

# TRYP THERAPEUTICS SUBMITS INVESTIGATIONAL NEW DRUG (IND) APPLICATION TO US FDA FOR PLANNED PHASE 2a CLINICAL TRIAL IN PATIENTS WITH IBS AT MASSACHUSETTS GENERAL HOSPITAL

Kelowna Canada, (May, 24 2023) -- <u>Tryp Therapeutics, Inc.</u> (CSE: TRYP) (OTCQB: TRYPF) ("Tryp" or the "Company"), a clinical-stage biotechnology company focused on developing intravenous-infused psilocin (the active metabolite of psilocybin) for diseases with high unmet medical needs, today announced it has submitted an Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA) for its planned Phase 2a clinical trial investigating the effects of psilocybin-assisted psychotherapy in the treatment of patients aged 21+ suffering from Irritable Bowel Syndrome (IBS) at Massachusetts General Hospital (MGH).

The planned open label study in collaboration with Harvard Medical School/Massachusetts General Hospital will evaluate the effect of psilocybin-assisted psychotherapy in patients with treatment-resistant IBS who experience chronic abdominal pain and other debilitating gastrointestinal symptoms. Many of these patients also suffer from fibromyalgia, anxiety and fatigue. The primary efficacy endpoint of the study will be improvement in abdominal pain. The proposed study will also explore changes in brain connectivity and responses to pain at baseline and at four weeks, six months and twelve months post the psychedelic drug sessions, along with numerous other secondary endpoints.

In recognition of this important development, Jim Gilligan, PhD, Chief Executive Officer of Tryp Therapeutics, said, "Tryp and our collaborators at Harvard/MGH believe there is tremendous potential for the treatment of debilitating IBS symptoms by utilizing the combined administration of psilocybin and psychotherapy. The clinical study will examine how psilocybin-assisted psychotherapy may alter brain networks involved in chronic abdominal pain and gastrointestinal-specific anxiety in patients with IBS to improve their symptoms. Submission of IND 163994 is an important step in advancing our program."

### **About Tryp Therapeutics**

Tryp Therapeutics is a clinical-stage biotechnology company focused on developing proprietary, novel formulations for the administration of psilocin in combination with psychotherapy to treat diseases with unmet medical needs. Tryp's lead program, TRP-8803, is a proprietary formulation of IV-infused psilocin (the active metabolite of psilocybin) that alleviates numerous shortcomings of oral psilocybin including: significantly reducing the time to onset of the psychedelic state, controlling the depth and duration of the psychedelic experience, and reducing the overall duration of the intervention to a commercially feasible timeframe. The Company has an ongoing Phase 2a clinical trial for the treatment of Binge Eating Disorder at the University of Florida, an upcoming Phase 2a clinical trial with the University of Michigan for the treatment of fibromyalgia and a planned Phase 2a trial for the treatment of irritable bowel syndrome at Mass General Hospital, all of which are utilizing TRP-8802 (synthetic, oral psilocybin) to demonstrate efficacy in these indications. Where a preliminary clinical benefit has been demonstrated, subsequent studies are expected to utilize TRP-8803 (IV-infused psilocin) which has the potential to further improve efficacy, safety and patient experience. For more information, please visit <a href="www.tryptherapeutics.com">www.tryptherapeutics.com</a>.

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## **Forward-Looking Information**

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Forward-looking information is necessarily based on a number of opinions, assumptions and estimates that, while considered reasonable by Tryp as of the date of this news release, are subject to known and unknown risks, uncertainties, assumptions and other factors that may cause the actual results, level of activity, performance or achievements to be materially different from those expressed or implied by such forward-looking information, including but not limited to the factors described in greater detail in the "Risk Factors" section of Tryp's final prospectus available at <a href="https://www.sedar.com">www.sedar.com</a>. These factors are not intended to represent a complete list of the factors that could affect Tryp; however, these factors should be considered carefully. There can be no assurance that such estimates and assumptions will prove to be correct. The forward-looking statements contained in this news release are made as of the date of this news release, and Tryp expressly disclaims any obligation to update or alter statements containing any forward-looking information, or the factors or assumptions underlying them, whether as a result of new information, future events or otherwise, except as required by law.

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