

# iCo Therapeutics Announces Ethics Approval for its Oral Amphotericin B Phase 1 Clinical Study

**November 22, 2017, Vancouver, Canada** — iCo Therapeutics Inc. ("iCo" or "the Company") (TSX-V: ICO) (OTCQB: ICOTF), and its recently formed subsidiary iCo Therapeutics Australia Pty Ltd., today announced that it has been granted ethics approval in Australia to conduct its proposed Phase 1 clinical study for Oral Amphotericin B. Amphotericin B is a well-known approved drug for the treatment of fungal and parasitic infections but the therapy is currently limited by intravenous infusion. iCo Therapeutics is developing a proprietary oral reformulation of Amphotericin B.

"Entry into the first clinical trial for the Company's Oral Amphotericin B candidate is a major corporate milestone for iCo Therapeutics" stated Andrew Rae, President and CEO of iCo Therapeutics Inc. "We currently look forward to study results from this Phase 1 trial in the first half of 2018."

Stated Dr. Kishor Wasan, Professor and Dean, College of Pharmacy and Nutrition, University of Saskatchewan, Adjunct Professor Faculty of Pharmaceutical Sciences, University of British Columbia and co-inventor, "this a major milestone for the Oral Amphotericin B technology and our research team. We are grateful to iCo Therapeutics for their support throughout multiple years of pre-clinical development and driving this technology to the clinic."

#### **About the Phase 1 Clinical Trial**

This is a randomized, double-masked, placebo-controlled, single dose ascending study to assess the safety, tolerability, and bioavailability of iCo-019 (Oral Amphotericin B) in healthy male and non-pregnant female subjects between 18-55 years of age. Subjects will be randomized into one of 4 cohorts, each representing an ascending single dose of treatment. Cohorts will be dosed sequentially. Each cohort will consist of eight (8) subjects where six (6) subjects will be randomized to receive the Investigational Product (IP) and two (2) subjects will be randomized to receive the Placebo. All subjects will be followed for 7 days after dosing.

The trial will be registered with the TGA in Australia via the Clinical Trial Notification process and involves Linear Clinical Research in Perth, Australia, partnered with global contract research organization (CRO) INC Research/inVentiv Health.

Results from the Phase 1 study are currently expected in Q2 2018.

## **About iCo Therapeutics**

iCo Therapeutics identifies existing development stage assets for use in underserved ocular and infectious diseases. Such assets may exhibit utility in non-ophthalmic conditions outside the Company's core focus areas and if so the Company will seek to capture further value via partnerships, such as its partnership with Immune Pharmaceuticals (NASDAQ: IMNP), which is in several Phase 2 studies involving iCo-008. iCo shares trade on the TSX Venture Exchange under the symbol "ICO" and on the OTCQB under the symbol "ICOTF".

For more information, visit the Company website at: www.icotherapeutics.com.

No regulatory authority has approved or disapproved the content of this press release. Neither the TSX Venture Exchange nor its Regulatory Services Provider (as that term is defined in the policies of the TSX Venture Exchange) accepts responsibility for the adequacy or accuracy of this press release.

### **Forward-Looking Statements**

Certain statements included in this press release may be considered "forward-looking information" within the meaning of applicable securities laws. Forward-looking information can be identified by words such as: "anticipate", "intend", "plan", "goal", "seek," "believe," "project," "estimate," "expect," "strategy," "future," "likely," "may," "should," "will" and similar references to future periods. Such statements involve known and unknown risks, uncertainties and other factors that may cause actual results, performance or achievements to be materially different from those implied by such statements, and therefore these statements should not be read as guarantees of future performance or results. All forward-looking statements are based on iCo's current beliefs as well as assumptions made by and information currently available to iCo and relate to, among other things, anticipated financial performance, business prospects, strategies, regulatory developments, market acceptance and future commitments. Readers are cautioned not to place undue reliance on these forward-looking statements, which are based only on information currently available to iCo and speak only as of the date of this press release. Due to risks and uncertainties, including the risks and uncertainties identified by iCo in its public securities filings and on its website, actual events may differ materially from current expectations. iCo disclaims any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

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