

## Receipt of regulatory permits for world-first clinical trial using TRP-8803 to treat Binge Eating Disorder

- Swinburne University secures required permit from Department of Health for TRP-8803 (iv-infused psilocin)
- TRP-8803 to be supplied to Swinburne shortly, ahead of first dosing this quarter and top-line results in Q4 CY25
- Patient screening well advanced following strong in-bound interest – first patient enrolment this month
- Open-label study will assess safety and efficacy of TRP-8803 when administered with psychotherapy in adults with Binge Eating Disorder (BED) - 12 patients to be administered TRP-8803 in two doses, 14 days apart

**Melbourne, Australia** – Tryptamine Therapeutics Limited (**'Tryp'**, **'TYP'** or the **'Company'**) (**ASX: TYP**), a clinical-stage biotechnology company, is pleased to provide the following update on patient recruitment and regulatory initiatives associated with its world-first clinical trial to treat Binge Eating Disorder (BED) using TRP-8803 (IV-infused psilocin) alongside Swinburne University (refer ASX announcement: 10 April 2025).

Swinburne University has received a 'Permit To Purchase Or Otherwise Obtain Poisons Or Other Controlled Substances For Industrial, Educational, Or Research Purposes' from the Department of Health, Victoria. This allows Tryp to commence supply of TRP-8803 to the university, ahead of first patient dosing this quarter. Batches of TRP-8803 is expected to be delivered in the near term, ensuring ample supply for the trial.

Following commencement of patient recruitment (refer ASX announcement: 21 July 2025), Tryp advises that patient screening is progressing well. Several potential participants have completed the initial application processes and will move through to face-to-face interviews next week. Following this, initial enrolments will begin with the commencement of baseline data collection, prior to administration of first dosing.

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

The trial's primary endpoint is to assess TRP-8803's safety when administered twice in BED patients and during follow up through the 12-week period after 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 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.

Tryp will also use resulting data to explore TRP-8803's utility on comorbidities that BED patients may suffer from, which will be used to finalise plans for future clinical development opportunities.

### Management commentary:

**Tryp Chief Executive Officer, Jason Carroll, said:** *"The Company continues to make very strong progress in relation to its trial with Swinburne and the receipt of this permit marks another milestone in our journey to deliver a potential treatment for BED, which is a far reaching and debilitating condition."*



*"Our focus will now shift to supplying Swinburne with TRP-8803 for use in the trial, as well as assisting with patient enrolment. Given the level of enquiries to date and progress with initial patient screening, we remain on track for first enrolment this month and first dosing this quarter."*

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 just 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](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.*