

India:
**Catalyst in
Drug Development**
for Neglected Diseases

Public Symposium
New Delhi, October 13, 2008

DNDi
Drugs for Neglected Diseases *initiative*



DNDi IN 2008

DNDi (Drugs for Neglected Diseases initiative) is a collaborative, patients' needs-driven, not-for-profit drug R&D organization that is currently developing new treatments against sleeping sickness (human African trypanosomiasis, HAT), visceral leishmaniasis (VL), Chagas disease, and malaria. The initiative's primary objective is to deliver six to eight new treatments by 2014 for these diseases and to establish a strong R&D portfolio. In doing so, DNDi is also working to use and strengthen existing capacities in disease-endemic countries, and raise awareness and advocate for the need to develop new treatments for the most neglected diseases.

DNDi has followed this mandate since it was established in 2003 by Institut Pasteur and Médecins Sans Frontières along with four publicly-funded research organizations in neglected disease-endemic countries – including the Indian Council for Medical Research (ICMR). Working in partnership with industry and academia, DNDi has built the largest ever R&D portfolio for the kinetoplastid diseases and currently has 6 clinical and 4 preclinical projects. DNDi successfully delivered its first product in 2007, a fixed-dose antimalarial ASAQ, followed in 2008 by ASMQ. Today, DNDi is a small team of permanent staff in Geneva along with 4 regional support offices in Kenya, India, Brazil, and Malaysia; an affiliate in North America, and 2 regional project support offices in the Democratic Republic of the Congo and Japan.

Learn more about DNDi's progress into 2008 on page 8.

DNDi's ACTIVITIES IN INDIA

With support from DNDi's founding member, the **India Council of Medical Research (ICMR)**, DNDi opened the **regional support office** in India in 2005 to support and catalyse DNDi's operational activities, namely in the field of two diseases, malaria and visceral leishmaniasis (VL). These two diseases are prevalent in India and affect more than 3 million Indians each year, according to Indian government estimates.

India has been the increasing focus of medical research as it bears a large burden of two types of diseases: on the one hand, that of neglected tropical diseases, which represent major health problems, and on the other, an increase in non-communicable lifestyle diseases. Consequently, no one can deny that India has become an emerging pharmaceutical hub where research costs are low and pools of skilled medical research and drug development experts are abundant. These elements make India a key country in the fight to address neglected diseases and are reasons why DNDi has been active in the country since its 2004. In fact, DNDi is currently carrying out more than 30% of its R&D activities in India.

Learn more about DNDi's activities and partners in India on pages 9 through 14.



13 October 2008

Dear guests, partners, friends, and key players in the fields of health and neglected diseases:

Welcome to DNDi India's public symposium exploring India's potential role as a catalyst in drug development for neglected diseases. This exciting event brings together DNDi's key Indian partners, as well as world renowned health experts, researchers, clinicians, and pharmaceutical executives to discuss not only the present, but also the future role of your country, India, in drug research and development, access, and capacity strengthening to combat neglected diseases.

We are honoured to have among us distinguished guests from the public and private sphere: representatives of national and local authorities, pharmaceutical firms, health related NGOs, academics, and research institutes. We would like to especially thank our two chairs – Dr. S.K. Bhattacharya, Director General of the Indian Council of Medical Research (ICMR), and Dr. Nirmal K. Ganguly of the Translational Health Science and Technology Institute – as well as the speakers and panelists who will bring their expertise to facilitate this discussion.

We would also like to acknowledge our devoted Indian partners who provide invaluable contributions to our R&D activities at various stages of drug development: the Indian Council of Medical Research (ICMR), the Central Drug Research Institute (CDRI), the National Institute of Malaria Research (NIMR), the Kala-azar Medical Research Centre, the Rajendra Memorial Research Institute of Medical Sciences, Advinus Therapeutics, GVK BIO, and Cipla.

