

ETHICS APPROVAL IN AUSTRALIA FOR PARA_OA_012 PHASE 3 TRIAL

KEY HIGHLIGHTS

- Successful submission and approval of the ethics application to Australia's centralised Human Research Ethics Committee for the pivotal PARA_OA_012 phase 3 trial.
 - First sites to be activated in Victoria and up to 10 sites total across Australia.
 - Following site activation recruitment activities will commence with the first participant dosing anticipated in Q2 CY2025.
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Paradigm Biopharmaceuticals Ltd (ASX: PAR) ("Paradigm" or "the Company"), a late-stage drug development company focused on delivering new therapies to address unmet medical needs, is pleased to announce that it has successfully attained centralised Human Research Ethics Committee (HREC) approval in Australia for its pivotal PARA_OA_012 Phase 3 clinical trial. This trial aims to evaluate the safety and efficacy of injectable pentosan polysulphate sodium (iPPS) for the treatment of knee osteoarthritis (OA).

This significant milestone streamlines the approval process across all participating sites, ensuring a more efficient and consistent ethical review framework. With centralised ethics approval in place, site preparations are now well underway, paving the way for timely initiation of the trial. The recruitment of the first subject remains on target with first participant dosing expected in Q2, reflecting Paradigm's commitment to maintaining the study's projected timelines and delivering meaningful outcomes in accordance with regulatory and ethical standards.

This milestone follows the selection of Advanced Clinical as the Clinical Research Organisation for the PARA_OA_012 phase 3 clinical trial. Advanced Clinical has a proven track record in osteoarthritis research, offering strong therapeutic expertise, global reach, operational excellence, and a patient-centric approach to trial execution.

Paradigm's Managing Director, Mr Paul Rennie commented: *"The ethics submission and subsequent approval by HREC for the PARA_OA_012 trial represents a critical milestone in our journey to bring iPPS to patients suffering from osteoarthritis. With our Australian sites ready to activate, we remain focused on our goal of enrolling and dosing the first subject in Q2 and advancing this transformative therapy through phase 3 development."*

Centralised Ethics Process in Australia

In Australia, the centralised HREC process plays a key role in clinical trial governance, streamlining ethics review for multicentre trials. The HREC approval allows Paradigm's phase 3 trial to proceed across multiple sites, significantly expediting site activation and participant recruitment.

Australian Sites Ready for Start-Up

Paradigm is pleased to report that key clinical trial sites in Australia are preparing to commence start-up activities upon receiving this HREC approval. Recruitment initiatives on track for Q1 CY2025 with first participant dosing anticipated in Q2 CY2025.

About the PARA_OA_012 Trial

The PARA_OA_012 trial is a pivotal Phase 3 study designed to confirm the therapeutic potential of iPPS for treating pain and improving function in patients with knee osteoarthritis. This randomised, double-blind, placebo-controlled trial will enrol approximately 466 participants globally, including key sites in Australia and the United States. The study's primary objectives focus on pain reduction and functional improvement as measured by validated scales.

This phase 3 trial builds on the positive outcomes of Paradigm's previous studies, including the PARA_OA_008 trial, which demonstrated significant clinical benefits in pain reduction and improved joint function for up to 12 months in patients treated with iPPS .

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About Paradigm Biopharmaceuticals Ltd.

Paradigm Biopharmaceuticals Ltd. (ASX: PAR) is a late-stage drug development company driven by a purpose to improve patients' health and quality of life by discovering, developing, and delivering pharmaceutical therapies. Paradigm's focus is developing injectable (subcutaneous) pentosan polysulfate sodium (iPPS) for the treatment of diseases with inflammatory pathogenesis, where the anti-inflammatory and chondroprotective properties of iPPS may be transformative to current care.

Forward Looking Statements

This Company announcement contains forward-looking statements, including statements regarding anticipated commencement dates or completions dates of preclinical or clinical trials, regulatory developments and regulatory approval. These forward-looking statements are not guarantees or predictions of future performance, and involve known and unknown risks, uncertainties and other factors, many of which are beyond our control, and which may cause actual results to differ materially from those expressed in the statements contained in this presentation. Readers are cautioned not to put undue reliance on forward-looking statements.

To learn more please visit: <https://paradigmbiopharma.com>

Approved for release by the Paradigm Board of Directors.

FOR FURTHER INFORMATION PLEASE CONTACT:

Simon White

Director of Investor Relations

Tel: +61 404 216 467

Paradigm Biopharmaceuticals Ltd

ABN: 94 169 346 963

Level 15, 500 Collins St, Melbourne, VIC, 3000, AUSTRALIA

Email: investorrelations@paradigmbiopharma.com