

## **Agreement for world first trial for the treatment of Binge Eating Disorder using TRP-8803 with Swinburne University**

- Agreement signed with Swinburne University of Technology to undertake 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)
- Trial will recruit 12 patients, in two six-person cohorts, with patients to be administered two doses of TRP-8803 two weeks apart with patient recruitment to occur this quarter
- Agreement follows success in a Phase 2a trial by the University of Florida which showed TRP-8802 (oral psilocybin) reduced BED episodes by greater than 80%
- BED was chosen to commence clinical development of TRP-8803 since<sup>i</sup>:
  - There are no approved treatments developed for BED
  - It is the most common eating disorder in the USA
  - BED is often present with other comorbid conditions including, but not limited to, depression, anxiety, PTSD and sleep disorders where psilocin has shown activity<sup>ii</sup>
  - 25-50% of obese patients who seek weight-loss treatment suffer from BED<sup>iii</sup>
- Trial to be conducted by Professor Susan Rossell, a leading cognitive neuropsychologist and Professorial Research Fellow at Swinburne's Centre for Mental Health
- Plans to progress additional clinical trials of TRP-8803 in a range of other neuropsychiatry conditions are well advanced.

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**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 executed a Clinical Trial Research Agreement ('CTRA' or 'the Agreement') with Swinburne University. As part of the Agreement, Tryp and Swinburne will commence an open-label trial to assess the safety, feasibility and efficacy of TRP-8803, when administered together with psychotherapy for adult patients with Binge Eating Disorder (BED).

The trial will dose 12 participants suffering from BED in two, six-patient patient cohorts. Each cohort will receive two doses of TRP-8803, administered 14 days apart in a monitored setting, following preparatory psychotherapy and integration. Cohort 1 will receive a mid-range dose, while cohort 2 will receive a high-range dose.

The primary objective is to assess the safety of two doses of TRP-8803 in BED patients and during follow up through the 12-week period following the first 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 four weeks post second dosing.

The trial will be undertaken at Swinburne University, Melbourne, Australia. Swinburne 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.

BED is the most common eating disorder in the US and the second most common eating disorder in Australia. It is associated with both obesity and psychiatric comorbidities, that include anxiety, depression, posttraumatic stress disorder (PTSD), as well as impulsive and compulsive disorders. Based on clinical precedents and relevant neuropharmacology research, psilocin has the potential to be an effective treatment solution for BED.

The decision to pursue BED follows positive interim data from the Company's study with the University of Florida for the application of oral TRP-8802 which showed a mean reduction of >80% in patient Binge Eating Scores.

The trial is expected to commence in this quarter with high level results anticipated in Q4 CY2025.

The Company also advises that plans to advance additional clinical trials on a larger cohort of patients across multiple neuropsychiatry indications are well advanced and expected to commence during H2 CY 2025.

#### **Management commentary:**

**Chief Executive Officer, Mr Jason Carroll said:** *"Our CTRA to commence this world-first clinical patient trial for our lead drug treatment TRP-8803 marks an important step forward in Tryp's clinical development pathway and builds off the strong results from our Phase 1b trials in H2 CY2024, where TRP-8803 met key safety parameters for a diverse subject population.*

*"We have worked diligently to prepare the trial framework alongside our partners at Swinburne in accordance with the highest standards of safety and quality control and are excited to commence patient recruitment and dosing as soon as possible.*

*"The proprietary dataset generated from this trial, as well as other clinical trials which are in the final stages of planning are expected to provide unique insights to further inform and optimise our clinical development and regulatory pathways for a truly innovative treatment. We look forward to providing additional updates on patient recruitment and trial commencement shortly."*

-ENDS-

#### **TRP-8803 overview:**

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 inherent reversibility, allowing for treatment to be halted quickly if patients experience adverse events. This critical safety benefit cannot be achieved using oral dosing.

#### **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 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](http://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](http://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.

<sup>1</sup> <https://www.niddk.nih.gov/health-information/weight-management/binge-eating-disorder/definition-facts>

"Keski-Rahkonen: Current Opinion in Psychiatry 34(6):p 525-531, November 2021. Epidemiology of Binge Eating Disorder: prevalence, course, comorbidity & risk factors

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<sup>iii</sup>Bruce et.al.; Journal of the ADA, Volume 96, Issue 1, Jan 1996, PP 58-61, Binge Eating Among the Overweight Population: A Serious and Prevalent Problem