The public event will be followed by the official launch of DNDi India office, which is located at the ICMR in New Delhi. This regional support office functions as a relay for DNDi's operational activities in India, which involve not only ongoing clinical trials, but a number of earlier stage projects as well as advocacy for greater attention to neglected diseases. Although activities have been ongoing since 2004, it's in recognition of the growth, value, and potential of these activities that we are now officially launching an office in India.

We are very pleased that you are here with us today and will have a chance to share your knowledge and wisdom with all those present. We look forward to future engagements as we work together to make a true difference in delivering adequate treatments to the most neglected patients.

Best regards,

Bernard Pécoul, MD, MPH
Executive Director, DNDi



AGENDA - beginning at 5:00 pm

India: Catalyst in Drug Development for Neglected Diseases?

5 years on: DND/i in India, from screening parasites to treating patients

Exploring the present and future role of India in drug research and development, access, and capacity strengthening for neglected diseases, this public symposium brings together world-renowned health experts, researchers, clinicians, and pharmaceutical executives from India and around the world, as well as DND/i's key Indian partners.

The symposium will be divided into two sessions,

- keynote presentations on the current situation followed by
- a panel discussion with experts, with audience questions to follow

KEYNOTE SESSION: EXPERIENCES IN DEVELOPING TREATMENTS AND ADDRESSING PATIENT NEEDS IN INDIA

Chair: Dr. S.K. Bhattacharya, Additional Director General, Indian Council of Medical Research

Welcoming remarks

Dr. Bhawna Sharma

Head, DND/i India Regional Support Office

**DND/i update – 5 years on,
progress made and challenges ahead**

Dr. Bernard Pécoul, MD, MPH

Executive Director, DND/i

**Opening address – Indian government
perspective on neglected diseases and
the control programmes**

Dr. Shiv Lal

Special Director, General Health Services
(Public Health) & Director National
Institute of Communicable Diseases,
Directorate General of Health Services,
Ministry of Health and Family Welfare

**Visceral leishmaniasis in India:
unmet patient needs and public health
priorities**

Dr. C.P. Thakur, MD

Emeritus Professor of Medicine, Balaji
Utthan Sansthan & Rajendra Memorial
Research Institute of Medical Sciences

**The changing R&D landscape in India
and its impact on neglected diseases in
India and worldwide**

Davinder S. Brar, MBA

Chairman, GVK Bio



BIOGRAPHICAL SKETCHES OF CHAIR AND SPEAKERS IN KEYNOTE

CHAIR

S.K. Bhattacharya, MD, Director General, Indian Council of Medical Research (ICMR)

Dr. Bhattacharya is a recognized expert in infectious diseases with expertise in clinical, epidemiological, and microbiological aspects. His contributions towards the elimination of kala-azar (leishmaniasis) are well-recognized; he has been involved with the World Health Organization (WHO) and private pharmaceutical companies in drug development, drug resistant parasite studies, and the control of these diseases in Bihar. He has served as a WHO Temporary Adviser in several WHO sponsored workshops for clinical training in India and abroad. He has published more than 300 scientific papers in his field of expertise.

SPEAKERS

Bernard Pécoul, MD, MPH, Executive Director, DNDi

Dr. Pécoul's has led DNDi since its founding in 2003. DNDi and its partners have built the largest and most robust R&D portfolio ever for three of the most neglected diseases (leishmaniasis, human African trypanosomiasis, and Chagas disease), and launched ASAQ and ASMQ, two low-cost, non-patented antimalarial combinations. Dr. Pécoul played a key role in the formation of DNDi as part of the Access to Essential Medicines Campaign of Médecins Sans Frontières (MSF). Prior to his involvement with the campaign, Dr. Pécoul was the Executive Director of MSF-France, a co-founder of Epicentre, and a MSF field physician in Africa, Latin America, and Asia. Dr. Pécoul obtained his MD from the University of Clermont Ferrand and his MPH from Tulane University.

