

Site Activation and First Patient Consent in Australia for Phase 3 Knee OA Study

Key Highlights

- First Australian site activated at Sportsmed Biologic, with Dr Philip Bloom as the Principal Investigator.
- First Australian patient has provided informed consent to participate in the phase 3 clinical trial.
- To date, 11 sites in Australia have been selected and agreed to participate in the PARA_OA_012 study.
- In the United States, 48 clinical sites are in advanced preparations for activation under the centralised ethics approval.

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 a series of important milestones in the global advancement of its phase 3 clinical trial (PARA_OA_012) evaluating injectable pentosan polysulfate sodium (iPPS) for the treatment of pain associated with knee osteoarthritis.

The Company has activated its first Australian clinical site at Sportsmed Biologic based in Melbourne. The site is led by Dr Phillip Bloom, a specialist sports physician with over two decades of clinical experience in osteoarthritis management. Dr Bloom has treated more than 300 patients with iPPS under Australia’s Special Access Scheme and has contributed extensively to Paradigm’s clinical development program to date. His leadership brings deep insight into both the product and the patient population targeted in this pivotal study.

In addition to site activation, the first Australian patient has now been formally consented into the trial. Informed consent is the initial step that allows a patient to participate after they have received and understood all relevant information about the study, including objectives, procedures, potential risks, and benefits. This milestone marks the commencement of patient enrolment within the Australian arm of the trial.

As of the date of this release, Paradigm has selected 11 clinical sites in Australia that have agreed to participate in the PARA_OA_012 study. These sites are in various stages of start-up and activation. In the United States, 48 clinical sites have now been selected and are actively preparing for activation. The Company remains on track to have first patient consent in the coming weeks with randomisation and dosing in the US to follow in the coming quarter, marking a critical step forward in its global development timeline.

Paul Rennie, Managing Director of Paradigm Biopharmaceuticals, said: “The activation of our first site in Australia and the consenting of our first patients in Australia, with the US soon to follow, mark a significant operational achievement for the Company. I am particularly pleased to see the high level of engagement from leading clinical investigators and trial sites. I am also pleased that the Company is progressing in line with our intended time schedule.”

The PARA_OA_012 trial is a randomised, double-blind, placebo-controlled phase 3 study that will evaluate the efficacy and safety of iPPS in 466 participants with moderate-to-severe knee osteoarthritis. The primary endpoint is the change from baseline in average daily pain at Day 112. Secondary endpoints include validated measures of pain and physical function (WOMAC), patient global impression of change (PGIC), rescue medication usage, and structural joint assessments via MRI and X-ray imaging.

Following prior FDA clearance of the trial protocol in November 2024, Paradigm has now completed to set up all the infrastructure needed to commence patient recruitment and dosing. This included establishment of validated electronic data capture systems compliant with regulatory standards, central and local laboratory networks, selection and engagement of its Contract Research Organisation (CRO), execution of agreements across selected US and Australian clinical sites, and manufacture and regulatory-compliant labelling of both the investigational product (iPPS) and placebo comparator (saline).

Paradigm will provide further updates as site activation continues, and patient recruitment scales up across both geographies.

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About Paradigm Biopharmaceuticals

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 current focus is developing iPPS for the treatment of diseases where inflammation plays a major pathogenic role, indicating a need for the anti-inflammatory and tissue regenerative properties of PPS, such as in osteoarthritis (phase 3) and mucopolysaccharidosis (phase 2).

Forward Looking Statements

This Company announcement contains or may contain 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.

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