



New Drugs for Neglected Patients

DNDi
Drugs for Neglected Diseases *initiative*

An Overview of DNDi – January 2015

DNDi: Patient Needs-Driven & Innovative R&D Model

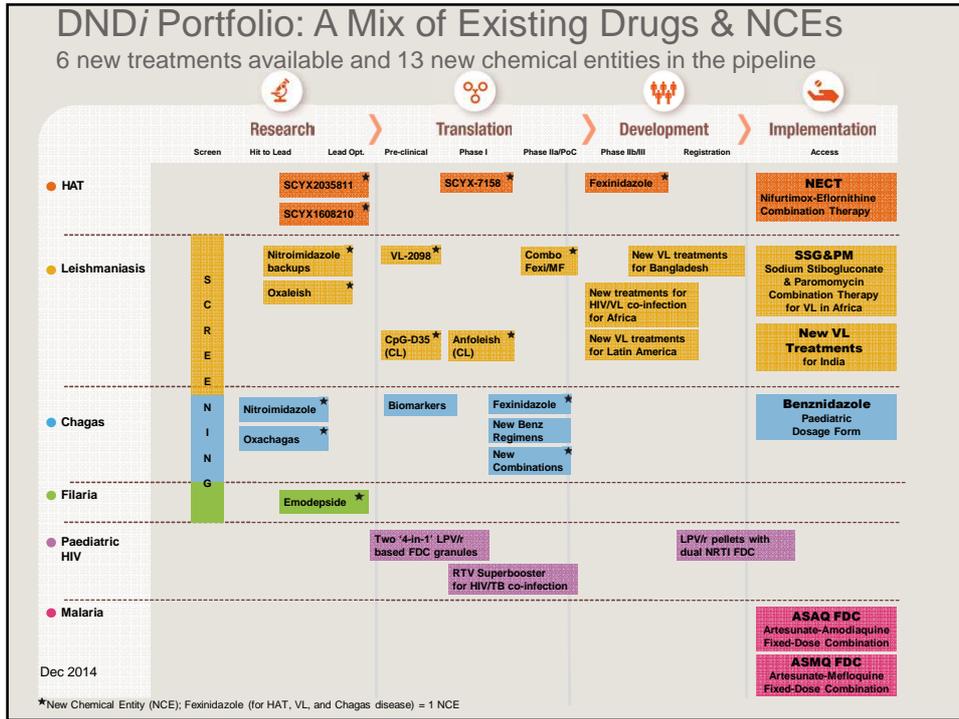
- Deliver **11 to 13 new treatments by 2018**
- Establish a **robust pipeline**
- Use and strengthen existing **capacity in disease-endemic countries**
- **Raise awareness** and advocate for increased **public leadership**

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



6 New Treatments Developed Since 2007

ASAQ (2007)
[Fixed-dose combination of artesunate + amodiaquine]
malaria

ASMQ (2008)
[Fixed-dose combination of artesunate + mefloquine]
malaria

NECT (2009)
[Nifurtimox-eflornithine combination therapy]
sleeping sickness stage 2

Easy to Use Affordable Field-Adapted Non-Patented

SSG&PM (2010)
[Sodium stibogluconate & paromomycin combination therapy]
VL

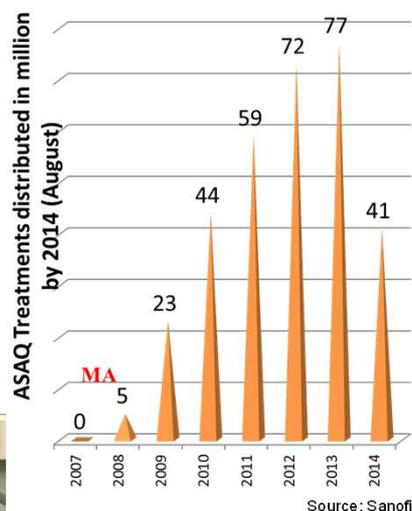
NEW VL TREATMENTS IN ASIA (2011)
[SD AmBisome® / PM+M / A®+M /]
VL

Benznidazole (2011)
12.5 mg
Paediatric dosage form of benznidazole
Chagas disease

Malaria: Develop ACTs in Fixed-dose Combos Over 320 Million Treatments of ASAQ FDC Distributed

- ❑ Pre-qualified by WHO in 2008
- ❑ Non-patented product
- ❑ Registered in 30 sub-Saharan African countries, India, Ecuador, and Colombia
- ❑ Only ACT FDC with a 3-year shelf life
- ❑ Ambitious risk management plan (Pharmacovigilance) with MMV and Sanofi
- ❑ Transfer of technology to Zenufa (Tanzania)

