Technologies : Rapid Diagnostic test for detection of Visceral Leishmaniasis (Kala-azar)
: Novel Liposomal Amphotericin B for Treatment of Kala-azar and fungal infections

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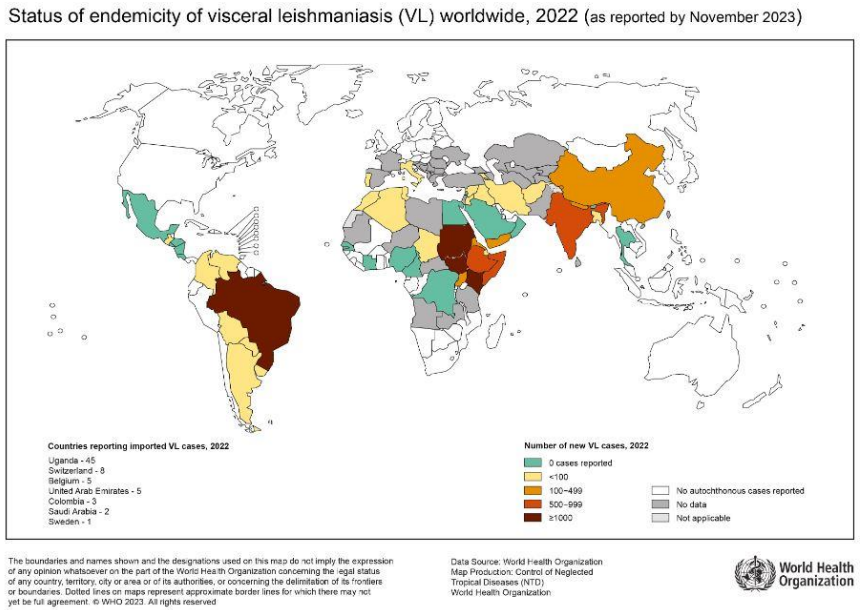
Visceral Leishmaniasis Life-threatening neglected tropical disease

Global Scenario



- 50,000 to 90,000 new cases of VL occur worldwide annually
- 90% cases occur in the Indian Subcontinent, Latin America and East Africa.
- The global leishmaniasis treatment market was valued at $97.9 million in 2022 and is projected to reach $135.8 million by 2029

Parasite

- *Leishmania donovani*
- *Leishmania infantum* (*syn. Leishmania chagasi)*

Vector: Sand fly

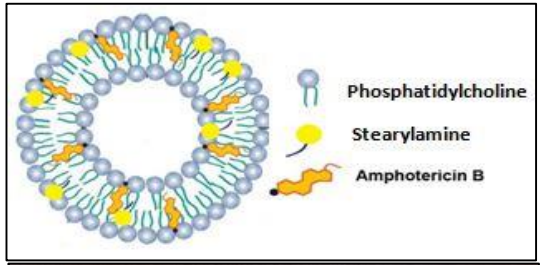
- *Phlebotomus argentipes (old world)*
- *Lutzomyia longipalpis (new world)*

Symptoms

- Fever
- Skin blackening
- Hepato-splenomegaly
- Anemia
- Weight loss
- Immuno-suppression

Prototype by IICB

Liposomal Formulation by IICB



Rapid Diagnostic test for detection of Visceral Leishmaniasis (Kala-azar) from Serum and Urine samples

