

DNDi update: 5 years on, progress made and challenges ahead

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Best science for the most neglected – New Delhi, Oct. 13, 2008

Respond to the Needs of Patients Suffering from Neglected Diseases



Malaria



Sleeping Sickness (HAT)



Visceral Leishmaniasis (VL)



Chagas Disease

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DNDi was created in 2003

7 Founding Partners

Indian Council of Medical Research (ICMR)

Kenya Medical Research Institute (KEMRI)

Malaysian MOH

Oswaldo Cruz Foundation Brazil

Médecins Sans Frontières (MSF)

Institut Pasteur France

WHO/TDR (permanent observer)



Vision

A collaborative, patients' needs-driven, virtual, non-profit drug R&D organisation to develop new treatments against the most neglected communicable diseases

Best science for the most neglected



Objectives

- Primary:
 - Deliver 6 8 new treatments by 2014 for leishmaniasis, sleeping sickness, Chagas disease, & malaria
 - Establish a robust portfolio for new generation of treatments
- Secondary:
 - Use and strengthen existing capacity in Disease
 Endemic countries
 - Raise awareness and advocate for increased public responsibility



Scope of Activities for DNDi

Major focus on kinetoplastid diseases (HAT / VL / Chagas)



3 Core Diseases

3 Core Diseases

- + malaria: facilitate availability of ASAQ and ASMQ
- + cutaneous leishmaniasis

DNDi Portfolio-Building Model



DNDi R&D Projects – 2008 Outlook



On the Way to Deliver 6 to 8 New Treatments by 2014





Partners All Over the World



Virtual Model Attracting Partnerships

250 Agreements Signed Since 2003



Synergies with other PDPs



DNDi's Indian R&D Partners



Selection of New Compounds Access to Chemical Diversity and Capacity to Optimize Leads



Selection of New Compounds Visceral Leishmaniasis Lead Optimisation Consortium



Objective: To obtain optimised leads by progressing 'hit' molecules proven to be safe and active against *Leishmania* parasites.

Status:

Full team in place at Advinus, with 2 promising series of synthetic compounds so far identified. Screening activities begun at CDRI in 2008.



Partners: Advinus, CDRI; LSHTM (UK), Drugabilis (France)

Compounds screened from: Anacor (US), IRD (France)

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Preclinical development Buparvaquone for VL

Objective: To explore new oral formulations, using selfemulsifying drug delivery systems (SEDDS), of buparvaquone.

Status:

Studies are ongoing to examine toxicology and PK/PD in animal models, and to confirm oral bioavailability using the SEDDS formulation.



If formulation with acceptable profile identified, development will progress to satisfy criteria specified for a clinical candidate. In addition, lead optimisation programme will be initiated around the buparvaquone scaffold.

Partners: Advinus; Drugabilis (France), LSTMH (UK)

Clinical development Combination therapy for VL

Objective: To identify a safe and short-course combination therapy using existing drugs already registered in region.

Status:

4-arm study began enrolment at 2 sites (Patna, Muzaffapur) in June 2008, with147 patients enrolled as of Sept. 08.

Enrolment to continue through 2009, and results expected by early 2010.

Partners: ICMR, Kala-azar Medical Research Centre, Rajendra Memorial Research Institute of Medical Sciences, GVK BIO



Clinical development - FACT Project 2 New Antimalarial Treatments: ASAQ & ASMQ:

2 new fixed-dose ACTs delivered in 2007 & 2008:

- Response to public health need
- Easy to use:
 - fewer tablets in regimen
 - paediatric strengths
 - ensure drugs are taken together and in correct proportions
- Affordable
- Available as public good



ASMQ (Farmanguinhos)



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Clinical development - FACT Project ASAQ in India

Objective: to demonstrate efficacy and tolerability of ASAQ in *P. falciparum* malaria cases.

Status:

- Clinical trials in India (N=300)
- 2 sites (Ranchi; Rourkela) enrolled 300 patients
- Study completed Q12008; Results presented at ICID and ICTM17 in 2008
- Consistent with previous studies with ASAQ in Africa
- Supports consideration of ASAQ as 1st-line therapy in India where appropriate



Partners: NIMR, GVK BIO

Clinical development - FACT Project ASMQ in India

Objective: to study population PK, tolerability and efficacy.

Status:

- Clinical trials in India (N=84)
- Dec 2007: Enrolment started at 2 sites (Goa; Mangalore).
 Sept. 08: 77 patients
- End of enrolment expected Q42008
- Results expected by Q32009

Partners: NIMR, GVK BIO



Clinical development - FACT Project Technology Transfer

ASMQ:

DNDi is facilitating South-South technology transfer between Brazil and India.





Non-exclusive licensing.

1st technology transfer project between public pharma and private pharma.

Partners: Farmanguinhós/Fiocruz, Cipla, Catalent

2004-2014 EUR 275 Million Estimated Expenses



91% Social Mission

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Well balanced public/private funders



2008 Donor Mix: EUR 22 Million



Advocacy: Ensure Public Leadership India has an important role to play

Political leadership to start and sustain the efforts in "essential health R&D"

- R&D priorities: to initiate and stimulate research for neglected diseases
- Sustainable funding
- Intellectual property
- Regulatory environment
- Research capacity and technology transfer



By working together in a creative way, PDPs, large and small pharma, and the public sector CAN bring innovation to neglected patients

Let's do it!

www.dndi.org