CUTANEOUS LEISHMANNIASIS
STRATEGY

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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)
  - 5-15%

- **Non-ulcerated multiple, large lesions**
  - 25-30%

- **1-3 ulcerated lesions, ≤ 4 cm**
  - 60-70%

**Activity / Project / Stage**

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

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

- **Combination: TT + Mil**
  - **Topical: Anfoleish** (Clinical)
Update and 2016 plans

**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

**Anfoleish (Colombia)**
- If initial cure meets our TPP (≥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

**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 for both VL and CL)
- Additional studies at LSTM&H

**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
Thank You