

Forum for Collaborative HIV Research

HCV DrAG Meeting #8  
Issues in HCV Drug Development

April 17, 2012

AC Hotel Barcelona Forum  
Paseo Taulat 278  
Barcelona 08019 Spain

AGENDA		
1:00 PM	LUNCH	AC Hotel Barcelona Forum Sagrada Familia, 4th Floor
2:00 PM	Welcome & introduction of new SC members	Nina Mani, PhD, MPH <i>Forum for Collaborative HIV Research</i>
2:10 PM	Brief recap of HCV DrAG & review of meeting goals	Robert Kauffman, MD, PhD <i>Vertex Pharmaceuticals Inc</i> Veronica Miller, PhD <i>Forum for Collaborative HIV Research</i> Jean-Michel Pawlotsky, MD, PhD <i>Henri Mondor Hospital, University of Paris-Est</i>
2:20 PM	Definitions/Nomenclature Working Group (DNWG) - Comments on manuscript submitted to Hepatology - Future issues with virologic response terms in clinical trials	Don Jensen, MD <i>University of Chicago</i> Veronica Miller, PhD <i>Forum for Collaborative HIV Research</i> Heiner Wedemeyer, MD <i>Hannover Medical School</i>
2:50 PM	Update: HCV drug resistance table from Phenotype Analysis Working Group (PAWG) - Finalization of figure and table - Publishing in Forum Annals - Publishing frequency - Linking resistance data to clinical outcomes	<b>Moderators:</b> Isabel Najera, PhD <i>Hoffmann La Roche</i> Veronica Miller, PhD <i>Forum for Collaborative HIV Research</i> <b>Discussants:</b> Richard Barnard, PhD <i>Merck</i> Matthias Gotte, PhD <i>McGill University</i> Patrick Harrington, PhD <i>FDA, Division of Antiviral Products</i> Johan Lennerstrand, PhD <i>Uppsala University</i> Fiona McPhee, DPhil <i>Bristol-Myers Squibb</i> Neil Parkin, PhD <i>Data First Consulting</i> Jacqueline Reeves, PhD <i>Monogram Biosciences</i> Joseph Scherer, MS <i>Boehringer-Ingelheim Pharmaceuticals, Inc.</i> Leen-Jan vanDoorn, PhD <i>DDL diagnostic laboratory</i>
3:10 PM	Trials in treatment experienced (IFN and DAA) subjects -Criteria for inclusion/exclusion in early vs. late phase studies - Discussion of issues: treatment exposure (type and duration) and response, extent of resistance-associated variants testing, etc.	<b>Moderators:</b> Jean-Michel Pawlotsky, MD, PhD <i>Henri Mondor Hospital, University of Paris-Est</i> John Sullivan-Bolyai, MD, MPH <i>Idenix Pharmaceuticals</i> <b>Discussants:</b> Patrick Harrington, PhD <i>FDA, Division of Antiviral Products</i> Eric Hughes, MD, PhD <i>Bristol-Myers Squibb</i> Filip Josephson, MD, PhD <i>Swedish MPA / European Medicines Agency</i> Luis Mendao <i>EATG</i> Kim Struble, PharmD <i>FDA</i> Bill Symonds, PharmD <i>Gilead Sciences</i>

4:10 PM	<p><b>Definition of interferon intolerant/incapable patients</b>  <b>- Regulatory perspectives</b>  <b>-Discussion</b></p>	<p><b>Moderators:</b>  Filip Josephson, MD, PhD  <i>Swedish MPA / European Medicines Agency</i>  Heiner Wedemeyer, MD  <i>Hannover Medical School</i></p> <p><b>Discussants:</b>  Don Jensen, MD  <i>University of Chicago</i>  Gaston Picchio, PhD  <i>Janssen R&amp;D, Infectious Disease Therapeutic Area</i>  Kim Struble, PharmD  <i>FDA</i>  Tracy Swan  <i>H-CAB/TAG</i></p>
4:40 PM	<b>BREAK</b>	
5:10 PM	<p><b>HCV drugs NDA submission: Recommendations for drug-drug interaction studies</b></p>	<p><b>Moderators:</b>  Geoff Dusheiko, MD  <i>Royal Free Hospital</i>  Robert Kauffman, MD, PhD  <i>Vertex Pharmaceuticals Inc</i></p> <p><b>Discussants:</b>  Patrick Harrington, PhD  <i>FDA, Division of Antiviral Products</i>  Filip Josephson, MD, PhD  <i>Swedish MPA / European Medicines Agency</i>  Kim Struble, PharmD  <i>FDA</i>  Tracy Swan  <i>H-CAB/TAG</i></p>
5:40 PM	<p><b>HCV Treatment Response Databases</b></p>	<p><b>Moderator:</b>  Veronica Miller, PhD  <i>Forum for Collaborative HIV Research</i></p> <p><b>Discussants:</b>  Carol Brosgart, MD  <i>UCSF</i>  Don Jensen, MD  <i>University of Chicago</i>  Luis Mendao  <i>EATG</i>  Jean-Michel Pawlotsky, MD, PhD  <i>Henri Mondor Hospital, University of Paris-Est</i></p>
6:20 PM	<p><b>Future of HCV research, clinical and public health activities</b></p>	<p><b>Moderator:</b>  Veronica Miller, PhD  <i>Forum for Collaborative HIV Research</i></p> <p><b>Discussants:</b>  Don Jensen, MD  <i>University of Chicago</i>  Sandra Lehrman, MD  <i>Merck</i>  Jean-Michel Pawlotsky, MD, PhD  <i>Henri Mondor Hospital, University of Paris-Est</i>  Tracy Swan  <i>H-CAB/TAG</i></p>
6:40 PM	<p><b>Proposed Roundtable Topics:</b>  <b>1) Inclusion of IDUs in HCV trials</b>  <b>2) Drug induced liver injury and HCV drug development</b></p>	<p><b>Moderator:</b>  Veronica Miller, PhD  <i>Forum for Collaborative HIV Research</i></p> <p><b>Discussants:</b>  Douglas Mayers MD  <i>Idenix Pharmaceuticals</i>  Jean-Michel Pawlotsky, MD, PhD  <i>Henri Mondor Hospital, University of Paris-Est</i>  Tracy Swan  <i>H-CAB/TAG</i>  Kim Struble, PharmD  <i>FDA</i></p>
7:00 PM	<p><b>Final Comments</b></p>	<p>Veronica Miller, PhD  Forum for Collaborative HIV Research  Jean-Michel Pawlotsky, MD, PhD  <i>Henri Mondor Hospital, University of Paris-Est</i></p>
	<b>ADJOURN</b>	
7:30 PM	<b>DINNER</b>	<p>Echo Healthy Restaurant  Diagonal Zero Barcelona Hotel</p>