



# NEW HOPE FOR NOVEL DRUGS FOR LEISHMANIASIS

Update of DNDi's leishmaniasis  
R&D pipeline



**DNDi**

Drugs for Neglected Diseases *initiative*

[www.dndi.org](http://www.dndi.org)

*Some 350 million people are at risk of developing leishmaniasis in one of its many forms – visceral, cutaneous, mucocutaneous and post kala-azar dermal leishmaniasis. Yet existing treatments present serious drawbacks: some are toxic; some are difficult to administer, posing a burden for health systems and for patients alike; for some, affordability and access are seriously limited; and resistance is emerging. The development of new treatments is thus a priority. For other groups of individuals such as asymptomatic cases, more fundamental scientific questions still need to be addressed. This review aims to present DNDi’s scientific strategy and an update on DNDi’s R&D pipeline for leishmaniasis.*



# TWO ENTIRELY NEW DRUGS NOMINATED AS PRE-CLINICAL CANDIDATES

DNDi's long-term objective is to bring safe, effective, oral treatments to leishmaniasis patients. And today, after more than a decade of research efforts, a new path is opening for the development of novel drugs for leishmaniasis.

Two entirely new chemical entities (NCEs) were nominated as pre-clinical candidates over the past year. Profiled with excellent efficacy against both visceral (VL) and cutaneous leishmaniasis (CL) in animal models, DNDI-6148 from the oxaborole class and DNDI-0690 from the nitroimidazole class have entered in pre-clinical development.

An immunomodulator to stimulate the innate immune system (CpG-D35) to fight CL, and to be used as an adjunct to drug therapy, is also currently in pre-clinical development. In addition, two other series are in advanced lead optimization, and additional compounds including NCEs coming from potential partners, close to pre-clinical

development should enter soon the R&D pipeline, making DNDi's portfolio the largest one for leishmaniasis. These unprecedented advances have the potential to transform the drug development landscape for VL and CL and raise the prospect of potential new treatments for neglected patients.

In the meantime, DNDi continues to ensure an uninterrupted supply of quality active series to the lead optimization programmes whilst securing back-up series to address the attrition rate inherent to R&D activities. To this end, partnerships with Pharma and biotech companies are critical in order to access their compound libraries and develop potential new treatments. *(see box 1)*

## BOX 1: BUILDING A ROBUST PORTFOLIO OF DRUG DISCOVERY FOR LEISHMANIASIS: THE NTD DRUG DISCOVERY BOOSTER

The "Neglected Tropical Diseases Drug Discovery Booster" consortium was launched in 2015 with the support of Global Health Innovative Technology Fund (GHIT Fund, Japan). It aims to accelerate, expand and cut the costs of early-stage discovery of new drugs for two highly neglected diseases: leishmaniasis and Chagas disease. This experiment brought DNDi together with six pharmaceutical companies (Eisai Co Ltd, Shionogi & Co Ltd, Takeda Pharmaceutical Company Limited, AstraZeneca plc., Celgene Global Health and, since April 2017, Merck KGaA).

Through a multilateral, simultaneous search process across participating companies, DNDi can access compounds generated over many decades of research. State-of-the-art technology is used to pinpoint compounds that have promising characteristics for further testing. The innovation not only lies in the multilateral approach, but also in the iterative nature of the search, meaning companies will continually examine their libraries for better matches as the search is refined.

In its two years of existence, the Booster has already launched 13 focused screening projects, most of which have resulted in improved anti-parasitic compounds. Each project has already saved tens of thousands of dollars in compound synthesis costs, and has sped up the drug discovery process by an estimated two or three times. The project is on track to deliver new series into DNDi's lead optimization portfolio in 2017.

# NEW TREATMENTS BASED ON EXISTING DRUGS FOR VL, PKDL, HIV/VL AND CL

DNDi also pursues a shorter-term strategy, with the objective of improving therapies based on existing drugs, and overcome the barriers around affordability, treatment duration, burden on health systems and patients, and the risk of resistance. To this end, a number of clinical trials are currently underway or in the preparation phase:

- A Phase III clinical trial testing a new combination therapy for primary VL will be soon conducted in Ethiopia, Kenya, Sudan, and Uganda.
- To address specific needs of patients living with post kala-azar dermal leishmaniasis (PKDL), two Phase II trials testing combination therapies are currently underway in India/Bangladesh and Sudan.
- Two PKDL infectivity studies are under preparation in Bangladesh and Sudan. The objective is to establish the infectivity of PKDL patients to sandflies, in order to determine if PKDL patients maintain inter-epidemic transmission of VL. If this is confirmed, early treatment of PKDL patients would be a critical element of any public health and elimination strategy (*see box 2*).
- The development of better treatment for HIV/VL is in progress, with promising results from a Phase III trial testing a combination therapy in Ethiopia.
- And a Phase II clinical trial using a combination of therapeutic approaches (thermotherapy and oral treatment) is currently being conducted in Peru and Colombia. More details of these projects are provided below.

