ASX Release **23 June 2025**

World first trial for Binge Eating Disorder treatment using TRP-8803 receives human ethics approval

- **Ethics approval received from the Swinburne University Human Research Ethics Committee to initiate an open-label study to assess the safety and efficacy of TRP-8803 (IV-infused psilocin), when administered with psychotherapy in adult patients with Binge Eating Disorder (BED)**
- **12 patients to be dosed with TRP-8803, administered in two doses, 14 days apart**
- **Patient recruitment currently underway with first dosing anticipated in Q3 CY25 and top-level results from Cohort 1 expected in Q4 CY25**
- **BED is the most common eating disorder in the US and second most common in Australia with significant unmet clinical need and market potential**
- **Adults with BED often suffer multiple other conditions including depression, anxiety, PTSD and compulsive behaviours – Data expected to provide Tryp with indication of TRP-8803's utility on BED comorbidities**

Melbourne, Australia – Tryptamine Therapeutics Limited ('**Tryp**' or the '**Company**') (**ASX: TYP**), a clinical-stage biopharmaceutical company focused on the development of TRP-8803 (a proprietary psilocin-based, IV-infused formulation with neuroplastic benefits), is pleased to advise it has received formal approval from the Swinburne University Human Research Ethics Committee (SUHREC) to initiate a world first clinical trial in collaboration with Swinburne University to assess the safety, efficacy and dosing flexibility of TRP-8803, when administered in concert with psychotherapy for adult patients with Binge Eating Disorder (BED).

The open-label trial will dose 12 participants suffering from BED in two patient cohorts. Each cohort will be administered two doses of TRP-8803, 14 days apart in a monitored setting. Both patient cohorts will receive Tryp's target therapeutic dose level with Cohort 1 dosed over 140 minutes and Cohort 2 patients dosed over 60 minutes. TRP-8803 will be administered to patients following preparatory psychotherapy and integration initiatives.

The trial's primary objective is to assess the safety and efficacy of two doses of TRP-8803 in BED patients and throughout follow up during the 12-weeks following the second dose. Secondary and exploratory objectives include evaluating the ability of TRP-8803 to induce a psychedelic state and effects of the frequency of binge-eating episodes and other weight-related indicators over four and 12 weeks from second dosing.

The Company is pursuing BED as it is the most common eating disorder in the US and the second most common in Australia. The condition is associated with both obesity and neuropsychiatric comorbidities, with sufferers often experiencing anxiety, depression, PTSD, as well as impulsive and compulsive behaviours.

This trial will provide valuable insight into the potential for TRP-8803 as an effective treatment for BED, while exploring its utility in other neuropsychiatric indications to be investigated in future clinical trials.

The trial follows positive interim data from the Company's study in collaboration with the University of Florida for the application of oral TRP-8802 (oral psilocybin) which demonstrated >80% improvement in patient Binge Eating scores.

Swinburne University has now initiated patient recruitment. Tryp expects first cohort dosing during Q3 CY25 and top-line results in Q4 CY25.

Management commentary:

Chief Executive Officer, Mr Jason Carroll said: *"While Binge Eating Disorder is not widely publicised, it is incredibly widespread with many sufferers also experiencing a range of other neuropsychiatric conditions including anxiety, depression and PTSD amongst others. While the primary objective of this world first trial is to assess TRP-8803's utility in Binge Eating Disorder, it will also provide valuable insight into how TRP-8803 may help with other neuropsychiatric disorders, in line with the Company's goal of delivering treatments to large, unmet conditions.*

With patient recruitment initiatives now underway, we look forward to first enrolment and the commencement of baseline data generation from participants, prior to first patient dosing.

We look forward to providing additional updates on our work with Swinburne over the coming weeks."

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

-ENDS-

Frequently Asked Questions

What is Binge Eating Disorder?

Binge Eating Disorder (BED) is when a person eats a large amount of food in a short amount of time and feels they cannot control what or how much they are eating.

How common is BED?

BED is the most common eating disorder in the United States and the second most prevalent in Australia. It affects people of all racial and ethnic groups. In the US, approximately 1.25% of adults experience BED each year, with women affected at twice the rate of men. Lifetime prevalence is estimated at around 2.8% of adults, equating to ~7.3 million Americans who have experienced BED at some point in their lives.

About 1.6% of teens age 13 to 18 years old are affected. A much larger percentage of teens and adults have episodes of binge eating or loss-of-control eating — which is the feeling that you cannot control your eating, regardless of how much food you eat — but at a rate that is not frequent enough to meet the criteria for binge eating disorder.

The average age at which binge eating disorder first occurs is 25 years. Nearly two-thirds of people who meet the criteria for binge eating disorder experience binge eating episodes over the span of one year or longer.

What other conditions do people with BED suffer?

BED is associated with both obesity and psychiatric comorbidities, that include anxiety, depression, post traumatic stress disorder (PTSD), as well as impulsive and compulsive disorders.

Over half of people with binge eating disorder report it caused them problems in social functioning, for example, it interferes with their normal daily activities and personal relationships.

What is TRP-8803?

TRP-8803 is the Company's lead asset. It is an innovative and scalable psilocin-based IV-infusion formulation with potential neuroplastic benefits. Neuroplasticity is the ability of neural networks in the brain to change through

growth and reorganisation. Treatments which improve neuroplasticity are known to cause adaptive structural and functional changes within the brain.

TRP-8803 offers multiple potential benefits over oral psilocybin, including a faster time to onset with more precise control of the depth and duration of the psychedelic state, while also offering significant overall reductions in the duration of treatment to a commercially feasible timeframe.

Importantly, TRP-8803's major advantage is safety with inherent reversibility, allowing for treatment to be halted quickly if patients experience adverse events. This critical safety benefit cannot be achieved using oral dosing.

Has the Company undertaken any clinical initiatives in BED previously?

Tryp has completed a Phase 2a study in collaboration with the University of Florida for the application of TRP-8802 (oral psilocybin), which showed a mean reduction of >80% in patient Binge Eating Scores.

What does this trial seek to explore?

The primary endpoint of this trial is to assess the safety of TRP-8803 across two doses in BED patients and throughout follow up during the 12-week period following the second dose.

Secondary and exploratory objectives include evaluating the ability of inducing the psychedelic state with TRP-8803 in a BED population and determining clinical activity and the effects of TRP-8803 on the frequency of binge-eating episodes and other weight-related indicators in a BED population, over four and 12 weeks from second dosing.

The Company will also evaluate data associated with other conditions, which the BED population may suffer from.

Who are Swinburne University?

Swinburne University is a world-class institution known for its commitment to innovation, industry engagement, and research. With a strong focus on real-world impact, Swinburne delivers cutting-edge education and fosters ground-breaking discoveries across a range of disciplines.

What are the next steps for the trial?

The next step is full patient recruitment and collection of 4 weeks of patient baseline data prior to administering the first TRP-8803 doses.

When can results be expected?

The Company is expecting to be able to report high level results during Q4 CY25.

About Tryptamine Therapeutics Limited:

Tryp Therapeutics is a clinical-stage biopharmaceutical 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 asset, TRP8803, is a proprietary, scalable and innovative formulation of IV-infused psilocin (the active metabolite of psilocybin) with neuroplastic benefits. It has the potential to alleviate numerous shortcomings of oral psilocybin including: significantly reducing the time to onset of the neuroplastic state, controlling the depth and duration of the neuroplastic 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 just completed a Phase 2a successful clinical trial for the treatment of fibromyalgia in collaboration with the University of Michigan and has an ongoing 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 will 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.