

HCV

*D*rug

*R*esistance

*A*dvisory

*G*roup

November 3, 2009

HCV DRAG: Purpose and Goals

- Purpose:
 - Bring together parties interested in and working in HCV drug resistance to discuss issues pertinent to HCV drug development and resistance testing
 - Composition: representatives from industry, academics, government, advocacy and regulatory agencies
- Goals:
 - Produce consensus recommendations of appropriate methodology for HCV resistance testing
 - For drug development
 - For clinical practice
 - Provide scientific guidance to facilitate discussion between industry, regulatory agencies, and other parties integral to HCV drug development and resistance

HCV DRAG: Steering Committee

- Dale Kempf (co-chair)
- Jean-Michel Pawlotsky (co-chair)
- Ira Jacobs (CWG)
- Ann Kwong (SAWG)
- Veronica Miller (FCHR)
- Nathalie Morgensztein (EMEA)
- Isabel Najera (PWG)
- Jules O'Rear (FDA Virology)
- Stuart Ray (Academic)
- Kimberly Struble (FDA Clinical)
- Tracy Swan (Advocacy)

HCV DRAG: Current Working Groups

- Sequence Analysis Working Group (SAWG)
 - Ann Kwong, head
- Phenotype Working Group (PWG)
 - Isabel Najera, head
- Clinical Working Group (CWG)
 - Ira Jacobson, head
- Database Working Group (DWG)
 - Jean-Michel Pawlotsky, head

HCV DRAG: Deliverables

- Presentations
 - HCV Resistance Workshop, Nov 2007
 - HepDart, Dec 2007
 - EASL Hep B and C Resistance Conference, Feb 2008
- Educational roundtables
 - HepDart, Dec 2009
- Public meetings
 - Joint meeting with FDA, fall 2009/winter 2010 (tbd)
 - HCV resistance CME (Planned for 2010)
- Manuscripts
 - SAWG
 - Manuscript ready for submission (back to back with PWG manuscript)
 - Target journal: *Gastroenterology*
 - PWG
 - Draft manuscript in preparation
 - CWG
 - Draft sections assigned

HCV DRAG: Today's Meeting

- Summary of Sequence Analysis WG and Phenotype WG recommendations
- Issues for Clinical WG
 - Viral load testing
 - Clinical trial design
 - Special populations
 - Combination therapy
- Expanded (early) access
- Public meetings
 - HepDART roundtable
 - FDA/Forum open meeting

HCV DRAG: Agenda

- Clinical Trial Design Ira Jacobson
- Special Populations Stuart Ray
- Combo Trials Jean-Michel Pawlotsky
- Expanded Access Veronica Miller
- SAWG and PWG Summaries
Ann Kwong, Isabel Najera
- HEPDART, FDA Public Meeting