## BOX 2: RESEARCH EFFORTS ARE STILL NEEDED NOT TO JEOPARDIZE CONTROL OF KALA AZAR IN SOUTH ASIA

The kala azar elimination programme was launched in South Asia in 2005, and aims to reach the target of elimination as a public health problem by the end of 2017. Progress towards the target has been impressive, as the programme has induced a sharp decrease in reported cases: in 2016, Bangladesh reported 862 cases, India 6245 and Nepal 206.

But research and funding efforts still need to be invested in specific areas that could be linked to a resurgence of kala azar in the region, and thus jeopardize the sustainability of these achievements.

The precise role in *Leishmania* transmission played by PKDL patients and asymptomatic infections has to be ascertained: could they serve as silent reservoirs? Do PKDL patients play a role in transmitting the parasite to sandflies and thus maintain transmission during inter-epidemic periods?

It has already been determined that large numbers of individuals in endemic areas are infected with *L. donovani* but do not develop any signs or symptoms of kala azar disease. Could asymptomatic carriers be infective to sand flies, meaning that specific control measures, for example through prophylactic treatment, be required?

When a new case is identified in an area where leishmaniasis was under control, it will be essential to prevent the spread of infection. Will we need to develop preventive vaccine? Are we satisfied with the currently available drugs to treat carriers and contacts? What are the predictive markers that can anticipate evolution to VL, to PKDL and failures or relapses after treatment?

Any new evidence in these areas would also help further define the needs for safer oral formulations for new treatments in South Asia.



## RESEARCH

### Leishmaniasis hit-to-lead

**Objective:** Identify new leads series from current ongoing Hit-to-Lead activities by taking advantage of the optimization consortia platform screening of compounds for VL.

**Main partners:** Epichem, Australia; Fundação de Apoio Universidade Federale de Sao Paolo, Brazil; Centre for Drug Candidate Optimization, Monash University, Australia; TCG Lifesciences, India; Sandexis, UK; WuXi AppTech, China; Laboratory of Microbiology, Parasitology and Hygiene, University of Antwerp, Belgium; London School of Hygiene and Tropical Medicine, UK; Griffith University, Australia; GlaxoSmithKline, Tres Cantos, Spain; Sanofi, France; Anacor Pharmaceuticals Inc., USA; Merck, USA; AstraZeneca, UK; AbbVie, USA.

### CURRENT STATUS

The project continues to evaluate hits identified from high-throughput screens and to begin the process of optimizing these new chemical series. If promising activity can be demonstrated in *in vivo* models of leishmaniasis, the series will be advanced into full lead optimization. This process of 'hit-to-lead' optimization is ongoing with multiple series from several pharmaceutical companies.



### DNDI-5421 & DNDI-5610 Oxaboroles

**Objective:** Maintain back-up oxaboroles which could replace the pre-clinical candidate DNDI-6148 in case it does not succeed in development.

**Main partners:** Anacor Pharmaceuticals, USA; Laboratory of Microbiology Parasitology and Hygiene, University of Antwerp, Belgium; London School of Hygiene and Tropical Medicine, UK; Sandexis, UK; Scynexis, USA; Wuxi AppTech, China.

DNDi and Anacor (now acquired by Pfizer) been working together over the last few years to identify oxaborole compounds. Five potential oxaborole back-up compounds have been identified, should the pre-clinical candidate DNDI-6148 not succeed in development. Two of these, DNDI-5421 and DNDI-5610, are the most advanced and are being kept ready in case insurmountable issues are identified for DNDI-6148. These compounds have highly efficacious profiles, and if DNDI-6148 should fail DNDi will assess their suitability as viable back-ups.

## Aminopyrazoles

**Objective:** Identify new leads series from current ongoing Hit-to-Lead activities by taking advantage of the optimization consortia platform screening of compounds.

**Main partners:** Takeda Pharmaceutical Company Ltd, Japan; WuXi AppTech, China; Laboratory of Microbiology, Parasitology and Hygiene, University of Antwerp, Belgium; London School of Hygiene and Tropical Medicine, UK; Pfizer, UK; Sandexis, UK.