C.P. Thakur, MD, Emeritus Professor of Medicine, Balaji Utthan Sansthan & Rajendra Memorial Research Institute of Medical Sciences

Dr. Thakur has been holding the portfolio of the Union Minister for Health and Family Welfare in the Government of India since May 2000. He revolutionized the concept of treatment of kala-azar and is recognised as an international authority in this field. His medical research work has largely concentrated on understanding kala-azar and the treatment for the disease which is rampant in his native state and which also affects parts of West Bengal. His current research includes the evaluation of the use of an anti-cancer drug in kala-azar with the WHO, evaluation of other drugs for resistant cases of kala-azar, and the typing of *Leishmania* parasites. Thakur has published more than 100 research papers in both national and international journals.

Davinder S. Brar, Promoter Chairman, GVK Bio

Davinder S. Brar joined GVK Biosciences as a Promoter Chairman in 2004. He has 30 years of experience in the pharma/life-sciences industry. He played a significant role in building Ranbaxy (India's largest pharma company) into a globally recognized generics company with a pipeline of specialty and innovator (NCE) drugs. He is also involved with several international pharma/life-sciences companies in a consulting/advisory role through Davix Management Services Pvt. Ltd.



Moving on from a presentation of the present situation and current needs, this panel discussion will feature 5-minute briefs from leaders in clinical research and drug development to provide their perspectives on what the future holds for neglected diseases and India.

PANEL SESSION: FUTURE ROLE OF INDIA IN BRINGING INNOVATION THAT WILL ADDRESS NEGLECTED DISEASES

How do we promote R&D innovation for neglected patients? What are the strengths and weaknesses of the current system? What incentives can be provided? What challenges remain?

**Chair: Prof. Nirmal K. Ganguly,
Distinguished Biotechnology Fellow and Advisor, Translational Health Science and Technology Institute**

**Visceral leishmaniasis in India:
what's ongoing and what remains to be done**

Dr. Shyam Sundar, MD
Professor of Medicine, Institute of Medical Sciences, Banaras Hindu University

Malaria in India: what's ongoing and what remains to be done

Dr. A.P. Dash, MD
Director, National Institute of Malaria Research (NIMR)

Perspectives on the R&D sector delivering innovation for neglected diseases in India from an insider's point of view

Rashmi Barbhaiya, PhD
CEO, Advinus Therapeutics

Opportunities to engage the Indian R&D sector in delivering innovation for neglected diseases worldwide

Dr. Shing Chang, PhD
R&D Director, DNDi

Audience Q&A session

Chair: Prof. Nirmal K. Ganguly

Concluding remarks

Prof. Nirmal K. Ganguly

AS OF 6:45 PM: RECEPTION TO CELEBRATE THE OFFICIAL OPENING OF DNDI INDIA OFFICE



BIOGRAPHICAL SKETCHES OF CHAIR AND SPEAKERS IN PANEL

CHAIR

Nirmal K. Ganguly, MD, MBBS, Distinguished Biotechnology Fellow and Advisor, Translational Health Science and Technology Institute

Prof. Nirmal K. Ganguly's was most recently the Director General of the Indian Council of Medical Research, New Delhi. He has also served as the General President (Elect) of the Indian Science Congress Association for the year 2004-2005 and was Acting Director at the Post Graduate Institute of Medical Education & Research, Chandigarh, and at the National Institute of Biologicals, NOIDA. His major research areas have been tropical diseases, cardiovascular diseases, and diarrhoeal diseases. He has authored over 725 publications and won over 100 awards internationally and nationally, including a nomination for the Dr. U.C Chaturvedi IAMM Lifetime Achievement distinction in 2007. On January 26, 2008, he was honoured with the prestigious Padma Bhushan Award by her Excellency, the President of India, in the field of medicine.

SPEAKERS

Shyam Sundar, MD, Professor of Medicine, Institute of Medical Sciences, Banaras Hindu University, India; Director, Kala-azar Medical Clinic, Muzaffarpur

Dr. Sundar is a Professor of Medicine at the Institute of Medical Sciences, Banaras Hindu University, where he uses immunological and molecular biology techniques to study the mechanisms of drug resistance of visceral leishmaniasis (VL). Notably, Prof Sundar established and is also the Director of the Kala-azar Research Centre, the first centre dedicated to the research and treatment of visceral leishmaniasis. This centre is at the forefront of the diagnosis and treatment of the disease in Muzaffarpur in the Indian state of Bihar. For two decades, Dr. Sundar has been involved in the study and treatment of VL, and has authored over 250 publications on this subject.

