iCo Therapeutics Announces Positive Oral Amphotericin Study

Vancouver, British Columbia--(Newsfile Corp. - June 12, 2017) - iCo Therapeutics (TSXV: ICO) (OTCQB: ICOTF) ("iCo" or "the Company"), today reported the successful conclusion of pre-clinical studies involving its lead oral Amphotericin B candidate, including compelling safety data from its pivotal 14 day GLP (Good Laboratory Practices compliant) toxicology study.

- Data from its IND enabling 14 day GLP study conducted in Toronto, Ontario facilities revealed that oral administration of Amphotericin B at a dose levels of up to 600 mg/ day once daily for 14 days, was well tolerated with no toxicologically significant histological findings (n=38 subjects)
- Data from a 7 day dose range finding study revealed no toxicities of oral Amphotericin B up to 1000mg/day and a previous bridging study showed oral bioavailability of amphotericin B from iCo-010 and iCo-019 and iCo-022 were similar with no significant differences noted between the formulation groups
- iCo is positioned to dose human subjects in a Phase 1 study in Q4 2017
- Positive 9 month stability data for lead candidate has recently been generated by the Company's contract manufacturer in Montreal, Canada
- iCo is currently soliciting requests for proposals from Australian contract research organizations, with vendor selection anticipated shortly to engage a party to run the Company's Phase 1 clinical trial. [Australia currently offers generous refundable tax credits which significantly lower overall costs for Phase 1]
- Multiple partnering discussions continue with Chinese, European, North American and Indian biopharmaceutical firms involved in due diligence under non-disclosure agreements

Stated Company CEO Andrew Rae, "given our significant leveraging of grant money we now are at the cusp of early human studies with our oral Amphotericin B candidate. Amphotericin B is an approved and highly effective anti-fungal agent and therefore our mission is not to prove the value of the drug itself, but instead the efficacy of an oral delivery system."

Professor and Dean Dr. Kishor M. Wasan from the University of Saskatchewan College of Pharmacy and Nutrition and Adjunct Distinguished Scholar Professor at UBC Pharmaceutical Sciences, co-inventor of the oral Amphotericin B technology, stated "these very positive results confirm the ability to delivery amphotericin B orally and in high enough tissue concentrations to elicit biological activity without significant toxicity. This is a major milestone for our technology as we look forward to the phase I clinical trials".

Positive Bridging Study Involving iCo-010 and Optimized Formulations

This study was designed to determine the pharmacokinetics of 100 mg of amphotericin B following a single oral dose of iCo-010 and also iCo-019 and iCo-022, two additional optimized oral formulations of amphotericin B. Tissue distribution of amphotericin B 24 hours following three days of single oral dose per day dosing of optimized formulations of amphotericin B in study subjects was also examined. The oral bioavailability of amphotericin B from iCo-010 and iCo-019 and iCo-022 were similar with no significant differences noted between the formulation groups for C_{max}, T_{max} and $AUC_{0\text{-}Tlast}$. The lack of a significant difference between the pharmacokinetic parameters for the three formulations suggest that each is capable of delivering similar levels of amphotericin B into the plasma. The levels observed in some of the tissues in this study were similar to range of tissue concentrations of amphotericin B, observed seven days following oral dosing in mice, tissue concentrations that were effective in producing a 69-96% reduction of fungal burden in a mouse model of systemic candidiasis (Source: Ibrahim, F, Sivak, O., Wasan, E.K., Bartlett, K. and Wasan, K.M. "Efficacy of an Oral and Tropically Stable Lipid-Based Formulation of Amphotericin B (iCo-010) in an Experimental Mouse Model of Systemic Candidiasis" Lipids in Health and Disease 12:158-163, 2013).

Positive Seven Day Dose Ranging Study

In a 7-day dose range finding study with our lead candidate (iCo-019), analysis of all generated data, including clinical observations, body weights, food consumption, clinical pathology, gross necropsy, organ weights and histopathology (kidneys and liver), revealed no test item-related toxicity in subjects that were treated orally with Amphotericin B twice a day, 12 hours apart at daily dose levels of up to 1000 mg/day.

Positive Fourteen Day GLP Toxicology Study

This pre-clinical study assessed the toxicity and toxicokinetics of Amphotericin B, when administered orally to subjects daily for a 14-day period. This study also assessed the progression or regression of any effects following a 14-day treatment-free recovery period in animals of the vehicle control and high dose groups. The 14 day GLP toxicology study revealed that oral administration of Amphotericin B (iCo-019), at a dose levels of up to 600 mg/ day once daily for 14 days, was well tolerated by male and female subjects with no toxicologically significant histological findings (n=38 subjects). There were no findings observed upon gross necropsy at the end of the treatment or recovery periods. The usage of oral formulation avoids infusion-related side effects associated with intravenous application of Amphotericin B.

Australian Phase 1 Clinical Study Targeted for Q4

Regarding an anticipated Phase 1 clinical trial, iCo is currently expecting an early study to occur in Australia. The Company is currently evaluating proposals from multiple contract research organizations in Australia where benefits may include a rate of up

to 43.5% in refundable tax credits for pre-clinical and clinical work conducted in the country, potential for expedited approvals via investigational review boards (IRBs) and overall lower regulatory costs.

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 statements" within the meaning of applicable securities laws. Forward-looking statements 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 newinformation, future events or otherwise, except as required by law.

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