

## **Australian Ethics Approval Received for Paradigm's PARA\_OA\_002 Pivotal Phase 3 Clinical Trial in Participants with Knee OA.**

**Paradigm Biopharmaceuticals Ltd (ASX: PAR) (Paradigm or the Company)**, a clinical stage biopharmaceutical company focussed on repurposing existing molecules for new indications with unmet medical needs, is pleased to announce it has received Australian ethics approval for its pivotal Phase 3 clinical trial, PARA\_OA\_002, to evaluate the treatment effects of pentosan polysulfate sodium (PPS) against placebo on participants with Knee Osteoarthritis Pain.

The primary endpoint in the pivotal study will be change from baseline at Day 56 in WOMAC™ pain with secondary outcomes to include change from baseline at multiple time points out to day 168 in WOMAC™ Pain and Function, Patient Global Impression of Change (PGIC) and Quality of Life (QoL).

Paradigm has identified 8 sites across 5 states (Vic, WA, Qld, SA and NSW) to conduct the Australian arm of the PARA\_OA\_002 study, with patient recruitment and screening to commence during Q4. The Company expects to receive a response from the US FDA prior to the end of September, for its Investigational New Drug (IND) application to begin the US arm of the study.

ClinicalTrials.gov Identifier: [NCT04809376](https://clinicaltrials.gov/ct2/show/study/NCT04809376)

### **Mr. Paul Rennie, Paradigm's Chief Executive Officer said:**

*"We are pleased to report that preparations to commence our Phase 3 clinical trial are progressing whilst we await the US FDA's response, expected at the end of September. We expect that, in addition to the 8 Australian sites, there will be clinical sites in UK and Europe and, subject to the FDA's response, in the US. Our preparation to expand into these additional sites is well underway. Commencing the Phase 3 clinical study is a significant milestone for the Company."*

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### **About WOMAC™ Scores**

The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)™ is a widely used, proprietary set of standardized questionnaires used by health professionals to evaluate the condition of patients with osteoarthritis of the knee and hip, including pain, stiffness, and physical functioning of the joints. It consists of 24 items divided into 3 subscales<sup>[8]</sup>:

- **Pain** (5 items): during walking, using stairs, in bed, sitting or lying, and standing upright.
- **Stiffness** (2 items): after first waking and later in the day.

- **Physical Function** (17 items): using stairs, rising from sitting, standing, bending, walking, getting in / out of a car, shopping, putting on / taking off socks, rising from bed, lying in bed, getting in / out of bath, sitting, getting on / off toilet, heavy domestic duties, light domestic duties.

### About injectable PPS

Injectable PPS is not currently registered in Australia. Injectable PPS for human use is currently only available by inclusion into a Paradigm-sponsored clinical trial or via the Therapeutic Goods Administration (TGA) Special Access Scheme (SAS) under limited and specific circumstances.

### About Paradigm Biopharmaceuticals

Paradigm Biopharmaceuticals LTD (ASX: PAR) is a late-stage drug development company with the mission to develop and commercialise PPS for the treatment of pain associated with musculoskeletal disorders driven by injury, inflammation, aging, degenerative disease, infection or genetic predisposition.

### 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 Paul Rennie, CEO & Interim Chairman.

Zilosul® is a registered Trademark of Paradigm Biopharmaceuticals Ltd (ASX: PAR).

To learn more please visit: [www.paradigmbiopharma.com](http://www.paradigmbiopharma.com)

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