27 November 2026

First Participants Dosed in Cohort 2 of Phase 1a Clinical Trial of RLS-2202

HIGHLIGHTS

- **First participants dosed in Cohort 2** of the Phase 1a bridging trial of RLS-2202, Patrys' intravenous (IV) quetiapine for delirium.
- **Why it matters:** Cohort 2 directly compares IV and oral quetiapine in the same volunteers, which is required to bridge RLS-2202 to oral quetiapine's established safety record under the FDA 505(b)(2) pathway, a potentially faster, lower-cost route to market.
- **Ready to execute**: GMP drug product has been released to the trial site (CMAX), and full validation of the assay that measures drug levels in the blood is underway.
- **On track**: final dosing is expected in December 2026, with topline results in Q1 CY27. Those results will support FDA engagement on an ICU patient study.

Patrys Limited (ASX: **PAB**) (**Patrys,** or the **Company**) is pleased to announce that the GMP-manufactured drug product has been released to the clinical trial site and dosing in Cohort 2 of its Phase 1a clinical trial of RLS-2202 in healthy volunteers has been initiated. Cohort 2 is the core of the bridging study, directly comparing RLS-2202 with oral quetiapine in the same participants. Full validation of the bioanalytical method to support analysis of trial samples has also commenced.

(**Click here to view this announcement in the Patrys InvestorHub**)

The Opportunity

Delirium is a serious, acute disturbance of brain function that affects up to 80% of mechanically ventilated ICU patients and is associated with longer hospital stays, higher costs and increased mortality. Despite this, there are no medicines approved by the U.S. Food and Drug Administration (FDA) for the prevention or treatment of delirium, and clinicians rely on off-label antipsychotics. Many critically ill patients cannot reliably take oral medication. RLS-2202 is designed to fill this gap: an intravenous formulation of quetiapine, a widely used oral atypical antipsychotic, intended to provide rapid and controllable treatment in hospitalised patients.

CEO, Dr Samantha South, said:

"Cohort 2 is a critical step in our bridging strategy. By dosing the same volunteers with both IV and oral quetiapine, we generate the comparison that lets us draw on decades of oral quetiapine data, and that is what makes the path to an ICU patient study efficient. I'd like to sincerely thank our clinical site for its recruitment efforts, which enabled us to initiate this cohort.

With GMP clinical supply released for Cohort 2 and full bioanalytical validation now underway, the key building blocks are in place to deliver Cohort 2 efficiently and to drive RLS-2202 through Phase 1 and into the next stage of development.

With no FDA-approved treatment for delirium, we believe a fast-acting intravenous option could make a real difference for ICU patients and the clinicians who care for them".

Clinical Trial Progress

The Company has begun Cohort 2 of its Phase 1a clinical trial of RLS-2202. Healthy volunteers in Group 1 have received their first dose in the first period of the crossover study and will stay at the trial site until they complete dosing in the second period. More volunteers will be enrolled in Group 2 until the cohort reaches 12 participants.

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 December 2026 and Patrys will continue to provide updates as the study progresses and additional milestones are achieved.

Manufacturing Update & Drug Product Release

The Company also advises that GMP-manufactured RLS-2202 drug product has been released and delivered to CMAX Clinical Research for use in Cohort 2 of the Phase 1a trial, with packaging and labelling completed and a stability program underway to support a shelf-life covering the Phase 1a and subsequent studies.

The batch was produced under cGMP and passed comprehensive quality control testing and batch record review, confirming it meets all pre-agreed specifications and is suitable for administration to human participants.

Bioanalytical Method Validation

Patrys has completed method development and a preliminary round of testing using Cohort 1 of the RLS-2202 Phase 1a study and has now begun full validation of the laboratory method used to measure quetiapine and its active by-product, norquetiapine, in participants' blood samples. Validation will confirm that the method is accurate, consistent and reliable, and that it can detect the required amounts of each compound, ahead of analysing Cohort 2 samples.

A fully validated method, in line with all relevant regulatory guidelines and quality standards, is a critical operational milestone because it ensures the data on how the drug moves through the body can be trusted. This information will guide decisions on how to safely increase doses during the study and help determine the right doses for future patient studies.

Phase 1a Trial Design and Significance

The Phase 1a study is a bridging study comparing RLS-2202, a new intravenous formulation of quetiapine, with oral quetiapine, which has a well-established safety profile. Intravenous delivery can produce a different exposure profile, such as a higher peak concentration and faster onset with no first-pass metabolism. Cohort 2 uses a cross-over design in which twelve healthy volunteers each receive both oral quetiapine and RLS-2202, separated by a four-day washout. This reduces the influence of individual differences in metabolism and allows a clearer comparison of exposure, supporting use of the existing oral safety data (FDA 505(b)(2) pathway) for the intravenous formulation. The study will also assess whether the intravenous formulation raises any additional safety concerns in healthy participants.

The resulting data are intended to support future engagement with regulators, including the U.S. Food and Drug Administration, on the design of the next RLS-2202 studies in ICU patients with delirium.

Next Steps

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

- Q4 CY26: Complete screening and enrolment of Cohort 2 participants.
- Q4 CY26: Validation of the bioanalytical assay in the range required for Cohort 2 analysis.

- Q1 CY27: Topline Phase 1a results available.
- 2027: Engagement with the FDA on the design of the next RLS-2202 study in ICU patients with delirium.

Patrys remains on track to complete dosing of the final participant in Cohort 2 in December 2026 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.