

INVESTIGATIONAL NEW DRUG (IND) APPLICATION UPDATE

Paradigm Biopharmaceuticals Ltd (ASX: PAR), a clinical stage biopharmaceutical company focussed on repurposing existing molecules for new indications with unmet clinical needs, reports today an update on its IND application to the US Food and Drug Administration (**FDA**) for the proposed pivotal clinical trial treating subjects with pain associated with Knee Osteoarthritis (**OA**).

Paradigm previously reported it submitted its over 30,000-page IND application to the US FDA, Friday 26th March 2021, and to date Paradigm has received few questions from the FDA during the current 30-day IND review period. Those few questions were answered by Paradigm within 48 hours of receipt.

On Friday April 23, Paradigm received a verbal indication from the FDA that the FDA would be putting further questions to Paradigm outside the 30-day IND review period. The FDA was unable to provide all questions within the initial IND review period and has advised it will submit them to Paradigm within the next 30 days. Many of the questions which, as we understand from the brief discussion with the FDA, are related to newly submitted non-clinical data (as part of the IND application).

Paradigm is ready to review and answer questions when they are received. Once in receipt of Paradigm's responses, the FDA will review within 30 days.

Paradigm is committed to keeping investors up to date with our development program and will update the timeline once we receive clarity.

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 & Interim Chairman.

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To learn more please visit: www.paradigmbiopharma.com

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