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Paradigm reports important global progress for the PARA_OA_002 phase 3 clinical trial evaluating Zilosul® for osteoarthritis.

KEY HIGHLIGHTS

- Regulatory and ethics approval are in place for the UK. The first UK screening site for the phase 3 study is now active, enabling Paradigm to commence screening and enrolling participants.
- Regulatory approval for the Para_OA_002 phase 3 trial has been granted by Health Canada

Paradigm Biopharmaceuticals Ltd (ASX: PAR) ("Paradigm" or "the Company"), a clinical stage biopharmaceutical company focussed on repurposing existing molecules for new indications with unmet clinical needs, is pleased to announce it has activated the first trial site in the UK. The Company has received UK regulatory and ethics approvals to proceed with the Para_OA_002 phase 3 clinical trial evaluating knee osteoarthritis (**OA**). Now that the first site is activated in the UK participant screening and enrolment will begin imminently. This first site is located at the University of Leeds under lead investigator Prof. Hemant Pandit. Paradigm aims to activate a total of seven sites across the UK for the phase 3 study. The remaining sites will be activated in the coming months.

Paradigm is also pleased to announce that the global PARA_OA_002 phase 3 osteoarthritis clinical trial has regulatory approval from Health Canada. An ethics submission has been made to the research ethics board in Canada, with approval pending. Once ethics approval has been granted, Paradigm will activate clinical sites to begin participant screening and enrolment for the phase 3 study. Paradigm plans to activate up to 10 sites across Canada.

Paradigm's phase 3 trial now has regulatory approvals to proceed from the US FDA, the UK Medicines and Healthcare products Regulatory Agency (MHRA), Health Canada, and the Australian TGA. Recruitment milestones will be announced as they are achieved.

Dr Donna Skerrett, Paradigm CMO commented: "*I am pleased we are moving forward with regulatory approval within another planned jurisdiction for the global phase 3 program. The interaction with Health Canada was positive throughout the regulatory process and the Company looks forward to announcing anticipated ethics approval and subsequent participant recruitment in Canada. Equally, the achievement by the Paradigm team to activate participant recruitment in the UK highlights Paradigm's ongoing execution of activities for this global phase 3 trial in knee OA.*".

About the Global Phase 3 Trial (Para_OA_002)

The purpose of this study is to measure the change in pain and function with subcutaneous injections of PPS compared with subcutaneous injections of placebo in participants with knee osteoarthritis (kOA) pain. This is a two-stage, adaptive, randomised, double-blind, placebo-controlled, multicentre (US/CAN/AUS/UK/EU) study that will evaluate the dose and treatment effect of PPS in participants with kOA pain. Stage 1 will comprise dose selection in phase 2b, with participants randomised receiving 1 of 3 PPS dose regimens or placebo for 6 weeks. The primary objective of stage 1 will be to select the dose for use in stage 2 and Paradigm's subsequent confirmatory trial (PARA_OA_003), the selected dose will be based on an optimal balance of efficacy and safety.

In stage 2, participants will be randomised 1:1 to receive the selected PPS dose regimen or placebo for 6 weeks. The primary endpoints in the pivotal study are change from baseline at Day 56 in the standardised WOMAC® pain questionnaire 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) assessments.

The global PARA_OA_002 phase 3 clinical trial is currently screening and enrolling participants in Australia, the US, and now the UK with sites in Europe and Canada to be activated in the 2H CY22.

Additional information on Paradigm's clinical trials can be found at ClinicalTrials.gov (002 - NCT04809376, 006 - NCT04814719) or via the Paradigm website www.paradigmbiopharma.com.

About Paradigm Biopharmaceuticals

Paradigm Biopharmaceuticals LTD (ASX: PAR) is a late-stage drug development company whose mission is to develop and commercialise Pentosan Polysulfate Sodium 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.

Authorised for release by the Paradigm Board of Directors.

To learn more please visit: www.paradigmbiopharma.com

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