HCV DRAG: Clinical Trial Design, Follow-up and Resistance: FDA and EMEA perspective

March 24, 2009
AGENDA

Meeting Location: Marriott Wardman Park Hotel
2660 Woodley Road, NW
Washington, DC 20008
Wilson Room on the Mezzanine Level

1:00 -2:00 PM		Lunch - Wilson Room (Mezzanine Level)	
2:00pm	15.00	Welcome & Introductions	Veronica Miller, Ann Kwong
2:15pm	15.00	Brief Recap of HepC HCV DRAG & Review of Meeting Goals	Dale Kempf
2:30pm	60.00	Panel Discussion: "Clinical Virology Lessons Learned with Respect to Resistance in Clinical Trials with Combinations Added to SOC; plus/minus IFN/Ribavarin and Lead-in Trial Design"	Moderator: Ann Kwong ; Panelists: Ann Kwong, Robert Ralston, Julian Symons, Gaston Picchio, Jules O'Rear
3:30pm	45.00	Clinical Trial Design: FDA & EMEA "Perspectives on Clinical Trials, including Definition of Treatment Experience" (brief presentations followed by panel discussion)	Moderator: Ira Jacobson ; Panelists: Jeffrey Murray, Nathalie Morgensztejn, Jules O'Rear
4:15pm	15.00	General Discussion	Veronica Miller, Dale Kempf (facilitators)
4:30pm	30.00	Break	
5:00pm	30.00	Long Term Follow up- Evolution of Variants in Patients with Drug Resistances: Lessons Learned in Setting Up a Registry and a Regulatory perspective	Robert Ralston, Jules O'Rear
5:30pm	15.00	General Discussion	Veronica Miller, Dale Kempf (facillitators)
5:45pm	45.00	Hepatologist & Virologist Perspectives (panel discussion) combine with discussion on "Reinfection vs New Infections and Treatment of Patients Who Have Experienced Treatment Failure"	Moderator: Jean-Michel Pawlotsky ; Panelists: Geoff Dusheiko, Xavier Forns, Don Jensen, Ira Jacobson, Stuart Ray
6:30pm	15.00	Resistance Literature Repository Database	Tara Kieffer, Jim Sullivan
6:45pm	10.00	HCV Sequence Databases -- Collaboration	Veronica Miller & Jean-Michel Pawlotsky