

## **PARADIGM SUBMITS RESPONSES TO US FDA QUESTIONS**

**Paradigm Biopharmaceuticals Ltd (ASX: PAR) (Paradigm)**, a clinical stage biopharmaceutical company focussed on repurposing existing molecules for new indications with unmet clinical needs, can report that the US Food and Drug Administration (**FDA**) has received Paradigm's responses to questions on its Investigational New Drug (**IND**) application.

In preparing its response, Paradigm consulted with multiple experts, including a US board certified pre-clinical toxicologist and a senior former FDA physician, to review the document and ensure the document contains sufficient information to be completely responsive to the questions raised by the agency. Paradigm believes the input from these experts increase the likelihood that Paradigm's response will meet the FDA requirements to be considered complete and sufficient for proceeding.

The FDA will now review Paradigm's responses over the next statutory 30-day (calendar) period within which they are required to respond. Paradigm will notify the market once it has been notified of an outcome by the FDA.

**Paradigm CMO, Dr Donna Skerrett, said:** *"We have responded to the FDA's questions following diligent reviews with our Internal team and consultants. We believe these responses are sufficient to assure the agency the program is supported by non-clinical and clinical data and that the objectives, rationale, and study design will aim to demonstrate the safety and effectiveness of PPS for patients with painful osteoarthritis of the knee. There is a clear unmet need for patients who have not had adequate responses to initial therapy for knee OA and have ongoing pain. Prior experience with PPS in clinical and nonclinical settings has demonstrated the potential to address this unmet need."*

**Paradigm CEO, Mr Paul Rennie, commented:** *"Feedback from the peer-review process confirms that Paradigm's clinical and regulatory teams have answered the FDA's questions with the detail expected by the FDA. Paradigm will inform the market once it has received feedback from the US FDA."*

*I would also like to highlight that Paradigm, during the self-imposed 30-day response time to the FDA questions, has progressed pre-clinical studies in two new indications of acute respiratory distress syndrome (**ARDS**) and heart failure at study centres in Australia and Europe, respectively. As recently announced, the orphan drug indication of MPS VI has received regulatory and ethics approval in Brazil for its Phase 2 clinical trial. Paradigm continues to execute on its disease-modifying osteoarthritis clinical trial PARA\_008. The Company has also filed two new patents over the use of PPS in new clinical indications with high unmet clinical needs."*

## 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, as well as other indication with high unmet medical need.

## Forward Looking Statements

This Company announcement contains forward-looking statements, including statements regarding anticipated commencement dates or completion 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 document. Readers are cautioned not to put undue reliance on forward-looking statements.

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Authorised for release by the Paradigm Board of Directors.

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

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