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Phase 3 OA Trial Continues Unchanged Following Formal DSMB 80% Safety Review, September Interim Analysis on Track

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.

The independent Data Safety Monitoring Board (DSMB) has completed its planned safety review of approximately 80% of participants who have completed dosing (Day 39) in the PARA_OA_012 study. Following its review of the available safety data, the DSMB has recommended that the trial continue without modification.

This represents the third formal DSMB safety review successfully completed during PARA_OA_012, following the previously scheduled 20% and 50% reviews, each of which also supported continuation of the study.

Completion of the 80% review represents another important de-risking milestone for the Phase 3 program as PARA_OA_012 progresses towards its next major clinical milestone, the planned interim analysis in September 2026.

The DSMB is an independent committee responsible for monitoring participant safety and the ongoing integrity and scientific validity of the clinical trial. The recommendation to continue the study unchanged following successive planned safety reviews supports continued execution of PARA_OA_012 as designed.

Next Major Milestone – Interim Analysis

With the 80% safety review now completed, Paradigm reaffirms its guidance that the PARA_OA_012 interim analysis remains on track for September 2026.

The pre-specified interim analysis represents the next major clinical milestone for the Company and will assess treatment effect on the study's primary pain endpoint at Day 112.

The interim analysis will be conducted in accordance with the pre-specified statistical analysis plan and independent DSMB process. Timing remains subject to completion of the required data cleaning, biometrics and independent review processes.

Paradigm Chief Medical Officer, Dr Donna Skerrett, commented: "The recommendation to continue PARA_OA_012 unchanged following the 80% safety review represents another important milestone for the Phase 3 program and builds on the outcomes of the earlier 20% and 50% DSMB reviews.

With three formal DSMB safety reviews now completed and the study continuing as designed, our focus turns to the September interim analysis and the assessment of

treatment effect at Day 112. We remain pleased with the execution of the study as we approach this important milestone for the program."

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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