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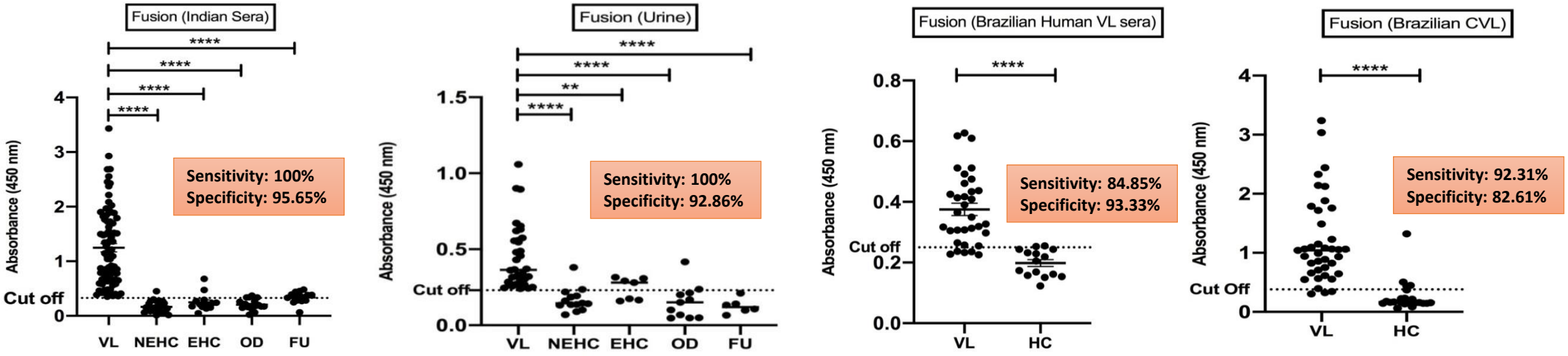
- A novel fusion antigen of leishmanial proteins for diagnosis of visceral leishmaniasis
- Validation against 150 Indian and 80 Brazilian patients and 60 canine serum samples shows 100% sensitivity.
- Validation against Indian 72 urine samples with 100% sensitivity.
- 100% non-reactive with post-treatment follow-up urine samples whereas commercially available rK39 shows 86% cross reaction.
- Lateral Flow Test prototype developed.
- Cost of Sampling: Less than 1 USD/Sample, Patent filed (PCT/IN2024/050371)

Sensitivity and Specificity Fusion Antigen:



Novel Liposomal Amphotericin B (Cat-LAmB) for Treatment of Visceral Leishmaniasis and fungal infections

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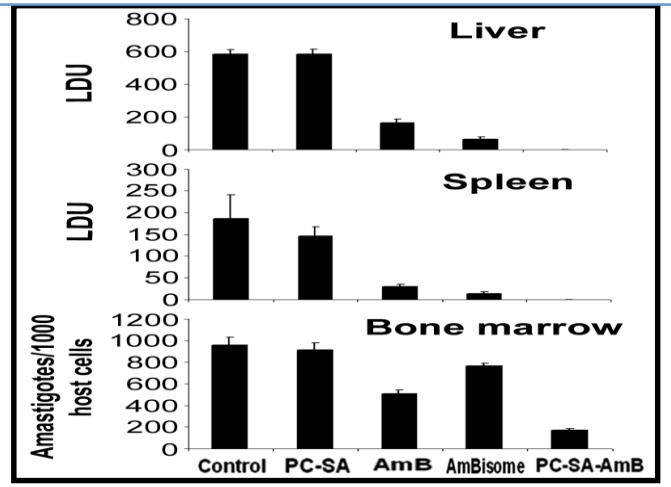
- A novel Amphotericin B formulation in cationic liposome (Cat-LAmB) that can completely cure experimental VL and candidasis in a single dose treatment. In-vitro MIC Assay with Cat-LAmB demonstrates better anti-fungal activity against human systemic fungal infections such as aspergillosis, candidasis, mucormycosis, etc compared to AmB Deoxycolate and AmBisome**.**
- **Competitive Advantage:** The single shot treatment with Cat-LAmB offers enhanced efficacy, reduced toxicity, and improved pharmacokinetics compared to conventional anti-leishmanial and antifungal therapies such as amphotericin B deoxycholate, AmBisome and Fungisome.
- The estimated cost of single dose therapy will be 45000 INR for leishmaniaisis and 70000 INR for fungal infections per person reducing the cost to 1/3rd of existing costs.
- **Stage of Development:** At TRL-6 , Lyophilisation of the formulation has been successfully done.
- Next steps: To carry out preclinical toxicity tests and repeat efficacy of the lyophilised formulation in animal studies to move to clinical trials to bring the product to the market.
- Patent granted in India. **PATENT NO. 264798**

Complete cure is induced by Cat-LAmB treatment in spleen and liver of established *L. donovani* infection in BALB/c mice



In vivo evaluation of Cat-LAmB against *Candida albicans* in BALB/c mice

Name of the group/ sample	Average C.F.U./gm kidney tissue
Positive Control (infection only)	2.1×10^7
Infection + Cationic Liposome	2.9×10^7
Infection + Cat-LAmB	No c.f.u. was observed
AmB Deoxycolate	1.1×10^3
AmBisome	8.3×10^2

All these studies were carried out in collaboration with Dr. P.K. Shukla, Microbiology division, CSIR-CDRI, Lucknow