A.P. Dash, MSc, PhD, DSc, Director, National Institute of Malaria Research (NIMR)

Dr. Dash is an expert in vector-borne diseases, such as malaria, filariasis, and dengue. He has more than 30 years of research experience in malaria & arthropod borne diseases and more than nine years in research administration as the Indian Director of the Institute of Life Sciences, the Regional Medical Research Centre for Tribals (ICMR), the Centre for Research in Medical Entomology (ICMR), and the National Institute of Malaria Research (ICMR). Dr. Dash also headed the International (WHO/TDR) Research Projects on filariasis, dengue, and malaria. He was awarded his M.Sc. and Ph.D. in Zoology, and his D.Sc. in Parasitology and Public Health from Utkal University, India. He has authored more than 70 publications and received several awards for his remarkable achievements.

Rashmi Barbhैया, PhD, CEO, Advinus Therapeutics, Bangalore

Dr. Barbhैया is a pharmaceutical executive with extensive global experience in handling diverse aspects of drug discovery and development. Previous positions held by Dr. Barbhैया include: President of Research and Development, Ranbaxy Research Laboratories, New Delhi, India and Vice President, Pharmaceutical Research Institute, Bristol-Meyers Squibb (BMS), Princeton, NJ. In his 21 years with BMS and 2.5 years with Ranbaxy, Dr. Barbhैया has been instrumental in the discovery and development of numerous new drugs and drug



delivery products. Dr. Barbhaiya has authored over 140 publications covering a broad range of therapeutic areas. He completed his post-doctoral training at the University of Florida and the University of Wisconsin after obtaining his PhD in Clinical Pharmacology from St. Bartholomew's Hospital Medical College, University of London.

Shing Chang, PhD, R&D Director, DNDi

Dr. Chang is responsible for building DNDi's project portfolio and advancing the discovery and development of new treatments for neglected diseases. Prior to DNDi, Dr. Chang was a pharmaceutical industry executive: serving as Senior Vice President, Drug Discovery and Chief Scientific Officer at ICOS Corporation; holding various management positions at Abbott Laboratories in diagnostics and pharmaceutical research, including seven years as Divisional Vice President, Infectious Disease Research, in the global pharmaceutical research and development division; and rising to Vice President, Preclinical and Development at Cetus Corporation after joining initially as one of its first molecular biologists. Dr. Chang completed post-doctoral fellowships at the University of Wisconsin and Stanford University. He received his PhD in Molecular Biology and Biochemistry from the University of California, Santa Barbara, and his BS in Biology from Fu-Jen Catholic University in Taiwan.



DNDi's MAIN PROGRESS INTO 2008

Malaria – delivery of the first two fixed-dose ACTs with paediatric strengths

- ASAQ – fixed-dose combination (FDC) of artesunate and amodiaquine for treatment of malaria in sub-Saharan Africa; launched in March 2007; registered in 23 disease-endemic countries; produced in landmark partnership with sanofi-aventis; www.actwithasaq.org
- ASMQ – FDC of artesunate and mefloquine for treatment of malaria in Latin America and Asia; registered in Brazil in March 2008; key partner: Farmanguinhos/Fiocruz; South-South technology transfer underway to Cipla for availability in Asia; in use by Brazilian national authorities as part of ongoing intervention study (25,000 patients); www.actwithasmq.org

Visceral Leishmaniasis (VL) – international partnerships for early stage drug development and to assess the product candidates in clinical research; ongoing clinical studies

