



# CUTANEOUS LEISHMANIASIS STRATEGY

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**DNDi**

Drugs for Neglected Diseases *initiative*

# CL Overall Objective

To achieve short, safe, non-invasive, efficacious, affordable and field-friendly treatments for CL or at least for lesions caused by *L. tropica* and *L. braziliensis*.

## Disease presentation

**Complicated Forms**  
(LR, DCL, PKDL)

**Non-ulcerated  
multiple, large lesions**

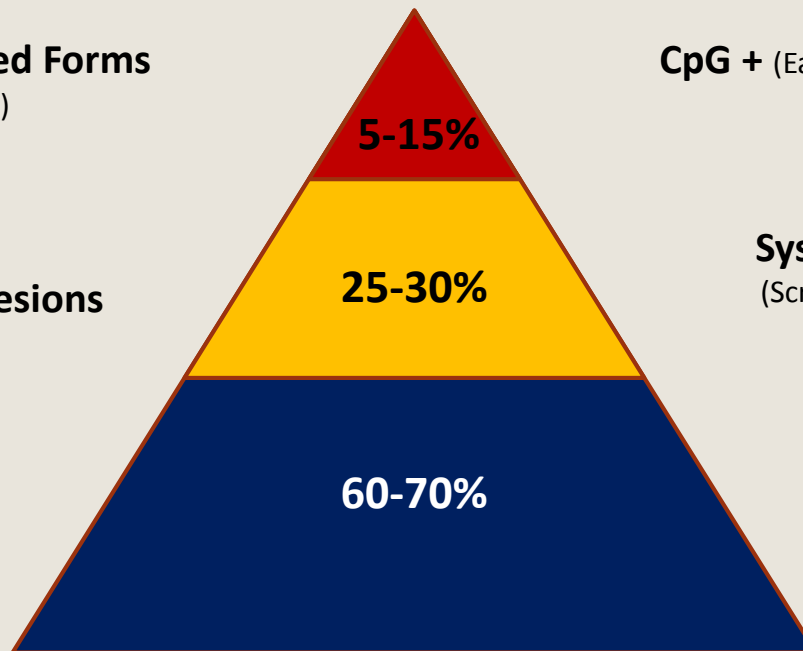
**1-3 ulcerated  
lesions, ≤ 4 cm**

## Activity / Project / Stage

**CpG +** (Early Pre-Clinical)

**Systemic Oral**  
(Screening Hit to Lead)

**Combination: TT + Mil**  
**Topical: Anfoleish**  
(Clinical)



# Update and 2016 plans

## Update

### **Anfoleish (Colombia)**

- Enrolment (80 subjects) completed by Nov 2015.
- PK study: Concentration of Amp B didn't reach any significant systemic exposure
- Overall, no safety issues. All subjects completed their treatment.
- D90 (Initial Cure) D180 (final cure) results available by the end of April and June 2016 respectively.

### **Combo (Peru & Colombia)**

- Protocol approved by SAC on Q3-2015 and by local EC on Dec 2015 in Peru and Jan 2016 in Colombia
- Contracts with study sites and CROs signed

## 2016 Plans

### **Anfoleish (Colombia)**

- If initial cure meets our TPP ( $\geq 65\%$  cure rate), a Go / No Go decision to continue with the development of Anfoleish will be take.
- If the decision is for No Go, then we need to look for options

### **Combo (Peru & Colombia)**

- Protocol amended on Jun 2016
- Approvals from regulatory authorities expected by Q3-2016. FPFV Sep 2016

# Update and 2016 plans

## Update

### **CpG D35 (CMC - Preclinical)**

- Agreements with different CROs for CMC-Tox studies signed
- Functional potency assays development ongoing.
- Production of 20 g lot of non-GMP CpG D35 completed.
- PBMC studies using samples from CL-PKDL patients on going

### **Oral Drugs (Screening – Lead Optimization)**

- Confirmatory *In vitro* / *In vivo* studies of several compounds against CL done at WRAIR.
- Two compounds nominated for PC development (active fro both VL and CL)
- Additional studies at LSTM&H

## 2016 Plans

### **CpG D35 (CMC - Preclinical)**

- Meeting of the AC on June 2016
- *In vivo* study (monkeys) to test the efficacy of the combination (CpG + Chemotherapy) will start on Aug 2016
- Studies to test stability\*, formulation development and clinical manufacture to ensure that meets quality requirements for GLP studies and GMP manufacturing completed by Q4-2016.

