



22 October 2026

RLS-2202 PHASE 1A TRIAL ADVANCES TO COHORT 2

HIGHLIGHTS

- Safety Review Committee has completed its review of Cohort 1 safety and pharmacokinetic data and determined the dose for Cohort 2 progression.
- Recruitment for Cohort 2 is expected to commence shortly.
- Patrys remains on track for completion of dosing in the Phase 1a clinical trial in Q4 2026.
- Successful completion of the study could materially streamline the clinical development pathway for a new intravenous treatment option for delirium

Patrys Limited (ASX: **PAB**) (**Patrys**, or the **Company**) is pleased to announce the successful progression to Cohort 2 following the safety review committee (SRC) evaluation of the first cohort data for the Phase 1a clinical trial of RLS-2202 in healthy volunteers.

Phase 1a Clinical Trial Progress

The Company advises that all four participants in the first cohort completed dosing and the protocol-defined safety observation period. Following review of the available safety, tolerability and pharmacokinetic data, the SRC concluded that RLS-2202 demonstrated an acceptable safety and tolerability profile at the initial dose level and has recommended progression to the second cohort at a dose determined in accordance with the study's predefined dose-escalation design.

Patrys remains focused on the careful and methodical execution of the trial, with participant safety and data quality as the highest priorities. Final participant dosing remains on track to be completed this quarter and Patrys will continue to provide updates as the study progresses and additional milestones are achieved.

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

CEO, Dr Samantha South, said:

"Completing Cohort 1 is a key milestone for the RLS-2202 program. The Safety Review Committee has recommended advancing to Cohort 2, and the exploratory results from Cohort 1 have already informed the dose for the next cohort. This is a meaningful step forward for the RLS-2202 program, and we are excited to be progressing to the next stage of the study."

Phase 1a Trial Design and Significance

The Phase 1a study is a strategically important, technically well-controlled bridging study. Quetiapine has a well-established safety profile as an oral drug, but RLS-2202 is a new intravenous formulation, and IV delivery can produce a different exposure profile (for example, a higher peak concentration and faster onset, with no first-pass metabolism). The study therefore aims to show how exposure to RLS-2202 compares with that of oral quetiapine, so that the existing oral safety and efficacy data can be used to support the IV formulation without repeating the full development program.



Cohort 2 uses a cross-over design to make this comparison. Twelve healthy volunteers will each receive both the reference oral quetiapine formulation and RLS-2202, separated by a four-day washout period. This cross-over design is intended to reduce the influence of individual differences in metabolism on the interpretation of results, providing a clearer understanding of the pharmacokinetic profile of intravenous RLS-2202 and support the bridging of the established oral safety experience to the intravenous formulation.

While the study does not introduce a new active molecule, its results are critical to the progression of the RLS-2202 program. The pharmacokinetic and safety data are intended to support the bridging of the established oral quetiapine experience to the intravenous formulation, inform the design of the next clinical study, and provide a foundation for future engagement with regulators, including the U.S. Food and Drug Administration.

In doing so, a successful study has the potential to materially reduce the development burden associated with establishing a new intravenous treatment option for delirium, a condition that can develop rapidly, is associated with serious consequences, and currently has limited options for rapid alleviation.

Next Steps

Following initiation of Cohort 2, the key upcoming milestones for the RLS-2202 Phase 1a study are:

- October 2026: GMP RLS-2202 for Cohort 2 dosing will be released and delivered to CMAX.
- Q4 2026: Complete screening and enrolment of Cohort 2 participants.
- Q4 2026: GLP Validation of the bioanalytical assay in the range required for Cohort 2 analysis.
- Q4 2026: Cohort 2 dosing expected to commence and be completed this quarter

Patrys remains on track to complete dosing of the final participant in Cohort 2 and intends to provide further updates as key clinical milestones are achieved and data from the study become available.

-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 announcement 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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