

**HCV DRAG: Clinical Trial Design**

November 3, 2009

AGENDA

Meeting Location:

Back Bay Ballroom C,

Boston Hotel, 39 Dalton Street, Boston MA

Sheraton

| 1:00 -2:00 PM |        | Buffett Lunch   |  |
|---------------|--------|---|--|
| 2:00pm        | 10.00  | Welcome & Introductions   | Veronica Miller, Jean-Michel Pawlotsky   |
| 2:10pm        | 10.00  | Brief Recap of HCV DRAG & Review of Meeting Goals   | Dale Kempf   |
| 2:20pm        | 20.00  | Summaries of Sequence Analysis WG and Phenotype Analysis WG recommendations   | Ann Kwong, Isabel Najera   |
| 2:40pm        | 10.00  | Discussion  |  |
| 2:50pm        | 20.00  | Thresholds in HCV Viral Load testing  | Gaston Picchio   |
| 3:10pm        | 10.00  | Discussion  |  |
| 3:20pm        | 15.00  | Review of outline for Clinical Trial Design WG Recommendations  | Ira Jacobson   |
| 3:35pm        | 30.00  | Stratification of potential study variables   | <b>Moderator:</b> Ira Jacobson;<br><b>Discussant:</b> Don Jensen   |
|               | 125.00 |   |  |
| 4:05pm        | 15.00  | Break   |  |
| 4:20pm        | 40.00  | Clinical trials in special patient populations  | <b>Moderator:</b> Stuart Ray; <b>Discussants:</b> Tracy Swan, Raf Crabbé, Geoff Dusheiko, Robert Ralston, Eric Hughes  |
| 5:00pm        | 45.00  | Considerations for trials with two or more DAA  | <b>Moderator:</b> Jean-Michel Pawlotsky;<br><b>Discussants:</b> Michelle Berrey, Shelley George, Fiona McPhee, Nathalie Morgensztejn, Russ Fleischer, Patrick Harrington |
| 5:45pm        | 10.00  | Discussion  |  |
| 5:55pm        | 30.00  | Expanded Access Programs: Overview, Specific patient populations; Safety data collection; Adverse event reporting and impact on naïve indication submission | <b>Moderator:</b> Veronica Miller;<br><b>Discussants:</b> Russ Fleischer, Nathalie Morgensztejn, Jules Levin, Lynda Dee  |
| 6:25pm        | 15.00  | Discussion  |  |
| 6:40pm        | 5.00   | HEP DART 2009 Education Roundtable  | Tracy Swan & Ann Kwong   |
| 6:45pm        | 5.00   | FDA-FCHR (EMA) open public meeting  | Veronica Miller  |
| 6:50pm        | 10.00  | Summary of meeting  | Dale Kempf   |
| 7:00pm        | 0.00   | Adjourn   |  |
|               | 175.00 |   |  |
|               |        | Dinner at Grill 23 & Bar<br>161 Berkeley Street, Boston, MA 02116<br>Corner of Berkeley and Stuart Streets in Boston's Back Bay<br>Telephone: 617-542-2255  |  |