- Lead Optimisation Partnership – 1st partnership of its kind for VL; activities implemented in 2007, 2 promising series of compounds so far identified; key partners: Advinus & CDRI
- VL Combination Trial – evaluating safe and short-course combination therapy using existing drugs registered in region in order to stave off parasitic resistance and provide a shorter, more effective treatment course; patient recruitment began in May 2008 in India
- Paromomycin Trial – more than 1,000 patients included in multi-centre trial in East Africa aimed at providing an improved, lower cost treatment
- Leishmaniasis East Africa Platform – research capacity strengthening in Africa for VL

Human African Trypanosomiasis (HAT, sleeping sickness) – products advancing into the clinic; international partnerships for discovery and clinical research

- Lead Optimisation Partnership – aims to progress molecules from early-stage screening research; activities ongoing; key partners: Scynexis & Pace University
- Fexinidazole – first compound mining success from DNDi's nitroimidazoles project; finalising preclinical studies; will enter first-in-human Phase I trials in early 2009
- Clinical Trial of Nifurtimox-Eflornithine Co-Administration – promising study data being finalised; shows for NECT as easier to use, more practical, and safe therapy; full dossier will be submitted to WHO Essential Medicines List in 2008
- HAT Platform – research capacity strengthening in Africa for HAT

Chagas Disease – cultivating Chagas pipeline in early stage development and for production of the first paediatric-strength tablets for a Chagas treatment

- Lead Optimisation Partnership – aims to progress molecules from early-stage screening research; teams established; Partners: Centre for Drug Candidate Optimization (CDCO), Epicchem, & Murdoch University (Australia); Federal University of Ouro Preto (Brazil)
- Paediatric Benznidazole – agreement established with LAFEPE to develop first benznidazole formulation for children; to be affordable and available as public good



DNDi's Current R&D Activities in India: From Discovery Through Clinical

Discovery projects: landmark agreement cements DNDi's optimisation efforts

In December 2007, DNDi signed a 5-year collaborative agreement with **Advinus Therapeutics** as primary partner in lead optimisation consortium for VL. The project is to obtain optimised leads by processing "hit" molecules with good safety profiles and proven activity against *Leishmania* parasites.

This consortium brings together expertise in chemistry, screening, pharmacology, and pre-formulation in order to optimise a molecule's drug properties - to be orally absorbed and reach the bloodstream, be distributed effectively to infection sites, remain intact in the body to kill the parasites, and yet not harm the patient.

- With a full team in place, Advinus Therapeutics in Bangalore has conducted an assessment of the first series of synthetic compounds and initiated chemistry-biology activities. Dedicated screening facilities at the **Central Drug Research Institute (CDRI)**, in Lucknow, will be established by the end of 2008 for *in vitro* and *in vivo* biological activities. If the results prove satisfactory following lead optimisation, the compounds will be taken forward for preclinical studies in animals and subsequent clinical investigations.

Ongoing clinical trials

MALARIA

Malaria is present in over 100 countries and threatens half of the world's population. In **sub-Saharan Africa**, where it is the **single leading cause of death for children under five**, malaria kills one child every 30 seconds – this translates to the deaths of approximately 3,000 children every day.

Malaria is unevenly distributed in India – 80% of the population lives in low transmission areas and 20% in a high transmission belt. The annual burden reported by the national malaria control program is 2 million confirmed cases and 1,000 deaths, whereas the WHO estimates 15 million cases and 20,000 deaths. India holds 77% of the Southeast Asia malaria burden. The region also witnesses a large number of *P. falciparum* cases (up to 50%) and chloroquine resistance.

Fixed-dose artemisinin-based combination therapy (FACT) projects

- **ASAQ**, the fixed-dose combination of artesunate (AS) and amodiaquine (AQ), launched in 2007, was the first drug to be made available by DNDi in an innovative partnership with sanofi-aventis. A clinical trial studying the drug's tolerability and effectiveness in real-life conditions for its eventual registration in India has recently been concluded. The study was carried out in partnership with the **Indian Council of Medical Research (ICMR)** and **National Institute of Malaria Research (NIMR)**, namely in Orissa and Jharkhand regions; study results were recently presented at



the XVII International Congress on Tropical Medicine and Malaria and will be submitted for publication in 2009.

