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Paradigm Confirms Progress Toward 25% Recruitment Milestone in Pivotal PARA_OA_012 Phase 3 Trial

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 recruitment progress for its pivotal Phase 3 PARA_OA_012 clinical trial evaluating injectable pentosan polysulfate sodium (iPPS) for the treatment of knee osteoarthritis.

Paradigm confirms that it has the required number of participants either enrolled or randomised to support achievement of the 25% recruitment milestone for the PARA_OA_012 trial. Due to the upcoming holiday period and temporary site shutdowns across several jurisdictions, a number of participants contributing to this milestone are scheduled to commence dosing in the new year.

This approach reflects the six-week dosing regimen and the requirement for both Paradigm and its global CRO to ensure participants are not exposed to any risk of missed doses during the holiday shutdown period. The Company believes this measured approach is appropriate to maintain protocol compliance, data quality and overall trial integrity.

Screening activity across the trial remains strong, with a significant pipeline of prospective participants. Paradigm expects the 50% recruitment milestone to be achieved shortly after completion of the 25% dosing milestone, as the majority of activated sites are expected to be actively enrolling from the beginning of the new year. Screening at the Moldova and Hong Kong sites is expected to commence in mid-January, further supporting recruitment momentum.

A key contributor to recruitment momentum in Australia has been the Company's targeted patient-outreach initiative with Medimark. Over the three-month period since launch, more than 13,000 individuals have visited the Hope4OA website. Of these, approximately 3,000 prospective participants have completed the online pre-screening questionnaire, with around 1,000 referrals subsequently passed through to Australian clinical sites to be booked for formal screening. The Company believes this initiative has been an effective and scalable channel to support recruitment across its Australian sites.

The interim analysis for PARA_OA_012 remains on track for mid-calendar year 2026. Primary endpoint analysis for the full patient cohort is expected in Q4 CY2026, consistent with previously communicated timelines.

Paradigm Managing Director, Paul Rennie, commented:" *We are pleased to confirm that Paradigm has approximately 25% of target recruitment either enrolled or randomised for our pivotal PARA_OA_012 Phase 3 trial. Given the upcoming holiday period and temporary site shutdowns, a small number of participants contributing to this cohort are scheduled to commence dosing early in the new year. This reflects the six-week dosing regimen and our commitment, together with our CRO, to maintaining protocol integrity by avoiding any risk of missed doses over the holiday period.*

Screening activity across the trial remains strong, and with the majority of sites expected to be actively enrolling from the beginning of the new year, we anticipate progressing rapidly toward the recruitment level required for the interim analysis. Screening at our Moldova and Hong Kong sites is expected to commence in mid-January, further supporting recruitment

momentum. Importantly, the interim analysis remains on track for mid-calendar year 2026, with primary endpoint analysis for the full cohort expected in Q4 CY2026.

On behalf of the entire Paradigm team, I would like to wish our investigators, partners, shareholders and broader stakeholders a safe and happy holiday period. We look forward to what is shaping up to be a very exciting and pivotal year ahead for Paradigm in 2026."

The PARA_OA_012 study is a global, randomised, double-blind, placebo-controlled Phase 3 trial designed to evaluate the efficacy and safety of injectable PPS in patients with knee osteoarthritis.

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).

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.

Authorised for release by the Paradigm Board of Directors.

Reference

1. https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/breakthrough-therapy?utm_source=chatgpt.com
2.

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

Paradigm Biopharma

For more information please visit:
https://investors.paradigmbiopharma.com