### CURRENT STATUS

The aminopyrazole class of compounds has shown promising early profiles for the treatment of both visceral and cutaneous leishmaniasis. Profiling of current and new leads in a panel of drug-sensitive and drug-resistant strains of *Leishmania*, exploration of the *in vivo* dose response, rat pharmacokinetics, and initial *in vitro* safety assays are all underway. The ongoing lead optimization programme aims to select an optimized lead.



### CURRENT STATUS

An *in vivo* proof-of-concept has been achieved for this series. An intensive lead optimization programme is ongoing with Celgene to identify an optimized lead.

## CGH VL series 1

**Objective:** Select a pre clinical candidate from the CGH VL series for the treatment of visceral leishmaniasis.

**Main partners:** Celgene Global Health, USA; Laboratory of Microbiology, Parasitology and Hygiene, University of Antwerp, Belgium; London School of Hygiene and Tropical Medicine, UK; WuXi AppTech, China; Sandexis, UK.

## DNDI-6148 oxaborole

**Objective:** Progress the pre-clinical development of DNDI-6148, a selected oxaborole for the treatment of leishmaniasis.

**Main partners:** Accelera, Italy; Anacor Pharmaceuticals Inc., USA; Laboratory of Microbiology, Parasitology and Hygiene, University of Antwerp, Belgium; London School of Hygiene and Tropical Medicine, UK; Sandexis, UK; Sara Pharm, Romania; Scynexis, USA; Syngene, India; Wil Research/Charles River, France; WuXi AppTech, China.

### CURRENT STATUS

In January 2016, DNDI-6148, from the oxaborole class, was nominated as a pre-clinical candidate for the treatment of VL. Pharmaceutical development activities (drug substance and drug product development and manufacture) have now been initiated, and the toxicity/safety pre-IND package was launched starting with dose range finding studies, along with refinement of ADME (absorption, distribution, metabolism and elimination), efficacy and safety profile to ensure a smooth transition from the pre-clinical phase to Phase I clinical phase, which should happen over the course of 2017.

## DNDI-0690 nitroimidazole

**Objective:** Progress the pre-clinical development of DNDi-0690, a selected nitroimidazole for the treatment of VL and possibly CL.

**Main partners:** London School of Hygiene and Tropical Medicine, UK; TB Alliance, USA; Auckland University, New Zealand; Laboratory of Microbiology, Parasitology and Hygiene, University of Antwerp, Belgium; WuXi AppTech, China; Aptuit, Italy; Accelera, Italy.

In 2016, DNDi activities focused on pharmaceutical development activities (drug substance and drug product development and manufacture), launching of toxicity/safety pre-IND package with dose range finding studies, as well as refinement of ADME, efficacy and safety profile to ensure a smooth transition from the pre-clinical phase to Phase I clinical phase, which should happen over the course of 2017.



### BOX 3: SHARING VL DATA TO FILL RESEARCH GAPS

*Launched in 2017 as a pilot project, the visceral leishmaniasis data platform aims to pool data from the few clinical trials on this neglected disease, and ultimately improve treatment outcomes for patients.*

Despite the devastating impact of VL and the large number of people affected, relatively few studies are undertaken. Through the VL data platform launched in collaboration with DNDi, the Infectious Diseases Data Observatory (IDDO) provides an opportunity for researchers to pool data from different clinical trials in order to enhance the statistical power of the available data. The VL data platform will thus provide a way of answering specific research questions that are not answered.

## CPG-D35(CL)

**Objective:** Produce an immunomodulator to stimulate the innate immune system to fight the parasitic infection as an adjunct to drug therapy.

**Main partners:** US Food and Drug Administration, USA; National Institutes of Health, USA; Ohio State University, USA; Nagasaki University, Japan; University of Osaka, Japan; GeneDesign Inc., Japan.

### CURRENT STATUS

Two studies, one *in vitro* and one *in vivo*, were initiated in 2016. The *in vivo* study aims to demonstrate if CpG-D35 – whether alone or in combination with antimonials chemotherapy – will lead to improved *Leishmania* infection outcomes, compared with antimonials alone. Results are expected by mid-2017. The *in vitro* study aims to assess the stimulatory capability of CpG-D35 in both peripheral blood mononuclear cells and whole blood samples from patients with both CL, due to different *Leishmania* species, and PKDL patients and to determine which host genes are modulated in these two conditions. Results are expected by the end of 2017.



## New CL combination therapies

**Objective:** Further explore opportunities to better use the existing approved treatment approaches for CL when used in combination.

**Main partners:** Programa de Estudio y Control de Enfermedades Tropicales, Universidad de Antioquia, Medellin, Colombia and Universidad Peruana Cayetano Heredia, Lima, Peru.