- **ASMQ**, the new fixed-dose combination of artesunate (AS) and mefloquine (MQ), developed by DNDi and Farmanguinhos/Fiocruz, was successfully registered in Brazil in March 2008. To facilitate its future availability in Southeast Asia, and upon approval from the ethics committee and the relevant national and local authorities, further clinical research with **the Indian Council of Medical Research (ICMR) and National Institute of Malaria Research (NIMR)**, is currently being conducted in the Goa and Mangalore regions. Further enabling the Southeast Asia expansion, Farmanguinhos/Fiocruz has agreed to the principle of technology transfer to the Indian pharmaceutical manufacturer, **Cipla**.

VISCERAL LEISHMANIASIS (VL)

Leishmaniasis affects approximately 12 million people in 88 countries. **Visceral leishmaniasis affects poor, remote populations in 70 countries** across Asia, East Africa, South America, and the Mediterranean region. The 7 most affected countries represent over 90% of all reported new cases.*

India has about 100,000 new cases of VL annually, of which approximately 90% are from Bihar.

Drug combination study

- **Clinical trials on VL combination therapies** of Ambisome® (lipid formulations of Amphotericin B), paromomycin, and miltefosine
Until recently, pentavalent antimony complex was one of very few standard VL treatments, despite all of its limitations: toxicity, lengthy treatment, and growing resistance. Presently, amphotericin B, paromomycin, and miltefosine have been evaluated and officially approved by all relevant authorities for the treatment of VL in India. All of these drugs have advantages and disadvantages with regards to cost, toxicity, length, and ease of administration. Therefore, to reduce the treatment period, to increase compliance, and to reduce the possibility of resistance developing, DNDi and its partners are investigating the use of combinations of these drugs to treat VL. A clinical study to evaluate various drug combinations has been initiated in collaboration with **ICMR and the Rajendra Memorial Research Institute (RMRI)**, at Patna, the **Kala-azar Medical Research Centre (KMRC)**, and **GVK Bio** at Muzaffarpur. This project will be extended to Nepal and Bangladesh. The data collected will be used to make a recommendation to the national control programs in highly endemic areas of VL in the region. A total of 147 patients have been recruited so far out of 640 for proposed clinical trials.



DND/*s* Awareness and Advocacy Efforts in India

Building awareness

DND/*i* India has undertaken a series of initiatives to strengthen its role in advocacy for patients suffering from neglected disease and to raise awareness for their plight. Likewise, DND/*s* communications activities focus on providing an accurate image of DND/*s* mission and objectives by promoting a widespread commitment to neglected diseases, in particular by the Indian government. Key messages are expanded upon to convey neglected disease concerns to those who can make difference in this field.

Throughout 2007/2008, DND/*i* India actively attended numerous scientific congresses and symposia, and provided relevant donors, intergovernmental organisations, non-governmental organizations (NGOs), Product Development Partnerships (PDPs), UN bodies, scientists, and the media with experience-based analyses on the challenges facing researchers in the field of neglected diseases and an explanation of DND/*s* role within this field, particularly its activities within the region.

Some examples of activities in India in the field of neglected diseases are:

