



28 August 2026

HUMAN RESEARCH ETHICS COMMITTEE APPROVAL SECURED FOR PHASE 1A CLINICAL TRIAL

HIGHLIGHTS

- Patrys has received Human Research Ethics Committee (HREC) approval for its Phase 1A clinical trial of RLS-2202
- The Phase 1A bridging study will evaluate the safety, tolerability, and pharmacokinetics of RLS-2202
- With HREC approval secured, the Company will now progress clinical site activation, participant screening and recruitment at CMAX
- First participant dosing remains on track to commence this quarter
- Receipt of HREC approval represents a significant regulatory milestone in the clinical development of RLS-2202

Patrys Limited (ASX: **PAB**) (**Patrys**, or the **Company**) is pleased to announce it has received Human Research Ethics Committee (HREC) approval to commence its Phase 1A clinical trial of RLS-2202 in healthy volunteers.

The Phase 1A study is designed to assess the safety, tolerability and pharmacokinetics of RLS-2202 in healthy volunteers. The study will generate important dosing information to inform subsequent stages of clinical development.

Receipt of HREC approval follows completion of the required regulatory and preparatory activities and represents an important milestone in the clinical development of RLS-2202. With ethics approval now in place, the Company will progress clinical site activation and the remaining study start-up activities ahead of first participant dosing, which remains on track for this quarter.

Patrys continues to work closely with its manufacturing, bioanalytical, clinical site and CRO partners to ensure the study is conducted to the highest standards of quality, safety and scientific rigour.

[\(Click here to view this announcement in the Patrys InvestorHub\)](#)

CEO, Dr Samantha South, said:

"We are pleased to have received ethics approval for our Phase 1A clinical trial. This is a significant step forward and reflects the strong progress being made across the program.

We are now focused on initiating the study, recruiting participants and generating data to support the next stages of clinical development for RLS-2202.

With first participant dosing expected this quarter, we look forward to providing shareholders with further updates as the study progresses.

Delirium remains a significant unmet medical need, and we look forward to advancing this important clinical program."



About the Approval

The HREC approval was granted by Bellberry on 27th August 2026, following review of the study protocol (Protocol No. PAB-2202-001), Investigator's Brochure, informed consent materials and the supporting data package for RLS-2202.

The approval permits the Company to proceed with its Phase 1A bridging study evaluating the safety, tolerability and pharmacokinetics of RLS-2202 following intravenous and oral administration in healthy adult volunteers. The study will be conducted at CMAX in South Australia.

Receipt of HREC approval represents a key milestone in the clinical development of RLS-2202 and enables Patrys to commence its Phase 1A clinical trial.

Trial Design

The Phase 1A study is a bridging trial designed to evaluate the safety, tolerability, and pharmacokinetic (PK) profile of RLS-2202 in healthy adult volunteers. The study will employ a sequential dose-escalation design, with progression between the two cohorts subject to review by an independent Safety Review Committee in accordance with the study protocol.

The primary objective is to assess the safety and tolerability of RLS-2202.

Secondary objectives include evaluation of:

- Pharmacokinetic profile; and
- Dose levels to support subsequent clinical development.

Data generated from this study will support dose selection and the design of subsequent clinical trials.

Next Steps

With ethics approval now in place, Patrys will proceed with the remaining study start-up activities, including:

- Notification to the Therapeutic Goods Administration (TGA) under the Clinical Trial Notification (CTN) Scheme, satisfying the remaining regulatory requirements prior to first participant dosing;
- Registration of the trial on the Australian New Zealand Clinical Trials Registry (ANZCTR);
- Clinical site initiation;
- Participant screening; and
- Participant enrolment.

The Company expects first participant dosing to occur this quarter following completion of these activities and will provide further updates as the trial progresses.

-Ends-



This announcement is authorised for release by the Board of Directors of Patrys Limited.

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About Patrys Limited

Patrys (ASX:PAB) is a clinical-stage company developing an injectable therapy for delirium alongside a differentiated deoxymab platform targeting immune-mediated inflammatory diseases. More information can be found at www.patrys.com.

Forward Looking Statements

This announcement may contain certain "forward-looking statements". Forward looking statements can generally be identified by the use of forward-looking words such as, "expect", "should", "could", "may", "predict", "plan", "will", "believe", "forecast", "estimate", "target" and other similar expressions. Indications of, and guidance on, future earnings and financial position and performance are also forward-looking statements. Forward-looking statements, opinions and estimates provided in this presentation are based on assumptions and contingencies which are subject to change without notice, as are statements about market and industry trends, which are based on interpretations of current market conditions. Forward-looking statements including projections, guidance on future earnings and estimates are provided as a general guide only and should not be relied upon as an indication or guarantee of future performance.

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