

Patient recruitment for world first trial for treatment of Binge Eating Disorder using TRP-8803 commences

- Recruitment for open-label study to assess safety, efficacy and feasibility of TRP-8803 (IV-infused psilocin), when administered with psychotherapy in adults with Binge Eating Disorder (BED)
- 12 patients to be recruited and administered TRP-8803 in two doses, 14 days apart
- Multiple in-bound enquiries received by Swinburne University – Patient screening to commence imminently
- First dosing to take place this quarter with top-line results expected Q4 CY2025
- BED is the most common eating disorder in the US and second most prevalent in Australia – comorbidities include depression, anxiety, PTSD and compulsive behaviours

Melbourne, Australia – Tryptamine Therapeutics Limited ('Tryp', 'TYP' or the 'Company') (ASX: TYP), a clinical-stage biotechnology company, is pleased to advise patient recruitment in the Company's world-first clinical trial to treat Binge Eating Disorder (BED) using TRP-8803 alongside Swinburne University has commenced.

This milestone follows execution of a Clinical Trial Research Agreement with Swinburne University to assess the safety, feasibility and efficacy of TRP-8803, when administered with psychotherapy for adult patients with BED (refer ASX announcement: 10 April 2025).

The trial will recruit 12 patients suffering from BED, in two-six person cohorts. Each cohort will be administered two doses of TRP-8803, 14 days apart in a monitored setting and following preparatory psychotherapy and integration. Cohort 1 will receive a mid-range dose, while the second cohort will be administered a high-range dose.

Recruitment commencement initiatives follow completion of a number of key activities, including governance approval, submission of relevant permits, completion of patient cohort protocols, staff recruitment, finalisation of patient-centric collateral and scheduling TRP-8803 product manufacturing for the clinical study.

Swinburne University has advised that it has received a number of in-bound enquiries from potential trial participants and prospective patient screening is expected to commence shortly. Interested parties are encouraged to contact bed-iv@swin.edu.au for further information regarding potential participation in the study.

First dosing is expected to occur this quarter, with high level results anticipated during Q4 CY2025. Success in the trial has the potential to unlock a considerably large market for Tryp, as BED is the most common eating disorder in the US and second most prevalent in Australia. It's commonly associated with both obesity and potentially severe psychiatric comorbidities including anxiety, depression, post traumatic stress disorder, and obsessive-compulsive disorders. Based on clinical precedents and relevant neuropharmacology findings, psilocin has been shown to be a potentially effective treatment solution for BED.

Management commentary:

Tryp Chief Executive Officer, Jason Carroll, said: "Commencement of patient recruitment marks a major milestone in Tryp's pursuit of this world first clinical trial opportunity. It follows a considerable level of work undertaken with



Swinburne to finalise the clinical trial requirements, which has laid a very strong foundation for the initiative.”

“To date, Swinburne has received considerable in-bound interest from a number of potential participants. This highlights the sheer prevalence of BED in Australia, the need for new treatment options as well as Tryp’s opportunity to provide a potential treatment for this widespread condition. We expect patient screening to commence imminently allowing for first patient dosing this quarter. I look forward to providing additional updates on enrolment and dosing in the coming weeks.”

This announcement has been authorised for release by the Board of Tryptamine Therapeutics Limited.

-ENDS-

About Tryptamine Therapeutics Limited

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) with potential to alleviate 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 completed a Phase 2a clinical trial for the treatment of binge eating disorder at the University of Florida, which demonstrated an average reduction in binge eating episodes of greater than 80%.

The Company also has also completed a Phase 2a clinical trial for the treatment of fibromyalgia in collaboration with the University of Michigan and has initiated a Phase 2a clinical trial in collaboration with Massachusetts General Hospital for the treatment of abdominal pain and visceral tenderness in patients suffering from irritable bowel syndrome.

Each of the studies is utilising TRP-8802 (synthetic, oral psilocybin) to demonstrate clinical benefit in these indications. Where a positive clinical response is demonstrated, subsequent studies are expected to utilise TRP-8803 (IV-infused psilocin), that has the potential to further improve efficacy, safety, and patient experience.

For more information, please visit www.tryptherapeutics.com.

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Risks associated with Psilocin

All medicines carry risks and specialist prescribers, such as registered psychiatrists are best placed to assess the suitability of a new medication against a patient’s individual circumstances and medical history before proceeding. Adverse effects of psilocybin and similar compounds, such as psilocin, can include temporary increase in blood pressure and a raised heart rate. There may be some risk of psychosis in predisposed individuals. These effects of psilocybin and its derivatives are unlikely at low doses and in the treatment regimens used in psychedelic-assisted psychotherapy and appropriately managed in a controlled environment with direct medical supervision.

Forward-Looking Information

Certain information in this news release, constitutes forward looking information. In some cases, but not necessarily in all cases, forward-looking information can be identified by the use of forward-looking terminology such as "plans", "targets", "expects" or "does not expect", "is expected", "an opportunity exists", "is positioned", "estimates", "intends", "assumes", "anticipates" or "does not anticipate" or "believes", or variations of such words and phrases or state that certain actions, events or results "may", "could", "would", "might", "will" or "will be taken", "occur" or "be achieved". In addition, any statements that refer to expectations, projections or other characterizations of future events or circumstances contain forward-looking information. Statements containing forward-looking information are not historical facts but instead represent management's expectations, estimates and projections regarding future events. 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 Replacement Prospectus available at www.asx.com.au. 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.