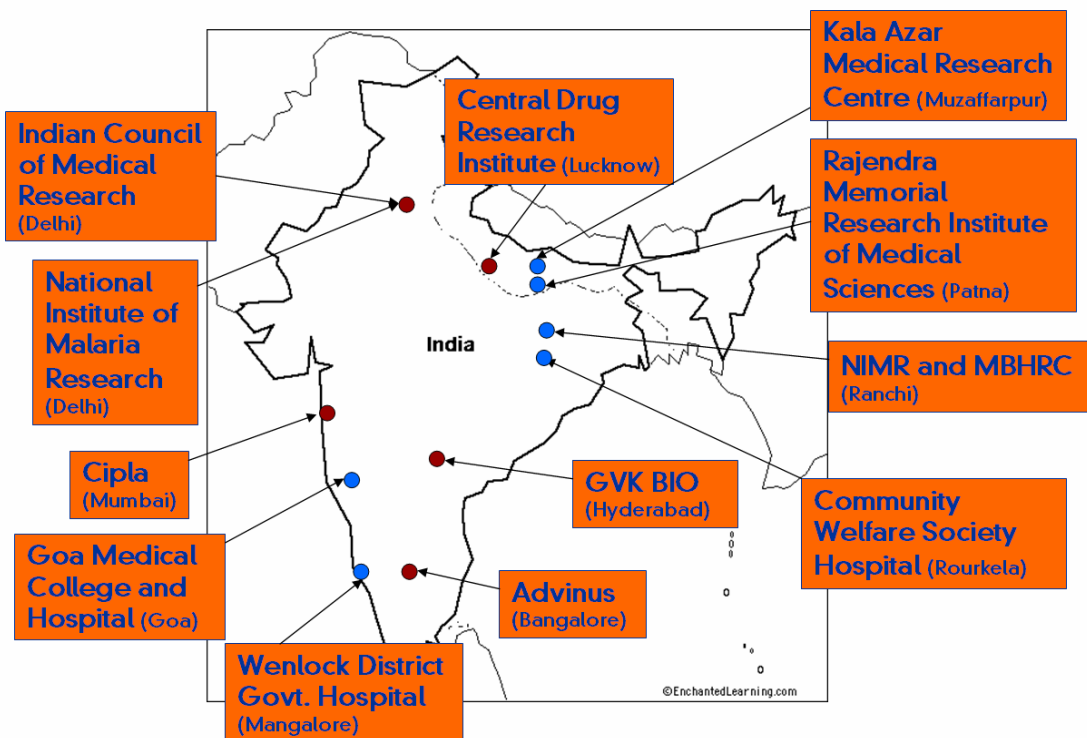
- The vision and mission of DND/*i* was translated into and published in Hindi in the ICMR bulletin, which is circulated to all relevant professionals throughout the country
- An article was written for the parliamentarians' newsletter to emphasise the need for drug development in neglected diseases
- During consultative IGWG meetings of the Government of India, the DND/*i* experience and view of research and development for neglected diseases were presented
- DND/*i* is a sponsor of the WorldLeish4 event that will take place February 3-7, 2009 in New Delhi. The event will be comprised of both plenary sessions and satellite symposia. The DND/*i* symposium will cover the span of DND/*s* R&D programme for visceral leishmaniasis, from early-stage discovery research done by the Institut de Recherche pour le Développement (IRD) to the Advinus-led lead optimisation consortium, one of DND/*s* Indian partners, to ongoing clinical research on combination therapy for VL
- Presentations of ASAQ clinical research were given during the 13th International Congress on Infectious Diseases (ICID), in Malaysia, and the 17th International Congress for Tropical Medicine and Malaria, in Korea



PROJECT PARTNERS

DND/s Indian project partners include the following: the Indian Council of Medical Research, the National Institute of Malaria Research, the Central Drug Research Institute, the Rajendra Memorial Research Institute, the Kala-azar Medical Research Centre, Cipla, Advinus Therapeutics, GVK Bio.

DNDi's Indian R&D Partners





PROJECT PARTNERS - DESCRIPTIONS

Advinus Therapeutics

Advinus is one of the leading R&D alliances and pharmaceutical research outsourcing companies, promoted by the Tatas, one of India's largest and most respected business houses, with total revenues of more than USD 17 billion and a market capitalization of more than USD 31 billion. With a history of leadership that goes back almost a century, the Tata group is renowned for its high standards of quality, ethics and commitment.

Advinus is the principal partner of the VL Lead Optimization Consortium, which identifies screened compounds with promising profiles to advance into preclinical studies. Advinus also works with DNDi on the preclinical development of buparvaquone, a promising oral treatment candidate for VL.

Central Drug Research Institute (CDRI)

CDRI is considered to be a pioneer research organisation in the field of biomedical research where all the infrastructure and expertise are available to develop a drug right from its concept to market. The very latest techniques and methodologies are employed for developing drugs, diagnostics, and vaccines to combat diseases prevalent among mankind in general and the Indian population in particular.

