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Patrys Initiates Manufacturing and Regulatory Pathway for RLS-2201 Clinical Trial

HIGHLIGHTS

- Engineering batch manufacturing successfully initiated at BioCina, marking a critical step toward clinical supply
- US regulatory advisor engagement initiated ahead of FDA pre-IND submission
- Contract Research Organisation (CRO) selection process underway for Phase 0 trial execution
- Company remains on track for clinical trial initiation in H2 2026

Patrys Limited (ASX: **PAB**) (**Patrys,** the **Company)**, is pleased to announce the commencement of key manufacturing and regulatory activities for the advancement of RLS-2201, the Company's proprietary injectable formulation of Quetiapine being developed to alleviate delirium.

Delirium affects between 30-70% of intensive care patients and currently lacks a rapid-acting injectable therapy approved for acute treatment.

These activities represent critical de-risking milestones that position the Company to initiate its first-in-human Phase 0 clinical trial in H2 2026.

CEO, Dr Samantha South, said:

"*With manufacturing development underway and regulatory engagement progressing, these activities represent important de-risking steps for the RLS-2201 program as we move toward entering clinical trials.*
By reformulating a well-known therapeutic into an injectable treatment designed for acute hospital use, we believe RLS-2201 has the potential to address a significant unmet need in the treatment of delirium."

Engineering Batch Manufacturing Initiated

The Company has initiated engineering batch manufacturing of RLS-2201 at BioCina, an Australian contract development and manufacturing organisation (**CDMO**) specialising in sterile injectable drug product formulation development and manufacturing, from clinical trial to commercial scale up capacity. The engineering batch represents the first production run of the reformulated product under conditions designed to replicate commercial-scale manufacturing processes.

The batch will support several key development activities, including:

- confirmation of manufacturing process reproducibility;
- generation of material for stability testing; and
- production of early material for use in clinical trial activities.

Successful completion of the engineering batch will enable the manufacture of GMP clinical trial material required for Phase I clinical trial dosing.

US Regulatory Engagement Underway

In parallel with manufacturing activities, the Company has commenced engagement with Facet Life Sciences, a specialist US regulatory affairs advisory group, to support the Company's eventual FDA investigational new drug application (IND) submission. These discussions are focused on:

- Leveraging the extensive existing safety and clinical data for oral Quetiapine;
- Defining the clinical development strategy for the RLS-2201 formulation;
- Confirming the planned Phase 0 clinical study design; and
- Preparing the regulatory documentation, inclusive of ethical frameworks required for the planned Phase I trial.

Early regulatory engagement is intended to ensure alignment with the FDA and incorporate agency feedback into the Company's clinical development pathway.

CRO Selection and Trial Planning

The Company is currently in advanced discussions with a shortlist of specialist Contract Research Organisations (CROs) experienced in early phase clinical trials. These discussions include:

- Clinical trial site selection;
- Subject recruitment strategy;
- Clinical operations management; and
- Regulatory and ethics approval support.

The Company expects to finalise its CRO appointment in Q2 CY2026 and will update shareholders following execution of a formal agreement.

About RLS-2201

RLS-2201 is a proprietary injectable formulation of Quetiapine, designed for use in acute care settings, to provide rapid, predictable and effective treatment of delirium.

By reformulating a well-established therapeutic agent into an injectable formulation suitable for acute hospital use, Patrys aims to address a significant unmet clinical need in the management 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-2201 formulation.

This regulatory approach provides the opportunity to accelerate clinical development timelines relative to traditional drug development programs.

RLS-2201 complements Patrys' core antibody 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.