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First Sites Activated and Initial Patients Consented in the United States for Phase 3 Knee OA Study

Key Highlights

- First clinical sites now activated in the United States under the centralised IRB process.
- First set of US patients have provided informed consent and entered screening for trial participation.

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 the first US clinical sites participating in its phase 3 PARA_OA_012 study have now been activated and the first US patients have provided informed consent and entered the screening process for participation in the study. The study is designed to evaluate injectable pentosan polysulfate sodium (iPPS) for the treatment of moderate-to-severe knee osteoarthritis (OA).

The activation of US sites marks another major operational milestone in the Company's global clinical development strategy, following the initial site activation and patient consent at Sportsmed Biologic in Australia earlier this month (see ASX announcement dated 3 June 2025).

Screening of patients has now commenced at multiple US sites, with first randomisation and dosing anticipated in the coming weeks. The study protocol has been cleared by the US FDA, and all US sites are operating under a central Institutional Review Board (IRB), streamlining activation and oversight across the country (see ASX announcements dated 28 November 2024 and 15 May 2025 respectively).

Paul Rennie, Managing Director of Paradigm, commented: "The initiation of US sites and the consent of our first patients in the United States is another step forward in progressing our global phase 3 study. This progress builds on strong site engagement and sets the foundation for accelerated patient recruitment across both Australia and the US."

The PARA_OA_012 study is a randomised, double-blind, placebo-controlled phase 3 study enrolling 466 participants with moderate-to-severe knee OA. The trial's primary endpoint is change from baseline in average daily pain at Day 112. Secondary endpoints include WOMAC scores for pain and physical function, PGIC, rescue medication use, and structural joint assessments via MRI and X-ray imaging.

Paradigm is targeting the activation of approximately 15 clinical sites across Australia and 50 sites across the United States to support the global execution of the PARA_OA_012 study. These sites have been strategically selected based on clinical expertise in osteoarthritis and geographic coverage to facilitate broad patient access. Site initiation is proceeding on a rolling basis, with several Australian and US centres now active and additional sites scheduled to come online throughout the remainder of CY2025. This staged activation model supports efficient ramp-up of patient screening, randomisation, and dosing across both regions.

Further updates will be provided as the study advances through the screening, randomisation, and dosing stages across the US and Australia.

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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.

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.

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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