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Patrys advances RLS-2202 toward Phase 1 Clinical Trial with key trial site and CRO appointments

HIGHLIGHTS

- Patrys appoints CMAX as Phase 1A clinical trial site to conduct the Company's bridging Phase 1A study to assess safety, tolerability, and pharmacokinetics (PK)
- Alithia Life Sciences appointed as Contract Research Organisation (CRO) to provide clinical trial management and oversight
- Both appointments represent significant milestones in the Company's progression toward clinical-stage development
- Subject to Human Research Ethics Committee (HREC) approval, Company remains on track for clinical trial initiation in Q3 2026

Patrys Limited (ASX: **PAB**) (**Patrys,** the **Company)**, is pleased to announce two key appointments in support of its upcoming Phase 1A clinical trial, representing a significant milestone in the progression of the RLS-2202 program toward clinical-stage development: the engagement of CMAX as the clinical trial site and Alithia Life Sciences (Alithia) as the Contract Research Organisation (CRO) to oversee clinical trial management and operational execution. Together, these organisations will play complementary and distinct roles in the planning, execution, and management of the Company's upcoming bridging PK, safety and tolerability study in healthy volunteers.

In March 2026, Patrys announced key manufacturing and regulatory de-risking activities for the RLS-2202 program ahead of clinical entry. These appointments mark the completion of a critical milestone that establishes the operational framework required to commence the Company's Phase 1A clinical development activities.

The selection of CMAX and Alithia followed a competitive evaluation process and reflects both organisations strong track records in delivering high-quality Phase 1 data, robust safety oversight, and efficient operational timelines.

Patrys plans to submit the Human Research Ethics Committee (HREC) application for the Phase 1A clinical trial in Q2 2026 and, pending approval, remains on track to commence dosing in Q3 2026.

CEO, Dr Samantha South, said:

"The appointments of CMAX and Alithia are critical to the execution of the RLS-2202 Phase 1A clinical trial and we are pleased to partner with highly experienced organisations with strong track records in early-stage clinical development and Phase 1 execution.

These appointments establish an important operational framework as we advance RLS-2202 toward first participant dosing and continue progressing the program towards clinical-stage development.

RLS-2202 is designed to address the significant unmet need for delirium treatment in acute care settings, and, subject to approvals, we remain on track for first participant dosing in Q3 CY2026."

Appointment of CMAX as Phase 1A Clinical Trial Site

CMAX is a specialised Phase 1 clinical unit based in Adelaide, with extensive experience in early-stage and first-in-human studies across a broad range of therapeutic areas.

CMAX is the physical clinical site where the RLS-2202 Phase 1A trial will be conducted and where study participants will be dosed and monitored. The selection of CMAX provides the Company with access to specialist Phase 1 infrastructure, experienced investigators, and established participant recruitment capabilities.

Appointment of Alithia Life Sciences as Contract Research Organisation (CRO)

Alithia is the CRO responsible for coordinating and managing the broader operational, regulatory, and clinical oversight aspects of the trial. Alithia's appointment is intended to ensure that the Phase 1 trial is executed to high operational and quality standards, enabling reliable interpretation of safety, tolerability and pharmacokinetic data.

As CRO, Alithia will provide services including project management, regulatory coordination, data management, monitoring protocol adherence, pharmacovigilance, vendor oversight, and trial administration to ensure the study is conducted in accordance with applicable regulatory and Good Clinical Practice (GCP) requirements, biostatistics, and reporting activities in accordance with GCP and regulatory expectations.

A/Prof Tina Soulis, Alithia's Founder and Director said "*This collaboration is exciting and we are proud to be involved in the journey of an Australian company doing great things*".

Next Steps

With the clinical site and CRO now appointed, the Company will proceed with finalisation of the clinical trial protocol, regulatory and ethics submissions, and initiation activities at CMAX, with first participant dosing targeted for Q3 CY2026, subject to approvals.

Patrys will continue to update shareholders regarding trial initiation timelines and regulatory submissions as the Phase 1 program progresses.

About RLS-2202

RLS-2202 is a proprietary injectable formulation of Quetiapine, designed for use in acute care settings, to provide rapid, predictable and effective treatment of delirium.

The program is expected to pursue the FDA 505(b)(2), regulatory pathway, alongside and equivalent international approval routes, allowing the Company to leverage the extensive existing clinical and safety data for Quetiapine while generating new data specific to the RLS-2202 IV formulation.

RLS-2202 complements Patrys' core antibody deoxymab platform and represents an additional value-creating program within the Company's development pipeline.

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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.