

## **Paradigm Selects Advanced Clinical as CRO for Phase 3 Clinical Trial**

### **KEY HIGHLIGHTS**

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- Paradigm has selected Advanced Clinical as its preferred Clinical Research Organisation for the Phase 3 trial (PARA\_OA\_012).
  - Advanced Clinical has a proven track record in osteoarthritis research, offering strong therapeutic expertise, global reach, operational excellence, and a patient-centric approach to trial execution.
  - The PARA\_OA\_012 study will enrol approximately 466 participants to assess PPS treatment for knee OA pain. With Advanced Clinical onboard, Paradigm is preparing for site activation and patient recruitment, targeting first participant dosed in Q2 CY2025.
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**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 the conclusion of its selection process for the Clinical Research Organisation (CRO) to support its pivotal phase 3 clinical trial, PARA\_OA\_012. Following a comprehensive review of capabilities, meetings, and program proposals, Paradigm has selected Advanced Clinical as its preferred partner for the execution of this critical trial.

Paradigm conducted an extensive evaluation process involving seven global CROs with expertise in osteoarthritis (OA) clinical research. From this group, the company shortlisted four CROs to provide detailed programme plans, including site activation and patient recruitment timelines. After thorough analysis and comparison, Advanced Clinical emerged as the optimal partner, demonstrating exceptional capabilities and alignment with Paradigm’s strategic goals for the phase 3 PARA\_OA\_012 trial.

**Paul Rennie, Managing Director of Paradigm, commented:** *“We are delighted to partner with Advanced Clinical for our pivotal phase 3 clinical trial, PARA\_OA\_012. Advanced Clinical’s expertise in clinical trial execution, regulatory strategy, and patient engagement makes it an ideal partner for Paradigm as we execute on the pivotal phase 3 osteoarthritis trial. With global capabilities and a strong track record in OA research, Advanced Clinical will support Paradigm in delivering a seamless trial, ensuring regulatory success, and accelerating the development of transformative therapies. This partnership represents a critical step forward in our journey to improve the lives of those suffering from osteoarthritis with the treatment of iPPS.”*

### **Next Steps**

With Advanced Clinical now onboard as the preferred CRO, Paradigm is focused on the next phase of trial preparation, including site activation and patient recruitment. Paradigm is anticipating centralised ethics approval for Australia to be received shortly, with the first sites to be activated in Victoria and up to 10 sites total across Australia. Following site

activation recruitment activities will commence with the first participant dosing anticipated in Q2 CY2025.

### About Advanced Clinical

Advanced Clinical is a leading global clinical development and strategic resourcing organization with a strong track record in managing complex clinical trials. Established in 1994, the company has become a trusted partner for emerging biopharma clients, delivering customised solutions across various therapeutic areas, including musculoskeletal disorders and osteoarthritis.

Headquartered in Chicago, Illinois, United States, Advanced Clinical has a global presence across North America, Europe, and Asia-Pacific (APAC). This reach allows the company to offer the scale and resources of a large organisation while maintaining the personalised service and responsiveness of a mid-market firm. Its experienced, award-winning leadership team ensures high-quality service and expert guidance throughout every clinical engagement.

Advanced Clinical brings deep expertise in osteoarthritis clinical programs, using innovative strategies to enhance patient recruitment, retention, and site engagement. The organisation has successfully partnered with pharmaceutical and biotech companies worldwide to execute trials efficiently, ensuring regulatory compliance and high-quality data collection. By combining therapeutic expertise with technology-driven solutions, Advanced Clinical helps accelerate the development of new osteoarthritis treatments while optimising trial execution.

Key strengths of Advanced Clinical include:

- **Therapeutic Expertise:** Extensive experience in musculoskeletal disorders, pain management, and osteoarthritis trials, with a strong understanding of disease progression and regulatory requirements.
- **Global Reach:** Headquartered in Chicago with operations in North America, Europe, and APAC, ensuring broad patient access through an established network of clinical sites and investigators.
- **Operational Excellence:** Proven capabilities in site activation, streamlined trial logistics, and data management, underpinned by advanced technology platforms.
- **Patient-Centric Approach:** Innovative strategies to improve patient engagement and retention throughout the clinical trial process.

### About PARA\_OA\_012

PARA\_OA\_012 is a randomised, double-blind, placebo-controlled, multi-centre study that will evaluate the dose and treatment effect of injectable pentosan polysulfate sodium (iPPS) in participants with knee OA pain. The study's primary objectives focus on pain reduction and functional improvement as measured by validated scales. The trial is expected enrol approximately 466 participants in a 1:1 randomisation design, with an interim analysis planned after the Day 112 pain data from approximately 50% of the total sample size has been collected.

This phase 3 trial builds on the positive outcomes of Paradigm's previous phase 2 studies, including the PARA\_OA\_008 trial, which demonstrated significant clinical benefits in pain reduction and improved joint function for up to 12 months in patients treated with iPPS .

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### **About Paradigm Biopharmaceuticals Ltd.**

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 iPPS, such as in osteoarthritis (phase 3) and mucopolysaccharidosis (phase 2).

### **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.

To learn more please visit: <https://paradigmbiopharma.com>

Approved for release by the Paradigm Board of Directors.

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