THE CURRENT DRUG PIPELINE FOR NIDs IN AFRICA
FOCUS ON DNDI’S PORTFOLIO
THANK YOU EDCTP-2!

Starting with the end in mind ...
Criteria for NTDs ...

- A proxy for poverty and disadvantage
- Affect populations with low visibility and little political voice
- Do not travel widely
- Cause stigma and discrimination, especially of girls and women
- Have an important impact on morbidity and mortality
- Are relatively neglected by research
- Can be controlled, prevented and possibly eliminated using effective and feasible tools

Other definitions:
Hotez et al, G-Finder, BVGH reports:

Total 49 ... ?
Priority setting: unmet medical needs

- Defined at foundation – FDC for malaria
- Defined at foundation – kinetoplastids
  - HAT: safer treatment for HAT… later oral treatment for stage 2 and stage 1 that can be used at primary care level
  - Leishmaniases
    - Safer treatment for VL - oral treatment/combination for all regions and all age groups for VL
    - Later --- need to address HIV/VL, PKDL, asymptomatic patients
    - Later … CL: topical/oral for L braziliensis and L tropica
  - Chagas: oral treatment for chronic indeterminate stage and pediatric dosage form
- Defined later and added as mini-portfolio:
  - Pediatric user-friendly ARV (PI) formulation
  - macrofilaricide
DNDi Portfolio-Building Model:
Address Immediate Patient Needs & Deliver Innovative Medicines

- **Long-term projects**
  - New chemical entities (NCEs)

- **Medium-term projects**
  - New formulations (fixed-dose combinations)
  - New indications of existing drugs

- **Short-term projects**
  - Completing registration dossier
  - Geographical extension

DNDi Portfolio-Building Model:
Address Immediate Patient Needs & Deliver Innovative Medicines

- **Discovery**
  - R
  - LS
  - LO

- **Pre-clinical**

- **Clinical**

- **Implementation**
Visceral Leishmaniasis - context

- 0.15-0.3 million annual incidence (VL).
- Six countries harbor 95% of 150,000-300,000 VL cases per year: (India, Bangladesh, Sudan, South Sudan, Ethiopia, Brazil)
- Anthroponotic in Asia, Africa and zoonotic in America.

Interlinked contexts with poorly described infection sources driving disease manifestation and outbreaks on top of a complex nutritional and immune picture.
Sleeping Sickness: From Unacceptable To Better, Towards Tools for Elimination

10 years ago:
- Eflornithine
- Melarsoprol

Since 2009:
- NECT

2016?
- Oral treatment & rapid diagnostic test
### HAT R&D activities

#### HAT Landscape/DNDi Activities 2013

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**DNDi Activities**

- L 8TMH 8TPH
- Pfizer series 8 (kambala)
- Oxaborole backup (Scyphaxin, Wuzi)
- Broad series B 31119 (Eplchan)
- 8CYX7163
- Fexinidazole backup (Scyphaxin, Wuzi)
- Fexinidazole
- NECT

**Legend**
- DNDI only
- DNDI in collaboration
- Other
Filariasis: different needs for macrofilaricide

For example in oncho/Loa co-infection
Filariasis R&D activities

DNDi Activities

DNDi only DNDi in collaboration other
**HAT**
- Nitroimidazole backup
- Oxaborole backup

**Leishmaniasis**
- Nitroimidazole backup
- VL-2098
- Fexinidazole

**Chagas Disease**
- Nitroimidazole series
- Fenarimol series
- K777
- Biomarkers
- Anfoleish (CL)

**Filarial Disease**
- Flubendazole

**Paediatric HIV**
- '4-in-1' LPV/r-based Fixed-Dose Combos
- RTV Superbooster HIV/TB co-infection

**Malaria**
- ASAQ FDC Fixed-Dose Combination
- ASMQ FDC Fixed-Dose Combination

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★ New Chemical Entity (NCE), Fexinidazole (for HAT and VL) = 1 NCE
Transversal needs – points to consider

- Surrogate markers of efficacy
- Pediatric clinical development / studies
- Need for late stage / PV / field trials
- Utilise and strengthen existing research capacities / platforms
- Laboratory normal ranges …
3 Clinical Platforms to Strengthen Research Capacities in Endemic Countries

Major Role of Regional Disease Platforms

- Defining patients’ needs and target product profile (TPP)
- Strengthening local capacities
- Conducting clinical trials in Good Clinical Practice (Phase II/III studies)
- Facilitating registration
- Accelerating implementation of new treatments (Phase IV & pharmacovigilance studies)
Partnerships: No One Can Do It Alone
A Global Network to Leverage Resources

Criteria for Success:

- Share the same vision
- Mutual understanding
- Involvement throughout the whole process
Thank you