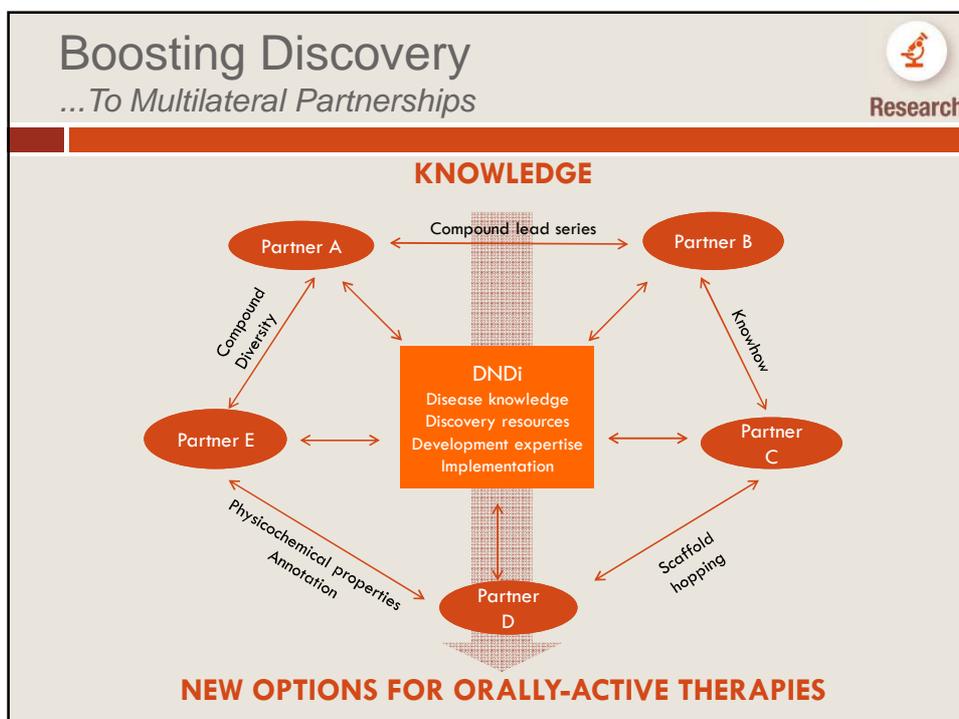
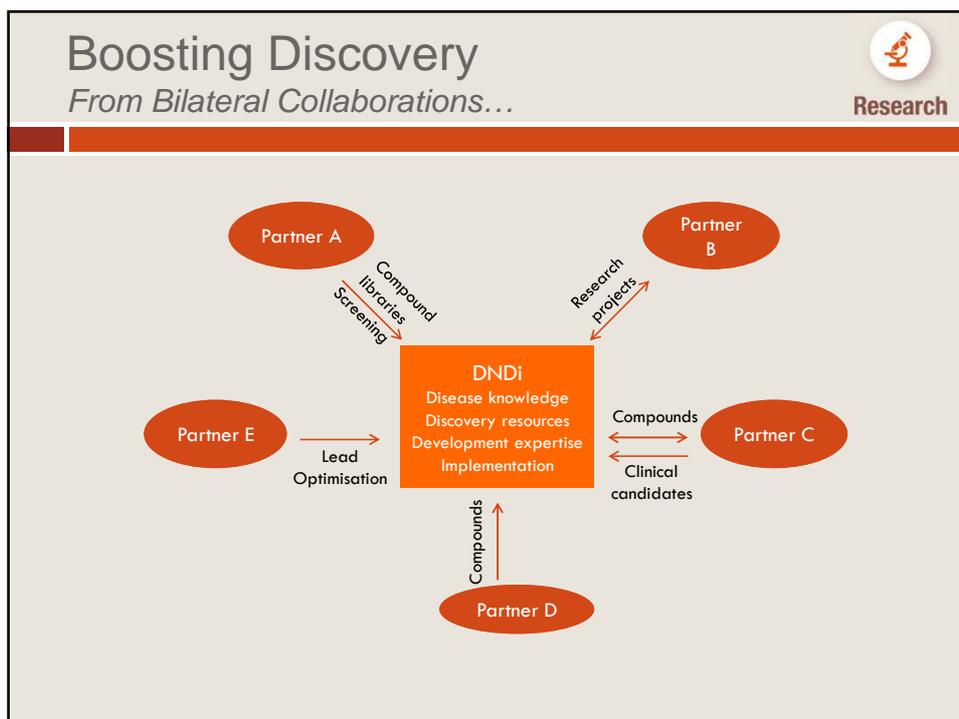
In partnership with Sanofi



Bayer collaboration on emodepside

- ❑ Emodepside is an anti-helminthic used in animal health by Bayer:
 - Active against human worms
 - Originally developed by Astellas
- ❑ Development agreement with Bayer:
 - Comprehensive collaboration from pre-clinical up to implementation
 - Roles and responsibilities clearly defined, with an emphasis on complementarities and collaborative spirit
 - Strong support from Bayer's top management
 - Extensive access provisions insuring affordability and availability
- ❑ Innovative collaboration:
 - Commitment from a Pharma partner to engage into insuring industrial development of a drug despite unknowns on precise needs (volumes, territory), infrastructure, distribution channels, financials, etc.

=> Partners to work together to gather information, establish strategies, in close link with endemic countries.



IP & Access: DNDi vision

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Affordable treatment and equitable access to patients in need

- Delinking the costs of R&D from the price of products
- DNDi activities not financed by IP revenues
- No partnership without overcoming IP barriers which could prevent access

Develop drugs as public goods, when possible

- Disseminate the results of DNDi work
- Encourage open publication of research data and technology transfer
- Decisions regarding ownership of patents and licensing terms made on a case-by-case basis

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Ensure Equitable Access through Patient-Oriented Licensing Schemes

DNDi's principles on licensing:

- *Royalty-free sub-licensable licenses* in the Field
- Licenses for R&D and manufacture: *world-wide*
- Licenses for distribution and sale: *all endemic regions, without exclusion*
- Sales in the public sector: *at cost plus* (lowest sustainable price)
⇒ Delinkage cost of final product / R&D costs
- Sales in the private sector: *possible margins but* linked to partner's *financial contribution*
- Limited confidentiality: to make *freely available information* generated about the product during its development (publications, databases, etc.)

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