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# Paradigm Engages NBCD to Expand Global Phase 3 Footprint

Key Highlights

- Paradigm engages NBCD A/S as a complimentary CRO to collaborate with Advanced Clinical and Paradigm's internal clinical team on its pivotal Phase 3 knee osteoarthritis trial.
- Four new high-performing clinical sites to be activated, one in Hong Kong and three in Moldova, expanding the program's global footprint.
- The Hong Kong site provides strategic alignment with the territory's new "1+" regulatory pathway, supporting future Greater Bay Area (GBA) commercial and regulatory opportunities.
- Screening and recruitment progressing well across active sites, with the interim analysis remaining on track for mid-2026.

**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 engagement of Nordic Bioscience Clinical Development (NBCD) A/S as a complimentary contract research organisation (CRO) to support the Company's ongoing pivotal Phase 3 PARA_OA_012 clinical program in knee osteoarthritis (OA).

Under the expanded CRO framework, NBCD will work collaboratively with Paradigm and Advanced Clinical, the Company's global lead CRO, to activate and manage four additional high-performing clinical sites, one in Hong Kong and three in Moldova. Both regions have been identified as top-tier centres with extensive experience in OA trials and proven screening and enrolment performance.

Paradigm anticipates finalising activation of sites at around 60 globally, including the Hong Kong and Moldova sites, which are expected to be activated in December 2025 and commence recruitment in January 2026. The inclusion of these sites supports Paradigm's focus on maintaining commercial readiness, ensuring strong timeline management, and enhancing data robustness across its pivotal Phase 3 program, while also expanding the Company's geographic footprint to include two additional high-performing regions.

Establishing a clinical presence in Hong Kong provides strategic alignment with the region's recently introduced "1+" regulatory mechanism. This pathway allows new drugs approved by a single recognised reference authority (rather than the previous requirement for two) to apply for registration in Hong Kong, provided supporting local clinical data and expert recognition are submitted[1]. The mechanism also enables potential extension of access to designated hospitals within the Greater Bay Area (GBA), representing a catchment of around 80 million people. By simplifying registration and accelerating access, the "1+" framework enhances Paradigm's future regulatory and commercial flexibility across both Hong Kong and the broader GBA region.

The Moldova sites offer complementary access to high-quality clinical infrastructure, experienced investigators, and a patient population suited to OA studies, enhancing diversity and data quality within the Phase 3 trial.

**Paradigm's Chief Medical Officer, Dr Donna Skerrett, commented:** "*We are pleased to welcome NBCD as a partner working alongside Advanced Clinical and our internal clinical operations team. NBCD brings deep musculoskeletal and OA trial experience, and the addition of these strategically chosen sites strengthens both the scientific and operational foundations of our pivotal Phase 3 program. Hong Kong, in particular, provides a meaningful bridge to the Greater Bay Area under the new '1+' framework, creating future regulatory and commercial optionality*."

NBCD A/S is a Copenhagen based CRO with deep expertise in musculoskeletal and osteoarthritis trials, combining scientific credibility with operational excellence. As part of the Nordic Bioscience group, NBCD has led multiple global OA programs and is recognised for its biomarker-driven trial design, robust data management, and strong site performance across Europe and Asia. NBCD's involvement adds specialist OA capability and strengthens data quality within Paradigm's global Phase 3 program.

Screening and recruitment across the Phase 3 PARA_OA_012 study continue to progress well, with patient enrolment rates tracking to plan. The Company confirms that the interim analysis remains on track for mid-2026, consistent with previously communicated timelines.

## 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.

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Authorised for release by the Paradigm Board of Directors.

Reference

1. https://www.drugoffice.gov.hk/eps/do/en/pharmaceutical_trade/onePlus_faq.html

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