ASX RELEASE 25th May 2021

INVESTIGATIONAL NEW DRUG (IND) APPLICATION QUESTIONS RECEIVED FROM US FOOD AND DRUG ADMINISTRATION (FDA)

Paradigm Biopharmaceuticals Ltd (ASX: PAR), a clinical stage biopharmaceutical company focussed on repurposing existing molecules for new indications with unmet clinical needs, reports it has received written feedback regarding the IND submission for our pivotal study evaluating PPS in knee OA.

The agency's feedback contained its positions and questions principally in relation to recently completed nonclinical studies. The agency also provided its suggested mitigation strategies to address its positions and questions, which included further detailed clinical monitoring.

Paradigm's responses to the FDA questions will include mitigation strategies consistent with the FDA's suggestions as well as clarification of existing study data. Paradigm is on track to submit its complete response to the agency within 30 days. A review and response from the FDA will then be due within 30 days of the receipt of Paradigm's response.

In parallel, Paradigm is continuing Phase 3 study start-up preparation at sites in the US and Australia. Additional sites may be added in order to ensure completion of this pivotal study, within the planned commercialisation timelines.

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 guaranteeing nor predicting 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 Paul Rennie, CEO & Chairman.

To learn more please visit: www.paradigmbiopharma.com

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