



iCo Therapeutics Inc (TSX-V: 'ICO')
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**iCo-009 is an oral formulation of Amphotericin B (AmpB).
No Oral Formulations Are Currently Commercially Available**

What is Amphotericin B?

- A broad spectrum, gold standard systemic anti-fungal & anti-parasitic drug
- 50+ years of clinical history
- Fungicidal, not fungistatic
- Does not interfere with liver enzymes (Cytochrome P450)
- Low pathogen resistance
- Available in 4 non-oral (intravenous “IV”) formulations with limitations
 - IV-related side effects
 - Potentially fatal kidney toxicity
 - Patients dependent on infusion
 - Latest, least toxic version is called “AmBisome®”

Why is Oral Drug Delivery of AmpB so important?

- Current AmpB formulations are only available via IV: limits use, IV-related side effects, potential for fatal kidney toxicity & requires 7-14 days in hospital
- Oral formulation could reduce hospital stays & toxicity, increase accessibility, & create additional markets
- AmpB use currently limited to severe fungal infections – with improved toxicity profile, more indications are possible (see potential indications below)

What are iCo-009’s advantages?

- Shorter path to approval (505(b)(2) strategy), lower cost for clinical development
- Potential for premium pricing
- iCo is the sole licensee of the technology developed at the University of British Columbia
- Represents new drug delivery technology: converting IV administered drugs to oral

Preclinical Results to Date

- iCo-009 has been tested against all commercial formulations of AmpB
- iCo-009 results in blood levels that are comparable to known IV AmpB products
- Dosing in models of Visceral Leishmaniasis (VL - a parasitic infection) resulted in greater than 99% parasite eradication- comparable to results seen with AmBisome®
- iCo has seen dramatic preclinical anti-fungal & anti-parasitic activity upon oral administration, with no observable toxicity traditionally associated with IV AmpB

Markets

- iCo-009 targets a large and growing market: incidence of serious systemic fungal infection has risen > 100% over the past 20 years. (Center for Disease Control)
- IV AmpB market currently \$300 M → iCo-009's market \$1B +

Potential Targeted Indications

- Preventative use in immunocompromised patients: febrile neutropenia after cancer treatment, diabetes, organ transplant, HIV/AIDS
- Step-down therapy in severe fungal infections after initial treatment with IV agents
- Orphan indications: Blastomycosis & Histoplasmosis
- Topical indications, ocular (keratitis, uveitis), dermatological (skin/nail fungal infections) and GI (esophageal candidiasis)
- Visceral Leishmaniasis (parasitic infection)

AmBisome IV is approved for empirical therapy for presumed fungal infections in:

- Febrile, neutropenic patients
- Patients with *Aspergillus*, *Candida* & *Cryptococcus* species refractory to conventional AmpB
- Patients with marked renal impairment or when severe toxicity precludes the use of conventional AmpB
- Visceral Leishmaniasis

What is iCo-009's clinical plan?

- iCo plans to use 505(b)(2) FDA strategy by building on AmpB's 50+ year history
- Potential to pursue Orphan Drug designation

2008: Exercised option

Pre-IND meeting held with FDA

Finalized formulation

Encouraging preclinical results seen in 2 fungal models

Dramatic results seen in 1 VL model

2009: Continued animal work

Preparations for Phase I trials

Efforts to obtain non-dilutive funding