Forum for Collaborative HIV Research

13TH HCV DRUG DEVELOPMENT ADVISORY GROUP MEETING

NOVEMBER 11, 2014
BOSTON, MA

WELCOME & MEETING GOALS

enhancing & facilitating HIV research

Veronica Miller, PhD
Forum for Collaborative HIV Research

Jean-Michel Pawlotsky, MD, PhD
Hopital Henri Mondor

Gaston Picchio, PhD
Johnson & Johnson

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HCV DrAG:
Moving the Field Forward

- Multi-stakeholder gathering
  - Expert participants from academia, community, government and industry
  - *Independent*, *neutral* & *safe* venue for dialogue
- Science & Policy
  - Updates
  - Implications
  - Revision as appropriate
  - Address gaps
- Opportunities for collaboration
  - Networks
  - Resources

Forum House Rules

- Closed meeting
  - Confidentiality of proceedings
- Expert dialogue vs. “presentation”
  - Moderated discussion
  - Perspectives from all stakeholder groups
- Everyone participates
  - No “observers”
  - Being present indicates willingness to contribute expert insights and perspectives

Update

- HCV Resistance Working Group
  - *Hepatitis C Virus Resistance Associated Substitutions: State of the Art Summary*
    - Clinically relevant polymorphisms and substitutions broken down genotype
    - In vitro phenotypic resistance data
    - Manuscript ready to submit to *Hepatology*

Update-2

- Patient Reported Outcomes Working Group
  - First face to face meeting Nov 8
  - Strong consensus re: value of PRO data and recognizing benefits of therapy beyond the liver
  - Key questions raised:
    - How to better communicate patient experience to clinicians, future patients and policy makers/payers?
    - How to incorporate PRO data collection into real world setting?
    - How to develop better tools to collect this information?
  - Next step: Review of existing data

Hepatitis c diagnostics-the bottleneck to unlocking a global market

- How to accelerate the development of HCV diagnostics for use in resource-limited settings?
- In collaboration with FIND
- Side meeting, Nov 11
  - Launch pad for future discussion and collaborations

The liver forum

- Address regulatory hurdles and advance drug development for the treatment of liver fibrosis
- First face to face meeting Nov 6
- Priority areas
  - Harmonization of type of data collected across clinical trials
  - Biosample repository
  - Mechanism to develop registry/natural cohort to follow patients for long term outcomes

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2015 National Summit on HCV and HIV Diagnosis, Prevention and Access to Care

- 4-6 June, 2015 in Arlington, VA
- Abstract driven conference with focus on best and emerging practices
  - Boots on the ground to high level federal leadership
- Plan to have global HCV session

Program Evaluation

- Please contribute to future HCV DrAG program planning by completing the online evaluation survey
  - distributed following today's program

Thanks

- HCV DrAG Steering Committee
- Nivedha Panneer MPH -HCV DrAG Proj Mgr
- Erik Lontok PhD - Resistance WG Proj Mgr
- Other Forum Staff (website, communications, etc.)
  - Ben Hauschild MPH
  - Robert Besaw MPH
- Margie & Dave Poole and IHL team

AGENDA

- Session 1
  - Control arms for future clinical trials
- Session 2
  - DAA considerations for the pediatric population
- Session 3
  - Management of patients who fail treatment
- Networking reception

Session 1: Control Arms for Future Clinical Trials

Jeff Murray, MD, PhD

Food and Drug Administration

Panel discussion

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Moderators:

Andrew Muir, MD
Duke University Medical Center

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
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?

Session 2: DAA Considerations In The Pediatric Population

Linda Lewis, MD

Food and Drug Administration

Panel discussion

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Moderator:

Veronica Miller, PhD
The 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?

Discussion questions

- 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?

BREAK

Panel discussion

Moderator:

Jean-Michel Pawlotsky, MD, PhD
Hopital Henri Mondor

Panelists:

Doug Dieterich, MD
Icahn School of Medicine

Tracy Swan
Treatment Action Group

Pat Harrington, PhD
Food and Drug Administration

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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?

Final Comments

Veronica Miller, PhD
Forum for Collaborative HIV Research

Jean-Michel Pawlotsky, MD, PhD
Hopital Henri Mondor

Gaston Picchio, PhD
Johnson & Johnson