Investing in the Development & Conservation of New Antibiotic Treatments: DNDi’s Engagement
Origins of DNDi

1999
- First meeting to describe the lack of R&D for neglected diseases
- MSF commits the Nobel Peace Prize money to the DND Working Group
- JAMA article: ‘Access to essential drugs in poor countries - A Lost Battle?’

July 2003
- Creation of DNDi
- Founding partners:
  - Institut Pasteur, France
  - Indian Council of Medical Research, India
  - Kenya Medical Research Institute, Kenya
  - Médecins Sans Frontières
  - Ministry of Health, Malaysia
  - Oswaldo Cruz Foundation/Fiocruz, Brazil
  - WHO – TDR (Special Programme for Research and Training in Tropical Diseases) as a permanent observer

AMR: In turn, DNDi is ready for history to repeat itself based on what we have learned.
Address Immediate Patient Needs & Deliver Innovative Medicines: Short- and Long-term

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

- **New formulations**
  - **New indications for existing drugs**
  - Medium-term projects

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

**Research**
- > 5 years

**Translation**
- 3-5 years

**Development**
- 1-2 years

**Implementation**

DNDi
Diagnoses, Develops, Delivers: For Neglected Diseases, Inc.
In a decade of R&D, 6 new treatments delivered

- 30 projects, 6 diseases areas
- 15 entirely new chemical entities (NCEs)
- Over 130 partnerships, most in endemic countries
- 150 staff, half in endemic countries & 600 people working on DNDi projects
- Over EUR 350 million raised equally from public and private sources
- 3 regional disease-specific clinical trial platforms and 2 technology transfers

✓ Easy to use
✓ Affordable
✓ Field-adapted
✓ Non-patented
DNDi’s success is only possible through innovative partnerships

CRITERIA FOR SUCCESS
- Share the same vision
- Mutual understanding
- Involvement throughout the whole process
Industrial Partnerships at All Stages of Development

- **HAT**
  - AbbVie
  - Advinus
  - Anacor
  - Astellas
  - AstraZen.
  - Bayer
  - BMS
  - Eisai
  - GSK
  - MSD
  - Novartis
  - Pfizer
  - Sanofi
  - Shinogi
  - Takeda

- **Leishmaniasis**
  - AbbVie
  - Advinus
  - Anacor
  - Astellas
  - AstraZen.
  - Bayer
  - BMS
  - Eisai
  - GSK
  - MSD
  - Novartis
  - Pfizer
  - Sanofi
  - Shinogi
  - Takeda

- **Chagas**
  - AbbVie
  - Advinus
  - Anacor
  - Astellas
  - Eisai
  - Scynexis
  - Gilead
  - Sanofi

- **Filaria**
  - AbbVie
  - Advinus
  - Anacor
  - Astellas
  - Novartis
  - Pfizer
  - Sanofi
  - J&J

- **Paediatric HIV**
  - AbbVie
  - Cipla

- **Mycetoma**
  - Eisai

- **Malaria**
  - Sanofi
  - Farmanguinhos
  - Cipla
  - Zenufa
Combating malaria resistance: 2002 WHO recommendations

ASAQ FDC: > 400 Million Treatments Distributed

- Pre-qualified by WHO in 2008
- <1 USD for adults, < 0.5 cents for children
- Easy-to-use, non-patented
- Registered: 30 African countries, India, Ecuador, Colombia
- First Risk Management Plan with MMV and Sanofi
- Transfer of technology to Zenufa (Tanzania)

In partnership with Sanofi
Creating large-volume drug screening capacity: Institut Pasteur Korea

- Access to screening capacity (HCS technology) for VL and Chagas since 2008
- > 1.5 Mio compounds screened to date in collaboration with multiple Pharma partnerships
e.g. for VL and Chagas: **20,000 compounds/month**
- Pasteur expertise in infectious diseases
- Technology developed as a public good
Exploring more open, collaborative drug discovery models

- A shift from bilateral to **multilateral collaboration**
- Companies working together on a **shared project**
- Ownership and intellectual property rules agreed in advance
- Three year countdown to launch in April 20015
- Project now underway and new companies ready to join
Partnering and research capacity building with MoHs and National Control Programmes

Major Role of Regional Disease Platforms:

• Strengthening local capacities
• Conducting clinical trials (Phase II/III studies)
• Facilitating registration
• Accelerating implementation of new treatments (Phase IV & pharmacovigilance studies)
• Defining patients’ needs and target product profile (TPP)
For each disease, a Target Product Profile to guide all decisions (example of paediatric HIV)

**IDEAL CHARACTERISTICS (TPP)**

- 4 ARVs in one
- Simple to open and use with water, milk, food
- Good taste
- No fridge needed
- Suitable for infants (<2 months - 3 years)
- TB-treatment compatible
- Affordable for governments

**PROCESS**

Modular format allows flexibility to replace drug in the combination

RTL

To be added during HIV/TB therapy

4-in-1 granules in Fixed-Dose Combinations
Our new Business Plan 2015-2023: A dynamic approach to address patient needs

Pipeline focus can quickly be adapted to:

• stay aligned with changes in the environment
• rapidly respond to urgent patient needs
• address specific regional needs

Disease Portfolio
Most neglected diseases remain at the core, with new diseases taken on progressively.
How we will do it… operationally

Idea sourcing
- Consultation Process

Idea translation
- Exploratory
- Feasibility
- Concept validation

Selection of appropriate model
- Include in DNDi Portfolio (Full or mini)

Implementation of disease programmes
- FULL PORTFOLIO
  - Research
  - Development
  - Implementation
  - €100 + million
- MINI PORTFOLIO
  - ~ €25 million
- SUPPORT
  - Up to €1 million

RANGE OF SUPPORT MODELS
- LIGHT ROLE
  - Build resource platform
  - Incubator
- ACTIVE ROLE
  - Knowledge sharing
  - Advocacy push
  - Advisory role
Next steps for DNDi to incubate the facility

• Board decision in December 2015: go/no go

• Need for securing political support and stakeholder input

• We are prepared to incubate the Facility, in the same way MSF incubated DNDi, and WHO/TDR incubated FIND and MMV

THANK YOU!