ILF/CIPHER Thematic Roundtable on Paediatric ARVs: 

*Stimulating development of the most needed formulations*

Room St. Moritz, Starling Hotel, Geneva, Switzerland

Monday, 7 March 2016, 13:00 – 16:30 CET
Objective for these slides: Complement the presentations on existing innovative models of collaboration, and feed the roundtable discussion on fast tracking the development of the most needed paediatric ARVs. Models presented:

- DNDi/Cipla Collaboration (4-in-1 LPV/r-based FDCs)
- Antiretroviral Pregnancy Registry
- HIV Cure Initiative
- Vaccine Adverse Event Reporting System
- Critical Path to TB Drug Regimens
- Medicines for Malaria Venture
DNDi/Cipla Collaboration
(4-in-1 LPV/r-based FDCs)

**Objective**
Develop and register two solid taste-masked first-line LPV/r-based fixed-dose formulations with two NRTIs (3TC + ABC or AZT)

- LPV/r + 3TC+ ABC
- LPV/r + 3TC + AZT

**Funding**
LPV/r + 3TC + ABC
LPV/r + 3TC + AZT

**Cipla**
Industrial scale-up, validation, manufacturing, registration, pharmacovigilance, distribution, recalls of the 4-in-1s

**DNDi**
Clinical studies (Phase II/III and implementation studies), certain access activities of the 4-in-1s.

Joint Steering committee – members from DNDi and Cipla working on R&D formulations
Antiretroviral Pregnancy Registry (APR)

Objectives

- Provide early warning signal of major teratogenicity
- Estimate risk of major birth defects and compare to that of general population
- Supplement data from animal toxicology, clinical, and epidemiological studies
- Designed to assist clinicians and patients in weighing potential risks and benefits of treatment

International registration of ARV (HIV and HBV) exposed Pregnant woman by HCP → Voluntary but strongly encouraged registration and follow up of pregnancy outcome by HCP → Review of data, establishment of consensus and recommendations by Advisory Committee → Issues discussed, data reviewed and interim report published semi-annually by Steering Committee

SPONSORSHIP

26 pharmaceutical companies representing 94 products

Management

(conduct clinical research and pharma consulting)

Steering Committee

Advisory Committee

CDC, FDA, NIH, Office of the Global AIDS Coordinator, and practicing physician specialists

Review the Registry data; develop the Consensus Statement; provide enhancements to the Registry; communication
HIV Cure Initiative

Objectives

Bring interested parties together so that HIV cure can be most rapidly achieved

The initiative is developing:
1. An **investment case** justifying the development of an HIV cure through a multi-stakeholder initiative
2. An **initiative framework** that sets out a high-level set of stakeholder commitments and benefits associated with their involvement
3. A **long-term roadmap** of activities and priorities

Provide

Scientific guidance and peer review to HIV cure R&D stakeholders

Augment

Existing HIV cure efforts, develop stronger relations among all stakeholders

Facilitate

Public-private partnerships/other collaborations among stakeholders

Advocate

For access to sufficient funding for the stakeholders to support HIV cure efforts

Funding

- Annenberg Foundation Trust
- NIH Office of AIDS Research
- Infectious Disease Research Institute
- Argos Therapeutics
- Gilead Sciences
- Merck
- ViiV Healthcare
Vaccine Adverse Event Reporting System

Objectives

- Detect new, unusual, or rare vaccine adverse events
- Monitor increases in and identify potential patient risk factors for particular types of adverse events
- Identify vaccine lots with increased numbers or types of reported adverse events;
- Assess the safety of newly licensed vaccines

Post- vaccination adverse events reported internationally by HCP, patients, state immunization program, manufacturers, others.

VAERS Database

VAERS staff or HCP team follow up on the request (right away and one year after)

Data sharing

- Co-sponsor
- Ensure that the event reflected is in product labelling
- Monitor reporting trend for vaccine lots
- Review reports serious events

Co-sponsor
- Evaluate trends
- Review reports of serious events
Critical Path to TB Drug Regimens

Objectives

CPTR initiative aims to speed the development and impact of new and markedly improved drug regimens for tuberculosis.
Medicines for Malaria Venture

Private Sector
(Biotech & Pharma)
1. Knowledge and expertise of drug development
2. Access to novel and proprietary compound libraries

Donors
1. Funding and support for R&D projects
2. Supporting specific interventions

Public Sector, Research & Academic Institutions, Governments, International organizations
1. Sharing of knowledge
2. Carrying out research
3. Advertising malaria treatment
4. Dialogue to shape the malaria agenda and policy implementation

Clinical centres in endemic and non endemic countries
1. Safety and efficacy of drugs
2. Training in clinical practice
3. Regulatory requirements of trial sites

Medicines for Malaria Venture

NGOs and non profit organizations
1. Bridging together the private and public sector
2. Advocacy initiatives
3. Product development partnerships

Objectives
Reduce the burden of malaria in disease-endemic countries by discovering, developing and facilitating delivery of new, effective and affordable antimalarial drugs.