When administered alone, the safety and efficacy profiles of current CL treatments (antimonials, miltefosine, and thermotherapy) are well established. Using a combination of therapeutic approaches may improve efficacy rates, reduce treatment duration, and improve the rate of adverse events. A combination of one single application of thermotherapy at 50°C for 30 seconds with a three-week course of oral miltefosine is currently being tested in Peru and Colombia order to gain information about safety and efficacy.

### CURRENT STATUS

First patients have been enrolled in Peru and final approvals for a second site in Colombia were obtained early 2017.

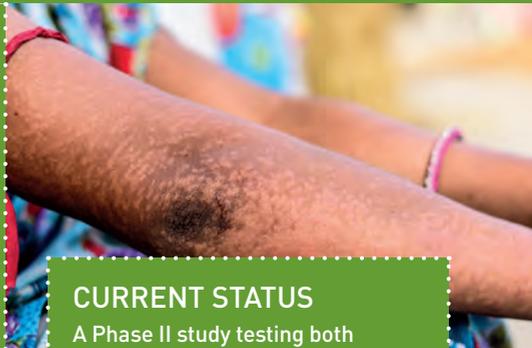
## New VL treatment for HIV/VL

**Objective:** Identify and deliver a safe and highly effective treatment for VL in HIV co-infected patients that will improve long-term survival of these patients.

**Main partners:** Gondar University Hospital, Ethiopia; Addis Ababa University, Ethiopia; London School of Hygiene and Tropical Medicine, UK; Institute of Tropical Medicine Antwerp, Belgium; Médecins Sans Frontières, the Netherlands; Uppsala University, Sweden; Gilead Sciences, USA; LEAP; the Netherlands Cancer Institute, the Netherlands; Utrecht University, the Netherlands; BaseCon, Denmark; UBC, Switzerland.

### CURRENT STATUS

In 2014, a Phase III study testing both AmBisome® monotherapy (at a higher dose than current practice) and a combination of AmBisome® and miltefosine was initiated at two sites in Ethiopia for the treatment of HIV/VL co-infection. After 59 patients had been enrolled, recruitment was interrupted at the time of the interim analysis, as efficacy at the end of treatment was lower than expected. Patients who had not achieved cure at the end of treatment were given a second cycle of the same treatment. With the extended treatment duration, results achieved with the combination treatment were found to be very promising, with the large majority of patients achieving VL cure. These results were based on a limited number of patients; a new HIV/VL cohort study is therefore under consideration to confirm the results.



### CURRENT STATUS

A Phase II study testing both AmBisome® monotherapy and a combination of AmBisome® and miltefosine is underway in India and Bangladesh to assess the safety and efficacy for patients with post-kala-azar dermal leishmaniasis (PKDL). A separate Phase II study to assess the safety and efficacy of both AmBisome® in combination with miltefosine, and paromomycin in combination with miltefosine, is planned in Sudan. In addition, two PKDL infectivity studies are under preparation in Bangladesh and Sudan. Their objective is to establish the infectivity of PKDL patients to sandflies, to determine if PKDL patients maintain inter-epidemic transmission of VL. If this is confirmed, early treatment of PKDL patients would be critical elements of any VL public health and elimination strategy.

## New treatments for PKDL

**Objective:** To determine the safety and efficacy of two treatment regimens for patients with PKDL, mainly in the Indian Sub-continent and East Africa.

**Main partners:** International Centre for Diarrhoeal Disease Research, Bangladesh; Rajendra Memorial Research Institute of Medical Sciences, India; Kala Azar Medical Research Centre, India; Institute of Medical Sciences, Banaras Hindu University, India; Uppsala University, Sweden; Institute of Endemic Disease, Khartoum University, Sudan; Ministry of Health, Sudan; LEAP.

## Miltefosine/paromomycin combination for Africa

**Objective:** Assess the efficacy and safety of two combination regimens of paromomycin and miltefosine as compared to SSG&PM for the treatment of primary VL patients in Eastern Africa.

**Main partners:** Institute of Endemic Disease, Khartoum University, Sudan; Kenya Medical Research Institute, Kenya; Kacheliba District Hospital, Kenya; Makerere University, Uganda; Amudat Hospital, Uganda; University of Gondar, Ethiopia; Research Foundation of the Netherlands Cancer Institute, the Netherlands; ; Leishmaniasis East Africa Platform.

