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Phase 3 OA Trial Continues Following Formal DSMB 20% Safety Review and Moldova Site Activated

Paradigm Biopharmaceuticals Ltd (ASX:PAR) ("Paradigm" or "the Company"), 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 provide an update on its pivotal Phase 3 PARA_OA_012 clinical trial, including completion of a planned Data Safety Monitoring Board (DSMB) safety review and continued site expansion to support the final phase of recruitment.

The independent DSMB has completed a planned safety review of approximately the first 20% of participants who have completed dosing (Day 39) in the PARA_OA_012 study.

Following this review the trial will continue to the 100% recruitment milestone of approximately 466 participants.

The DSMB is an independent committee responsible for monitoring participant safety and ensuring the integrity and scientific validity of the trial. Completion of this review represents an important early milestone in the Phase 3 program and supports continued execution of the study as designed.

Moldova Site Activation Supports Final Recruitment Phase

Paradigm also advises that the first clinical trial site in Moldova has now been activated, with the remaining two sites expected to be activated shortly.

The expansion into Moldova has been undertaken as part of a targeted strategy to support the final phase of recruitment and maintain strong enrolment momentum across the global study. The region offers access to high-quality clinical sites, experienced investigators, and efficient patient recruitment pathways, which are expected to contribute meaningfully to timely completion of enrolment.

Importantly, the addition of these sites is focused on accelerating the final tranche of participants required for the study, ensuring continuity of recruitment as earlier sites mature and approach capacity.

With enrolment already progressing at a strong pace, the activation of Moldova sites is expected to support completion of 100% enrolment and dosing during the current quarter (Q2 CY2026), in line with Paradigm's targeted timelines.

Interim Analysis Timing

With recruitment and dosing progressing strongly, the study remains on track for interim analysis at approximately August 2026. Timing remains subject to independent processes including data cleaning, biometrics, and DSMB review timelines, and may extend into September 2026.

Paradigm Chief Medical Officer, Dr Donna Skerrett, commented: "*The DSMB has provided us with an in depth review the safety profile of iPPS in this study. With recruitment advancing at pace and additional sites coming online, we are well positioned to complete enrolment and interim analysis in the coming months, which will provide an important assessment of treatment effect at Day 112.*"

About the Phase 3 PARA_OA_012 Clinical Trial

PARA_OA_012 is a randomised, double-blind, placebo-controlled, multicentre Phase 3 clinical trial evaluating injectable pentosan polysulfate sodium (iPPS) in participants with knee osteoarthritis (kOA).

The study is designed to enrol approximately 466 participants, randomised 1:1 to receive iPPS or placebo over a 6-week treatment period. The primary endpoint is the change in pain intensity at Day 112, measured as the weekly average of daily pain scores.

Secondary endpoints include measures of function, patient-reported outcomes, and structural assessments, providing a comprehensive dataset to support regulatory evaluation.

An interim analysis is planned once approximately 50% of participants reach Day 112, with outcomes guiding continuation in line with the study's predefined statistical framework.

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 injectable (subcutaneous) pentosan polysulfate sodium (**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).

Authorised for release by the Paradigm Board of Directors.

To learn more please visit: www.paradigmbiopharma.com

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