Rummaging Through Pharma’s Attic: DNDi’s model and patent pools

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DNDi

DNDi Vision

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

7 Founding Partners

- Indian Council for Medical Research (ICMR)
- Kenya Medical Research Institute (KEMRI)
- Malaysian MOH
- Oswaldo Cruz Foundation Brazil
- Medecins Sans Frontieres (MSF)
- Institut Pasteur France
- WHO/TDR (permanent observer)

DNDi 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
### DNDi R&D Portfolio – June 2009

**Exploratory**
- Drug combination (Chagas)
- Oxaborole (HAT)
- Nitroimidazole backup (HAT)
- Alternative formulations Amphotericin B (VL)
- Amphotericin B (VL)

**Stage 2 HAT**
- NECT Nifurtimox - Eflornithine Co Administration
- ASAQ (Malaria) Fixed Dose Artesunate - Mefloquine
- ASAQ (Malaria)
- NECT Nifurtimox - Eflornithine Co Administration

**Stage 3 HAT**
- Combination therapy (VL in Africa)
- Combination therapy (VL in Africa)
- Combination therapy (VL in Latin America) – in preparation
- Paediatric benznidazole (Chagas)
- Paediatric benznidazole (Chagas)

**VL LO Consortium**
- Advinus
- CDRI

**2 HAT LO Consortium**
- Pace Univ
- CDCO

**Chagas LO Consortium**
- Scynexis
- Pace Univ
- CDCO
- Epichem
- Murdoch Univ

**Reference screening centres:**
- LSHTM, Swiss Tropical Institute, University of Antwerp

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**VL:** visceral leishmaniasis (kala azar)
**HAT:** human African trypanomiasis (sleeping sickness)
Fexinidazole

Clinical Candidate for Treatment of African Trypanosomiasis – Currently in Phase I

Originally developed by Hoechst
Partnered with Sanofi-aventis

Ravuconazole

C14 α demethylase inhibitor
To enter clinical development for treatment of Chagas' Disease

Licensed from Eisai Co.
Pediatric Benznidazole

Standard therapy for treatment of Chagas’ Disease

Co-development with Lafepe (Brazil)

Oxaboroles for HAT

Under development as clinical candidates for treatment of Stage 2 African Trypanosomiasis

Licensed from ANACOR Inc.
Lead Optimization with SCYNEXIS Inc.
Access to Compound Libraries

GSK
Merck & Co., Inc.
Scynexis Inc.
Pfizer
Genomics Institute of the Novartis Research Foundation
Novartis Institute for Tropical Diseases
Basilea

Patent Pools
Patent Pooling

• March 2009
  – GSK initiates patent pool for Neglected Tropical diseases 80+ families
• July 2009
  – Alnylam joins the pool with RNAi technology

Patent Pool

In patent law, a **patent pool** is a consortium of at least two companies agreeing to cross-license patents relating to a particular technology. The consortium may also license the patents to third parties. Pools usually have standardized licensing terms between partners and with third parties.

Examples:
  – The Radio Frequency Identification Domain RFID Consortium picked Via Licensing to administer its patent pool in September 2006 (20 companies)
  – DVD Six Licensing Group – DVD Formats (9 Companies)
A compound according to formula (I)

R1 and R1a are independently hydrogen; hydroxy; (C1-6)alkoxy unsubstituted or substituted by (C1-6)alkoxy, amino, piperidyl, guanidino or amidino any of which is optionally N-substituted by one or two (C1-6)alkyl, acyl or (C1-6)alkysulphonyl groups, CONH2, hydroxy, (C1-6)alkylthio, heterocyclylthio, heterocyclyloxy, arylthio, acylthio, acyloxy or (C1-6)alkysulphonyloxy; (C1-6)alkoxy-substituted(C1-6)alkyl, halogen; (C1-6)alkyl; (C1-6)alkylthio; trifluoromethyl; trifluoromethoxy; nitro; cyano; azido; acyl; acyloxy, acylthio; (C1-6)alkysulphonyl; (C1-6)alkysulphoxide; arylsulphonyl; arylsulphoxide or an amino, piperidyl, guanidino or amidino group optionally N-substituted by one or two (C1-6)alkyl, acyl or (C1-6)alkysulphonyl groups; provided that when Z1, Z2, Z3, Z4 and Z5 are CR1a or CH, then R1 is not hydrogen;

A is a substituted or unsubstituted 5 membered aromatic heterocyclic ring of formula (C):

wherein:

W1 and W2 are each independently selected from N, O, S, and CR8;
W3 is N or C;
W4 is N, O, S, or CR8;
each R8 is independently selected from hydrogen; hydroxy; halogen; trifluoromethyl; trifluoromethoxy; cyano; nitro; azido; acyl; acyloxy; acylthio; amino, mono- and di-(C1-6)alkylamino; and substituted and unsubstituted (C1-6)alkoxy, (C1-6)alkyl, (C3-7)cycloalkyl, aminocarbonyl, (C1-6)alkylthio, (C1-6)alkysulphonyl, and (C1-6)alkysulphoxide;
Pharma patents cover chemical space
They do not usually divulge useful SAR
What can a neglected diseases patent pool offer?

Patent Pool Opportunities

Standardized license agreements
  – Between patent holders
  – With development partners
  – Value current IP and improvements
    “Throw it in the pool”
Access to “Intellectual Capital”
A mechanism to deal with IP contamination
Access to compounds/representative libraries
Patent Pool

The model is evolving

GSK Seeks partners and suggestions

Coordination by an independent third party is anticipated

An Opportunity exists to build a new collaborative model

Thank you!