### **Oral Drugs (Screening – Lead Optimization)**

- Continue with PC development studies (Q2-2017)
- Continue with the screening of additional compounds.
- Waiting for additional data for D121.
- Explore other opportunities for development of topical formulations.

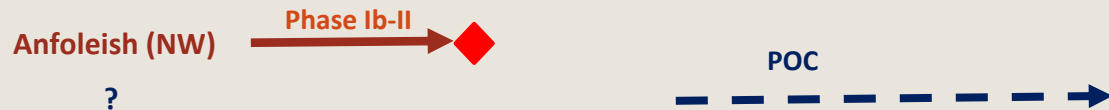
# 2016 Strategic Considerations

- A topical treatment continues to be the best treatment option for subjects with small lesions in size and number and for those who for any reason can't take a systemic treatment.
- CL in the OW continues to be a major and increasing problem. No good treatment options are available for infections due to *L. tropica* or *L. aethiopica*. Current pipeline / landscape for both topical and systemic treatments makes us believe that we need to wait 5 -10 years to have an alternative treatment.
- Identify and assess CL research groups in the Old World, mainly in Iran, Turkey and Morocco since currently they represent the best options to work on CL due to *L. tropica*.
- Continuing strengthening the development of RedLeish in LA and assess the feasibility of expand it to include CL researchers from the Old World.
- Support the development of activities to organize the 6WL

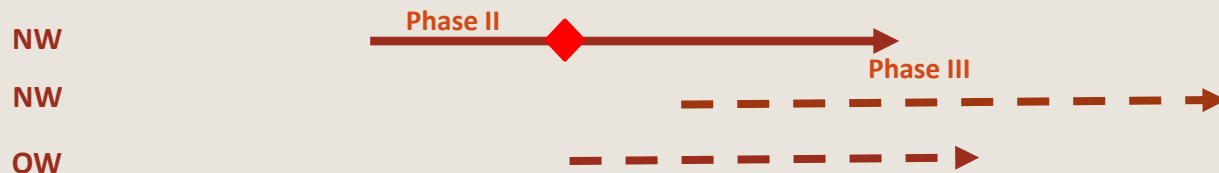
# CL Roadmap



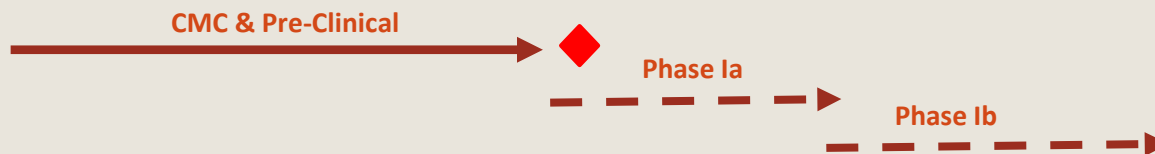
## TOPICAL



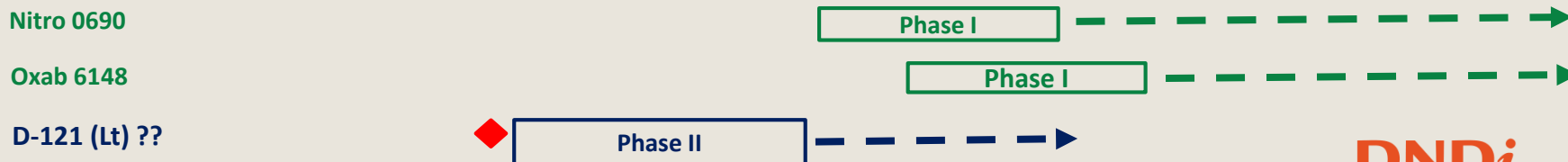
## COMBO



## CpG-D35



## Orals



◆ Go / No Go



# Thank You