### CURRENT STATUS

A Phase III clinical trial will be conducted in East Africa to compare the efficacy and safety of two combination regimens of miltefosine and paromomycin with the current standard VL treatment sodium stibogluconate (SSG)-paromomycin, in both paediatric and adult patients. Sites will be located in Kenya, Sudan, Uganda and Ethiopia. If the combination is proven safe and efficacious, current treatment would no longer rely on SSG, an injectable drug, which would be replaced with miltefosine, an oral drug. A safer, more field-adapted, patient-friendly treatment would particularly benefit children, who represent a high proportion of the population at risk in East Africa. The trial protocols have been submitted to ethics committees and regulatory authorities early 2017.

## New VL treatments – Latin America

**Objective:** Assess the efficacy and safety of amphotericin B deoxycholate, AmBisome® and AmBisome® combined with Glucantime®, as compared to the first-line treatment, Glucantime®, for the treatment of VL patients in Brazil, supporting the Brazilian Ministry of Health and its partners.

**Main partners:** BRAZIL: Rene Rachou Research Center– Fiocruz-MG, Belo Horizonte; Paediatric Hospital Joao Paulo II – FHEMIG, Belo Horizonte; Brasilia University; Montes Claros State University; Piaui Federal University, Teresina; Sergipe Federal University, Aracaju; Leishmaniasis Control Programme/Ministry of Health; Universidade Estadual do Rio de Janeiro; Hospital Sao José de Doencas Infecciosas, Fortaleza.

### CURRENT STATUS

In 2011, a Phase IV study sponsored by the Brazilian Ministry of Health was initiated at five sites in Brazil to evaluate the efficacy and safety of Amphotericin B deoxycholate, AmBisome® and a combination of AmBisome® and Glucantime®, in comparison to Glucantime®, the existing first-line treatment of VL. 378 patients were recruited. Brazil's national guidelines for VL were revised in 2013 based on the interim safety data from the trial. While Glucantime® remains the first-line treatment, AmBisome® replaced Amphotericin B deoxycholate as a second-line treatment. The final results of this trial were presented to the Ministry of Health, and are expected to guide further policy change in Brazil.

## SSG&PM Africa

Main partners (since project start): Ministries of Health of Uganda, Sudan, Kenya, and Ethiopia; Institute of Endemic Disease, Khartoum University, Sudan; Kenya Medical Research Institute, Kenya; Médecins Sans Frontières, Switzerland and Holland; London School of Hygiene and Tropical Medicine, UK; IDA Foundation, the Netherlands; Gondar University Hospital, Ethiopia; Addis Ababa University, Ethiopia; Arba Minch Hospital, Ethiopia; Makerere University, Uganda; Amudat Hospital, Uganda; LEAP.

Following DND/clinical trials in East Africa which showed that sodium stibogluconate & paromomycin (SSG&PM) was as safe and effective as the existing standard treatment, WHO recommended the combination be used in the region. Treatment now lasts 17 days instead of 30 days with SSG monotherapy and costs less. More patients can be treated during outbreaks, and the regimen has the potential to fend off resistance and prolong the life of both drugs.

## New VL treatments – Asia

Main partners (since project start): INDIA: Indian Council of Medical Research; Rajendra Memorial Research Institute of Medical Sciences; Bihar State Health Society; National Vector Borne Disease Control Programme; Kala Azar Medical Research Centre; GVK Biosciences; BANGLADESH: Ministry of Health and Family Welfare; International Centre for Diarrhoeal Disease Research;

Existing treatment options for VL in South Asia caused severe side effects and were growing ineffective due to resistance. Research was needed to assess the safety and efficacy of and patient compliance to various new treatment options. The Phase III trial conducted in India in 2008-2010 demonstrated the efficacy of combination therapies based on AmBisome®, miltefosine, and paromomycin, and an additional study by Sundar et al. showed the efficacy of single-dose AmBisome® given as an intravenous infusion. To facilitate the introduction of these new treatments for VL in South Asia, DND/

conducted safety and effectiveness studies, including a pilot project in the Bihar State of India (2012-2015) implementing combination therapies at the primary healthcare level, and single-dose AmBisome® at the hospital level.

These regimens were observed to be safe and effective and, based on the study results, the Indian National Roadmap for Kala-Azar Elimination in August 2014 recommended use of single dose AmBisome® as a first option treatment for VL patients, with paromomycin and miltefosine as a second option; a policy also reflected in Bangladesh and Nepal. This removal of miltefosine monotherapy is an important policy change. The pilot study continued following up patients, documenting 12 month treatment outcomes, at the request of the national program; this follow up was completed in September 2015. Site close out activities were completed in January 2016.

In Bangladesh, a two-step Phase III study conducted from 2010-2014 in 602 patients (first in hospital settings, then in primary healthcare centres) used the same combination therapies as those tested in India. All tested treatments demonstrated excellent cure rates and were well tolerated by patients, in support of policy change in the country.



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