Reflections on 10 Years of Challenges and Successes of the DNDi Partnership Model

Dr. Bernard Pécout, Executive Director
OUTLINE

- The Landscape
- The DNDi Model
- Research & Development and Key Milestones
- Main Challenges
Since 1999, from ideas to realization …

- **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?’

- **2002**
  - DND Working Group Malaysia meeting

- **July 2003**
  - Creation of DNDi (7 founding members)

- **2007**
  - First DNDi treatment registered…
Time to Revisit the Fatal Imbalance?

From 1975 to 2004

Tropical diseases: 18 new drugs (incl. 8 for malaria)

Tuberculosis: 3 new drugs

1.3% 21 new drugs for neglected diseases

98.7% 1,535 new drugs for other diseases

A changing landscape for neglected disease R&D

- Big Pharma & Biotechs
- WHO
- Public institutions in endemic countries
- Generics & Pharma
- Philanthropy
- New Funding Mechanisms
- Governments
- PPPs & PDPs

A dynamized critical mass of neglected disease players
But for Neglected Patients, Reality Remains the Same…

- Poorest of the poor
- Living in remote areas
- Socioeconomic burden on family and community
- Marginalized & voiceless patients
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DNDi: Patient Needs-Driven & Innovative R&D Model

- Deliver 11 to 13 new treatments by 2018
- Establish a robust pipeline
- Use and strengthen existing capacity in disease-endemic countries
- Raise awareness and advocate for increased public leadership

**Founding Partners**

- Indian Council for Medical Research (ICMR)
- Kenya Medical Research Institute (KEMRI)
- Malaysian MOH
- Oswaldo Cruz Foundation, Brazil
- Médecins Sans Frontières (MSF)
- Institut Pasteur France
- TDR (permanent observer)

**7 worldwide offices**
Scope of Disease & Level of Investment
€ 400M for 2003-2018

=> 11 to 13 Treatments

- Leishmaniasis
  - Disc.
  - # treatments: 2 Deliv., 3 Hypot.
- HAT
  - Disc.
  - # treatments: 1 Deliv., 1 Hypot.
- Chagas
  - Disc.
  - # treatments: 1 Deliv., 1 Hypot.
- Helminth infections
- Paediatric HIV
- Other NTDs
- Malaria

Est. Budget 2011-2018:
- ~ €100m: Mini-portfolios To be built
- €50-60m: Disease(s) to be chosen
- €20-30m: Completed
- < €10m: Completed

Decision on # treatments:
- Deliv.: 2
- Hypot.: 3
Dedicated Teams Worldwide
Over 550 People Committed to DNDi’s Vision
A Global Network to Leverage Resources
More Than 100 R&D Partners

- Balance of public and private partnerships worldwide

- CROs 14%
- Pharmas/ Biotechs 19%
- MoH/ Gov. org./ Hospitals 12%
- NGOs/ PDPs 13%
- Academia 42%

December 2011
Building Sustainable Research Networks for Neglected Diseases

Pan Asian Network for neglected diseases
Screening and discovery research

HAT, LEAP and Chagas Platforms
Clinical trials and Implementation
Private Donors/Funders
- Médecins Sans Frontières (€49M)
- Bill & Melinda Gates Foundation (€42M)
- Wellcome Trust (€5M)
- Other Private Foundations (incl. Medicor, €1.7M)

Public Donors
- United Kingdom – DFID (€40M)
- Netherlands – DGIS (€17M)
- Spain – AECID (€12M)
- France – AFD & MAEE (€9.3M)
- Germany – KFW & GTZ (€9M)
- Switzerland – SDC & Geneva (€ 4.2M)
- USA – NIH/NIAID (€2M)
- European Union – FP5,6,7& EDCTP (€4.2M)
- The Global Fund – AMFm (€0.5M)

Trust-based Donor Relations & Diversification
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DNDi Portfolio-Building Model:
Address Immediate Patient Needs & Deliver Innovative Medicines

- Long-term projects
  - New chemical entities (NCEs)
  - New formulations (fixed-dose combinations)
  - New indications of existing drugs

- Medium-term projects
  - Completing registration dossier
  - Geographical extension

- Short-term projects
  - Geographical extension

Discovery: R, LS, LO
Pre-clinical
Clinical
Implementation
# DNDi Portfolio: A Mix of Existing Drugs & NCEs

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<th>Pre-clinical</th>
<th>Clinical</th>
<th>Implementation</th>
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<td>Nitroimidazole backup</td>
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<td>NECT (Stage 2 HAT) Nifurtimox - Efionithine Co-administration</td>
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<td>New VL treatments – Bangladesh</td>
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<td>VL-2098 (VL)</td>
<td>New VL treatments – Africa • AmBisome® • Miltefosine</td>
<td>New VL treatments in Asia (SD AmBisome®, 3 drug combinations)</td>
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<tr>
<td></td>
<td>Nitroimidazole backup (VL)</td>
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<td>Topical Amp B (CL)</td>
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<td><strong>Chagas</strong></td>
<td>Nitroimidazole</td>
<td>Azoles E1224 &amp; Biomarkers</td>
<td>Benznidazole Paed. Dosage form</td>
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<td>Fenarimol series</td>
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<td><strong>Helminths</strong></td>
<td>Flubendazole - Macrofilaricide</td>
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<td><strong>Paed. HIV</strong></td>
<td>Improved PI for 1st-line</td>
<td>PI sprinkles (CHAPAS-2)</td>
<td>ASAQ Fixed-Dose Artesunate/ Amodiaquine</td>
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<td><strong>Malaria</strong></td>
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<td>‘Superboosting’ – TB/HIV</td>
<td>ASMQ Fixed-Dose Artesunate/ Mefloquine</td>
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</tbody>
</table>

June 2012

✓ : NCE
6 New Treatments Developed Since 2007

- Easy to Use
- Affordable
- Field-Adapted
- Non-Patented
ASAQ Implemented in Partnership with Sanofi
More than 170M Treatments Distributed

- Registered in 2007, prequalified by WHO in 2008
- Registered in 30 sub-Saharan African countries, in India, Bangladesh and Colombia

Transfer of technology to Zenufa Tanzania
ASMQ Developed through a South-South Partnership
Small Tablets - Paediatric Strengths & Easy to Use

- Developed with Farmanguinhos (Brazil), Universiti Sains Malaysia (Malaysia), Shoklo Malaria Research Unit, and University Mahidol (Thailand)
- Successful technology transfer to Cipla (India)
- ASMQ registered in Brazil (2008), India (2011) and Malaysia (2012)
- WHO prequalification (Sept 2012)
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Main Challenges for Sustainable R&D for Neglected Patients

- IP & Open Innovation Platforms
- Overcoming Regulatory Barriers
- Sustainable Financing & New Incentives for R&D
A dynamized critical mass of Neglected Disease players

WHO

Public institutions in endemic countries

Big Pharma & Biotechs

Generics & Pharma

Philanthropy

New Funding Mechanisms

Governments

PPPs & PDPs

Public institutions in endemic countries

Governments
A Global Framework to Secure Coordination and Sustainability

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- Philanthropy
- New Funding Mechanisms
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DNDi
Drugs for Neglected Diseases initiative
Thank You to All Our Partners & Donors