23 September 2026

FIRST PARTICIPANTS DOSED IN RLS-2202 PHASE 1A CLINICAL TRIAL

HIGHLIGHTS

- First participants dosed in the Phase 1a clinical trial of RLS-2202, marking the commencement of human clinical evaluation of Patrys' proprietary intravenous formulation of quetiapine.
- The study is designed to evaluate safety, tolerability and pharmacokinetics, and generate the data required to inform dose selection and the next stage of clinical development.
- RLS-2202 is being developed as a potential intravenous treatment option for delirium in acute care settings.
- Independent Safety Review Committee meeting scheduled for October ahead of potential progression to Cohort 2, with final participant dosing remaining targeted for next quarter.

Patrys Limited (ASX: **PAB**) (**Patrys,** or the **Company**) is pleased to announce that the first participants have been dosed in Cohort 1 of the Phase 1a clinical trial of RLS-2202 in healthy volunteers.

The commencement of dosing marks RLS-2202's transition into human clinical evaluation, with the study now generating clinical data to inform the next stage of the program.

CEO, Dr Samantha South, said:

"We are delighted to announce the dosing of the first participants in our Phase 1a clinical trial. This is a major milestone for RLS-2202 and for Patrys. We have now moved from developing the formulation and preparing for the clinic to generating human clinical data. We look forward to evaluating the clinical data, as these results will inform the strategy for advancement into later-stage development."

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

Phase 1a Clinical Trial

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.

In Cohort 1, each participant will receive both the reference oral formulation of quetiapine and RLS-2202, separated by a four-day washout period. The study employs a 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 its pharmacokinetic profile and dose levels to support subsequent clinical development.

Importance of the Phase 1a study

Quetiapine has an extensive history of oral use in the treatment of schizophrenia and bipolar disorder. RLS-2202 is being developed as an IV formulation, with the objective of providing an alternate, faster and safer, route of administration for patients with delirium in acute-care clinical settings.

The Phase 1a study is designed to assess the safety and tolerability of IV administration of RLS-2202, including whether there are any clinically meaningful differences from the established profile of oral quetiapine.

It will also identify the dose range and pharmacokinetic profile to guide subsequent clinical development. These findings will inform the design of future trials evaluating the efficacy of IV quetiapine in the target patient population and, subject to positive results, support a potential pathway to regulatory approval. The results are also expected to inform regulatory discussions regarding the extent to which the established safety information for oral quetiapine may be relevant to the RLS-2202 development program.

Manufacturing Update

Patrys has completed GMP manufacturing and filling of the RLS-2202 clinical trial material required for Cohort 2.

The manufactured product is now undergoing the required quality control testing prior to release for clinical use. Subject to successful completion of this testing and release of the material, the Company expects to have sufficient clinical trial material to support dosing of Cohort 2 and the associated planned trial activities.

Next Steps

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

- October 2026: The independent Safety Review Committee is scheduled to review the available Cohort 1 safety data prior to progression to Cohort 2.
- Q4 CY26: Subject to a satisfactory safety review and successful quality control testing and release of the Cohort 2 clinical material, Patrys expects to commence dosing of Cohort 2.
- Q4 CY26: Patrys remains on track to complete dosing of the final participant in Cohort 2.

Patrys 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 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.