV RNA measurement cut-off for future DAA clinical development?
   a. Discussion of data analysis carried out so far
   b. Define a single cut-off valid for future DAA clinical development in the following scenarios:
      i. Pros and Cons to use for RGT
         1. Target not detected
         2. <LLOQ
         3. <25IU/ml or other
      ii. On treatment versus confirmation of SVR – can a unified rule be achieved?

4:45 PM **BREAK**

5:15 PM Trials in Current Drug Users and Patients on Opiate Substitution Therapy

Moderators:
Tracy Swan
TAG, HCAB, ATAC

Mark Sulkowski, MD
JHU, Division of Infectious Diseases

Discussants:
Michelle Berrey, MD, MPH
Pharmasset

Daniel Raymond
Harm Reduction Coalition

Russ Fleischer, PA-C, MPH
FDA/Division of Antiviral Products

Stephen Rossi, PharmD
Gilead Sciences

Filip Josephson, MD, PhD
Swedish MPA / EMA

Diana Sylvestre, MD
UCSF/OASIS Clinics

Alain Litwin, MD, MPH
Albert Einstein College of Medicine and Montefiore Medical Center

Andrew Talal, MD, MPH
Weill Cornell Medical College

Marion Peters, MD
UCSF

Discussions

1. Why is it important to include these populations in DAA trials?
2. Why isn't there any specific guidance from FDA or EMA on inclusion of current drug users or patients on opiate substitution therapy (OST)?
3. Assuming there is adequate information on drug-drug interaction studies, at what stage/phase should current drug users and people on OST be included in clinical trials?
4. Are there additional interaction studies that should be performed to facilitate safe and effective use of DAAs in these populations?
5. What are common reasons for excluding these populations from clinical trials, and how can these be addressed?
6. How can investigators assess which OST patients are good candidates for clinical trials — what are the criteria that really matter?
7. What resources/tools/metrics could help facilitate enrollment of these populations in clinical trials?

6:30 PM HCV Drug Resistance Table Update

Moderators:
Isabel Najera, PhD
Hoffmann La Roche

Veronica Miller, PhD
Forum for Collaborative HIV Research

Discussants:
Richard Barnard, PhD
Merck

George Kukolj, PhD
Boehringer Ingelheim Canada Ltd. R&D

Patrick Harrington, PhD
FDA/DAVP

Neil Parkin, PhD
Data First Consulting

Filip Josephson, MD, PhD
Swedish MPA / EMA

Christos Petropoulos, PhD
Monogram Biosciences

Tara Kieffer, PhD
Vertex Pharmaceuticals, Inc.

7:00 PM Summary of Meeting

Ann Kwong, PhD
Vertex Pharmaceuticals, Inc.

Jean-Michel Pawlotsky, MD, PhD
Hôpital Henri Mondor

Adjourn

7:30 PM Dinner at First Crush Restaurant
101 Cyril Magnin Street
San Francisco, CA 94102