



Partnering

along the path

to deliver

better treatments

for visceral leishmaniasis

Ongoing Studies on Improved Treatments

Tuesday, February 3, 2009 - Auditorium 1: 11.30-13.30

DNDi

Drugs for Neglected Diseases *initiative*

LEAP

Leishmaniasis East Africa Platform



Leishmaniasis East Africa Platform (LEAP)

Dr. Monique Wasunna

Kenya Medical Research Institute; DNDi Africa

4th World Congress on Leishmaniasis

February 3-7, 2009

Lucknow, *INDIA*

DNDi

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LEAP – Where We Started

- Formed in August 2003 in Khartoum, Sudan
- Facilitated by DNDi office based in KEMRI
- First task was to determine regional needs for VL
- Funded by DNDi

The LEAP Team

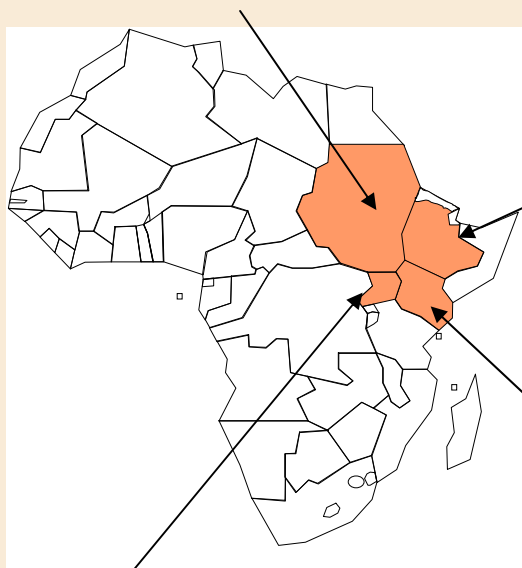


(Photo courtesy of Dr M Wasunna)

Leishmaniasis East Africa Platform (LEAP)

SUDAN: 3 sites (Kassab, Dooka, Um El Kher)

IED, Univ. of Khartoum
Federal Ministry of Health



ETHIOPIA: 2 sites (Gondar, Arba Minch)

Addis Ababa Univ.
Gondar Univ.
DACA
Ministry of Health



DNDi



MSF
IOWH -India
IDA
TDR
Industry partners

KENYA: 2 sites (Nairobi, Kimalel)

KEMRI
Ministry of Health

UGANDA: 1 site (Amudat)

- Makerere Univ.
- Ministry of Health

A group of scientists and institutions working on developing clinical trial capacity to bring new treatments to patients

LEAP Objectives



- Evaluate, validate and register improved treatment options for VL in East African region
 - Ethiopia, Kenya, Sudan and Uganda
- Strengthen capacity for treatment, evaluation and clinical research in the region

VL in East Africa

- Sudan
 - estimated annual incidence: 15 000 – 20 000 cases
 - PKDL occurs in up to 50% of VL patients
- Ethiopia
 - estimated annual incidence: 4 000 cases
 - VL is prevalent mostly in arid lowland areas
 - up to 40% of cases reported in Ethiopia are HIV co-infected
- Kenya
 - estimated annual incidence of 4 000 cases
 - prevalent in semi-arid, poor and remote districts where termite hills are colonized by the sandfly vector
- Uganda
 - up to 200 cases treated/yr. Some cases from Kenya

Impact of VL in Eastern Africa

- Mainly disease of children (over 60%)
- Malnutrition common
- Prevalent among the poor
- Population displacements have exacerbated the spread of the disease
- Population mortality of VL can be up to 36%
- Low economic and agricultural activity = poor social economic activity
- Scarce or non-existent treatment options



(Photo courtesy of Prof. A Hailu)

Determining Regional Needs - Leishmaniasis

- Current treatment concerns – safety, resistance, inconvenience
- VL varies by region and therefore may need more than one approach?

Opportunities: Leishmaniasis



- Pursue regional approach: Clinical trial network involving health and regulatory authorities
- Consensus to prioritise needs e.g. focused clinical trials
- Complete evaluation of SSG/PM/combination
- Need to evaluate combination therapy with AmBisome®
- Develop joint proposals

LEAP's Activities

- Determining unmet treatment needs
 - o Safe
 - o Efficacious
 - o Short course
 - o Affordable
 - o Registered
 - o Field adapted
- Testing new treatments for VL in East Africa
 - o Paromomycin clinical trial for registration
- Capacity strengthening
 - o Training
 - o Infrastructure

Achievements of LEAP

- LEAP 0104 Paromomycin multi-centre clinical trial & AmBisome® combination trial for Africa
- Strengthening clinical trial capacity in Ethiopia, Kenya, Sudan and Uganda
 - Personnel, e.g.
 - GCP/GLP training for investigators, nursing staff and laboratory technologists
 - Establishment and training of DSMB
 - Training of clinical trial monitors
 - Communications, e.g.
 - Regular communications – biannual meetings
 - Infrastructure, e.g.
 - Arba Minch in February 2006; Gondar in May 2008
 - Building of 2 research and treatment centres in Ethiopia

Gondar, Ethiopia – old ward



(Photo courtesy of S Ellis)

Gondar, Ethiopia – new ward inaugurated May 2008



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LEISHMANIASIS RESEARCH & TREATMENT CENTRE

Arba Minch, Ethiopia



DNDi

Drugs for Neglected Diseases initiative

(Photo courtesy of Dr C Royce)

LEAP

Leishmaniasis East Africa Platform

Kassab, Sudan



DNDi

Drugs for Neglected Diseases initiative

LEAP

Leishmaniasis East Africa Platform

Amudat, Uganda



Kimalel, Kenya



Advantages of LEAP Platform

- Strengthened clinical research capacities
- No duplication of effort – time taken to get meaningful results minimised
- Registration of much needed, newer VL drugs in all member countries
- Sourcing of research funds easier
- Owned by members (hence, trusted by community)
 - Governments will readily give support because they are members of LEAP
- Translating research results into policy

Challenges

- Communication
- Different languages
- Poor infrastructure
- Different regulatory environments
- Importation of trial equipment and drugs
- Climate & logistics
- Funding



Moving Forward...

- Complete ongoing study in 2009
- Begin dose-finding study to determine optimal single dose of AmBisome® for use in combination
- Begin Phase II study evaluating combinations
 - SSG plus single dose AmBisome®
 - Miltefosine plus single-dose AmBisome®
 - Miltefosine alone

Concluding Remarks

- Solid gains have been made
- Clinical research capacity strengthened
- Regional partnership: LEAP a success story
- Many patient needs still unmet

Acknowledgements

- LEAP members
- Patients and communities
- Research teams
- Ministries of Health, regulatory authorities, cooperating institutes
- Donors
- DND*i*

Asante Sana



What's Next?

- Paromomycin
 - Complete ongoing study in 2009
 - recruiting: Ethiopia, Kenya, Sudan, Uganda
 - What's the proper use?
- Continue research for new treatment combinations across region
 - AmBisome® dose-finding
 - Phase II combo: AmBisome®, SSG, miltefosine

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