CDRI acts as a screening centre for DNDi on both HAT- and VL-related projects that will feed promising candidates into the respective lead optimization consortiums. CDRI has already screened approximately 8,000 compounds for activity against HAT and VL.

Cipla

Originally founded in 1935 as The Chemical, Industrial & Pharmaceutical Laboratories (CIPLA), Cipla is a prominent Indian pharmaceutical company, best-known worldwide for producing generics, namely low-cost anti-AIDS drugs for HIV-positive patients in developing countries. Cipla also makes drugs to treat cardiovascular disease, arthritis, diabetes, weight control, depression and many other health conditions. Its products are distributed in more than 180 countries worldwide. Cipla is renowned both locally and internationally for its high standards, quality, efficacy, and affordability of medicines.

Cipla serves as DNDi's Indian pharmaceutical development and manufacturing partner for ASMQ, facilitating the drug's availability across Southeast Asia.

GVK BIO

GVK BIO is a part of the USD 1 billion GVK group. GVK is a diversified enterprise having interests in infrastructure, services, and manufacturing. GVK BIO is one of India's premier contract research organisations (CROs), providing an integrated platform of research services across the pharmaceutical R&D value chain to a growing number of global pharmaceutical and biotechnology companies.

GVK Bio assists in managing DNDi's VL Combination Therapy, ASAQ, and ASMQ clinical trials.



Indian Council of Medical Research (ICMR)

ICMR, the apex body in India for the formulation, coordination, and promotion of biomedical research, is one of the oldest medical research bodies in the world. The Council promotes biomedical research in the country through intramural (Permanent Research Institutes and Regional Medical Research Centres), as well as extramural research (Centres for Advanced Research, Task Force and Open-ended research).

ICMR is one of DNDi's founding partners and continues to provide clinical trial and research support for DNDi's VL Combination Therapy, ASAQ, and ASMQ projects.

Kala Azar Medical Research Centre

The first of its kind, the Kala-azar Medical Research Centre, founded in 1994, is a recognised centre dedicated to visceral leishmaniasis or kala-azar treatment. It has successfully treated so far thousands of patients affected by this disease across India and collaborates with worldwide experts in clinical research. Its many achievements include conducting the first trials of miltefosine and leading the pivotal Phase III miltefosine trial, which contributed to the drug's registration in India, the first country in the world to do so. The centre also conducted the first testing of the rK39 strip test and led the pivotal Phase III trial on paromomycin leading to its registration.

The Kala-azar Medical Research Centre is a clinical trial site for DNDi's VL Combination Therapy project.

National Institute of Malaria Research (NIMR)

Established in 1977 as the Malaria Research Centre, it was renamed as the National Institute of Malaria Research recently in November 2005. NIMR is one of the institutes of the Indian Council of Medical Research (an autonomous body under the Ministry of Health & Family Welfare, Govt. of India). The primary task of the Institute is to find short term as well as long term solutions to the problems of malaria through basic, applied, and operational field research. The Institute also plays a key role in manpower resource development through trainings/workshops and transfer of technology. It has more than 50 scientific experts with a network of well-developed laboratories in Delhi carrying out research on all aspects of malaria along with 10 field laboratories in malaria endemic areas, which serve as testing grounds for new technologies and help in the transfer of technologies.

NIMR assists in conducting DNDi's ASAQ and ASMQ clinical trials in India.

Rajendra Memorial Research Institute of Medical Sciences

Rajendra Memorial Research Institute of Medical Sciences (RMRI), Agamkuan, Patna is one of the permanent Institutes of the Indian Council of Medical Research. Its main thrust is research into the different aspects of visceral leishmaniasis, including clinical, vector biology and control, immunological, biochemical, molecular biology, pathological, parasitological and social. The institute's laboratories are assessed regularly by WHO/TDR clinical monitors.

RMRI assists in conducting clinical trials for DNDi's VL Combination Therapy project.

Best science for the most neglected



Drugs for Neglected Diseases *initiative*

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