School of Public Health
UNIVERSITY OF CALIFORNIA, BERKELEY

Forum for Collaborative HIV Research

10th HCV DrAG Meeting: Issues in HCV Drug Development

April 23, 2013
Hotel Pulitzer, Amsterdam
Prinsengracht 315-331 1016 GZ
Amsterdam The Netherlands
Tuinzaal Room

AGENDA

2:30 PM **Opening Reception**

3:00 PM **Welcome & Brief Recap of HCV DrAG Meeting Rules & Review of Meeting Goals**

Robert Kauffman, MD, PhD
Vertex Pharmaceuticals Inc

Veronica Miller, PhD
Forum for Collaborative HIV Research

Jean-Michel Pawlotsky, MD, PhD
Henri Mondor University Hospital

3:10 PM **SESSION 1**
Review and Discussion of Currently Available HCV Geno(sub)typing Assays

Moderators:

Filip Josephson, MD, PhD
Swedish MPA / EMA

Robert Kauffman, MD, PhD
Vertex Pharmaceuticals Inc

Panelists:

Gavin Cloherty, PhD
Abbott Molecular

Gabrielle Heilek, PhD
Roche Molecular Systems

Dwight DuBois, MD
Cenetron

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

Michael Fried, MD
University of North Carolina, Chapel Hill

Hongmei Mo, MD
Gilead Sciences Inc

Patrick Harrington, PhD
FDA/DAVP

Discussion

- Status of current geno(sub)type 1 assays: assay performance and utility in clinical trials vs. clinical practice
- Accurate subtyping in non-genotype 1 HCV infections: assay performance and which non-1 genotypes should be the focus for diagnostic development purposes
- Proposal for a shared pool of samples for diagnostic testing purposes

4:15 PM **SESSION 2**

Phenotypic Assays: Technical and Translational Considerations

Can phenotypic data be used to bridge to other HCV genotypes if clinical and phenotypic data are available for one HCV genotype, while only phenotypic data is available for another HCV genotype?

Moderators:

Jean-Michel Pawlotsky, MD, PhD
Henri Mondor University Hospital

Robert Kauffman, MD, PhD
Vertex Pharmaceuticals Inc

Panelists:

Patrick Harrington, PhD
FDA/DAVP

Fiona McPhee, PhD
Bristol-Myers Squibb

Anita Howe, PhD
Merck Research Laboratories

Hongmei Mo, MD
Gilead Sciences Inc

Filip Josephson, MD, PhD
Swedish MPA / EMA

Tami Pilot-Matias, PhD
AbbVie

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

Jacqueline Reeves, PhD
Monogram Biosciences

Oliver Lenz, PhD
Janssen Pharmaceuticals ID&V

Discussion

A. Phenotypic assays and potential methods that could bridge drug susceptibility information between geno(sub)types

- Methods for estimating activity of a drug in different genotypes through relative potency measurements
- Replicon constructs for phenotypic assessments: consensus sequences or clinical isolates
- Reference standards for genotype 1 and non-genotype 1 studies
- Phenotypic assays: Identifying the role(s) of different mutants in patient samples

B. Translating results of phenotypic assays to determine clinical relevance: bridging *in vitro* data to ascertain clinical outcome(s)

- Modeling and/or quantifying the resistance barrier for a drug with consideration to its potency and durability in various geno(sub)types
- The role of phenotypic assays in interferon-free regimens
- Phenotypic assessments and the role of PK and protein binding

5:30 PM **BREAK**

5:45 PM **SESSION 3**
Pharmacokinetics and Drug Interaction Studies

Moderators:
David Back, PhD
University of Liverpool

Ira Jacobson, MD
Weill Cornell Medical College

Panelists:
Vikram Arya, PhD, FCP
FDA/DAVP

Jules Levin
NATAP

Courtney Fletcher, PharmD
University of Nebraska

Gene Morse, PharmD, FCCP, BCPS
University at Buffalo

Filip Josephson, MD, PhD
Swedish MPA / EMA

Andrew Owen, PhD
University of Liverpool

Jennifer Kiser, PharmD
University of Colorado

Shirley Seo, PhD
FDA/DAVP

Andrew Talal, MD, MPH
University at Buffalo

Discussion
Future directions in pharmacokinetics and drug interaction studies: Populations that need to be addressed, standardization of assays, identification of drug classes and/or panels of drugs for studies

7:00 PM **Final Comments**

Robert Kauffman, MD, PhD
Vertex Pharmaceuticals Inc

Veronica Miller, PhD
Forum for Collaborative HIV Research

7:10 PM **Adjourn and Closing Reception**