13th HCV Drug Development Advisory Group Meeting
Sheraton Boston, Republic Ballroom, 2nd Floor
39 Dalton Street
Boston, Massachusetts 02199
November 11, 2014

AGENDA

2:30 PM	**Opening Reception** *Light refreshments will be served.*	**Republic Foyer**
3:00 PM	**Welcome to HCV DrAG Meeting #13**	Veronica Miller, PhD *Forum for Collaborative HIV Research* Jean-Michel Pawlotsky, MD, PhD *Henri Mondor University Hospital* Gaston Picchio, PhD *Johnson & Johnson*
3:05 PM	**Updates on HCV DrAG and Forum Activities**	Nivedha Panneer, MPH *Forum for Collaborative HIV Research*
3:10 PM	**SESSION 1: Control arms for future clinical trials**	
	Current FDA Thinking	Jeff Murray, MD, MPH *Food and Drug Administration*
3:20 PM	**Moderators:** Andrew Muir, MD, MHS *Duke University*	Gaston Picchio, PhD *Johnson & Johnson*
	Panelists: Jordan Feld, MD, MPH *University Health Network Western Division*	Jules Levin, BA *NATAP*
	Jens Kort, MD, PhD *AbbVie*	Jeff Murray, MD, MPH *Food and Drug Administration*

Discussion Questions:

- How do you balance drug development costs with the need for robust data when assessing the most appropriate clinical trial design for future trials?
- Are there patient populations where an active control arm would be preferable?
- Are there patient populations where a historical control design would be preferable?

4:35 PM **SESSION 2: DAA considerations in the pediatric population**

Regulatory post-marketing requirements in children — Linda Lewis, MD, *Food and Drug Administration*

4:45 PM **Moderators:**

Veronica Miller, PhD, *Forum for Collaborative HIV Research*

Tracy Swan, *Treatment Action Group*

Panelists:

Polly Clayden, *HIV i-Base*

Maureen Jonas, MD, *Boston Children's Hospital*

Manal El-Sayed, MD, *Ain Shams University*

Linda Lewis, MD, *Food and Drug Administration*

Giuseppe Indolfi, MD, *Meyer Children's University Hospital of Florence*

Discussion Questions:

- How do you balance post-marketing requirements for developing pediatric formulations with the challenges of performing studies in children?
- Given the availability of safe and highly effective combination DAA regimens, how can we mobilize pediatric hepatologists to identify and treat children with chronic HCV before they develop more advanced fibrosis?
- What would be the ideal regimen(s) for use in children?
- What should be included in a target product profile for an HCV pediatric regimen?
- What additional research opportunities exist in the prevention of mother to child transmission of HCV?

6:00 PM **Coffee Break** — **Republic Foyer**

6:15 PM **SESSION 3: Management of patients who fail treatment**

Moderator:

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

Panelists:

Doug Dieterich, MD, *Icahn School of Medicine*

Tracy Swan, *Treatment Action Group*

Pat Harrington, PhD, *Food and Drug Administration*

Discussion Questions:

- What additional data is needed to inform management of patients who fail treatment?
- In which instances may retreatment with second-line therapy be withheld? How long is "long enough" to wait to retreat patients?
- What role does adherence, drug resistance, and cost of treatment play in retreatment decisions?

7:15 PM	**Final Comments**	Veronica Miller, PhD *Forum for Collaborative HIV Research* Jean-Michel Pawlotsky, MD, PhD *Henri Mondor University Hospital* Gaston Picchio, PhD *Johnson & Johnson*
7:20 PM	**Adjourn and Evening Reception** *Hors d'oeuvres and drinks will be served.*	**Republic Foyer**