ASX RELEASE 17th March 2022

Paradigm has received regulatory and ethics approvals for the PARA_OA_002 clinical trial in the UK.

KEY HIGHLIGHTS

- Regulatory and ethics approval has been received from the Medicines and Healthcare products Regulatory Agency (**MHRA**) in the United Kingdom (**UK**).
- Paradigm now has all the required approvals in place to commence clinical trial site activation in the UK for PARA_OA_002.
- Paradigm was granted permission to become part of the pilot test phase rollout of the combined regulatory and ethics applications, thereby reducing both time and costs.
- 5 sites in the UK are planned for initiation and activation to enrol participants with knee OA into the PARA_OA_002 study.

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 received regulatory and ethics approval from the MHRA in the UK. Paradigm now has all the required approvals in place to commence clinical trial activities in the UK for its global Phase 3 PARA_OA_002 clinical trial and expects to imminently commence enrolling participants with knee OA into the PARA_OA_002 study in 5 sites in the UK.

On January 1st, 2022, the UK implemented a new system for a combined review of Regulatory and Ethics applications for Clinical Trials of Investigational Medicinal Products (**CTIMPs**). The combined review offers the sponsor (Paradigm) a single application submission and co-ordinated review leading to a single UK decision for CTIMPs. Prior to the implementation of the new system, Paradigm was granted permission to become part of the pilot test phase roll out. As early adopters of the new process, Paradigm received additional support and direct communication from the UK regulators, a consolidated regulatory and ethics review, quicker review times, and reduced costs.

Dr Donna Skerrett, Paradigm Chief Medical Officer and Interim CEO commented: "*We are very pleased to have received the combined regulatory and ethics approval in the UK from the MHRA, which is another milestone, as we continue to progress with clinical site initiation of our phase 3 PARA_OA_002 study in Australia, the US and now in the UK*".

About Paradigm Biopharmaceuticals

Paradigm Biopharmaceuticals LTD (ASX: PAR) is a late-stage drug development company with the mission 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 Paradigm Chairman, Mr Paul Rennie.

To learn more please visit: www.paradigmbiopharma.com

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