Treatment Scientific Committee Session

Theodore Ruel, Chair
University of California, San Francisco, USA
June 24, 2021
Objective for Treatment

- Advance ART of pregnant and postpartum women with HIV, aiming to optimize maternal and child health outcomes, and accelerate the evaluation [pharmacokinetics (PK), safety, antiviral efficacy], licensure and optimal use of potent and durable ARVs for pregnant women and infants, children and adolescents with HIV.
Research Priorities

1) Characterize the PK properties and dosing of ARVs and relevant drug-drug interactions among women during pregnancy and lactation, and their infants.

2) Evaluate novel prophylaxis regimens for infants born to women with HIV.

3) Identify and rapidly evaluate the PK, safety and antiviral efficacy of the most promising ARVs for first-line treatment, accelerating licensure for pediatric populations living with HIV.
How do we achieve those priorities?

▸ Partner with industry for registrational trials of new agents

▸ Perform additional studies to address data gaps in key populations and scenarios

▸ Provide leadership for treatment guidelines around the globe – identifying priority agents and research gaps

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1. **Refine key principles** around optimal approaches: develop a framework for prioritization, acceleration and optimization of type and timing of studies in pregnant women.

2. **Review and refine best practices**

3. **Formulate strategic action plan** for promoting the inclusion of pregnant women in research prior to drug regulatory authorization.
1. Review rationale to optimize postnatal prophylaxis in the evolving treatment landscape
2. Identify scenarios to inform the development of potential postnatal prophylaxis strategies
3. Define the target drug characteristics and candidates
4. Reach consensus on an optimal research approach to investigate alternative postnatal prophylaxis strategies

**Virtual Workshop on**

**Postnatal prophylaxis to reach elimination of vertical transmission: optimizing research and accelerating access to innovation**

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<table>
<thead>
<tr>
<th>Start Time</th>
<th>Topic</th>
<th>Presenter</th>
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<tbody>
<tr>
<td>10:30</td>
<td>Treatment Agenda and Current Activities</td>
<td>Ted Ruel, MD</td>
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<td>10:40</td>
<td>Role for Long Acting Formulations in Pediatrics and Pregnant Women</td>
<td>Mo Archary, MBChB</td>
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<td>10:45</td>
<td>The Front of the Pipeline in Adults</td>
<td>Charlie Flexner, MD (Johns Hopkins University)</td>
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<td>11:00</td>
<td>Microarray Patch Platform</td>
<td>Manjari Quintanar-Solares, MD, MPH (PATH)</td>
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<td>11:15</td>
<td>ImplantablePossibilities</td>
<td>Marc Baum, PhD (Oak Crest Institute of Science)</td>
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<td>11:30</td>
<td>Comments from Community</td>
<td>Aisha Gava (Uganda) and Thabo Makete (South Africa)</td>
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<td>11:45</td>
<td>Discussion/Q&amp;A</td>
<td>All Presenters</td>
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<td>12:00</td>
<td>Adjourn</td>
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Please post your questions along the way for the Q&A!

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Who is the TSC?

Committee Members
Linda Barlow-Mosha, Makerere Univ - Johns Hopkins Univ Research Collaboration
Brookie Best, University of California, San Diego
Carolyn Bolton, Centre for infectious Disease Research in Zambia
Edmund Capparelli, University of California, San Diego
Diana Clarke, Boston Medical Center
Lee Fairlie, Wits Reproductive Health & HIV Institute
Liz Lowenthal, University of Pennsylvania School of Medicine
Mark Mirochnick, Boston Medical Center
Jorge Pinto, Federal University of Minas Gerais
Andy Wiznia, Albert Einstein College of Medicine

SDMC Representatives
Kathryn Gray, SDAC, Harvard School of Public Health
Pearl Samson, SDAC, Harvard School of Public Health
Sean Brummel, SDAC, Harvard School of Public Health
Barbara Heckman, DMC, Frontier Science

Chair and Vice-chair
Ted Ruel, University of California, San Francisco
Mo Archary, University of KwaZulu-Natal

NIH Representatives
Renee Browning, DAIDS
Ellen Townley, DAIDS
Dwight Yin, NIAID
Tafadzwa S. Kasambira, DAIDS

Community Advisory Board Representatives
Aisha Gava, Uganda
Thabo Makete, South Africa

Leadership and Operations Center
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Shane Reynolds, IMPAACT Operations Center, FHI 360
Veronica Toone, IMPAACT Operations Center, FHI 360
Sharon Nachman, IMPAACT Network Chair, SUNY at Stony Brook
THANKS!

To the speakers, to the committee and to you for your attention ...
Acknowledgments

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