ASX RELEASE 3rd AUGUST 2021

PARADIGM MAKES PROGRESS WITH IND APPLICATION. FDA REQUIRES CLARIFICATION ON ONE QUESTION. CLINICAL STARTUP ACTIVITES CONTINUE IN AUSTRALIA AND EUROPE

Paradigm Biopharmaceuticals Ltd (ASX: PAR) ("Paradigm" or "the Company"), reports it has received written feedback from the US Food and Drug Administration (**FDA or the Agency**) 30th July 2021, regarding Paradigm's Investigational New Drug (**IND**) application submitted 26th March 2021.

Paradigm previously reported (ASX announcement 25th May 2021) it had received written feedback from the US FDA, requesting answers to six questions relating to Paradigm's IND submission. The Company provided a response to the six questions raised by the FDA (ASX announcement 30th June 2021) triggering another 30-day review period.

Response received from the US FDA

Paradigm received a written response from the FDA on 30th July, in which the Agency accepted Paradigm's responses to five of the six questions received. The FDA response requires further clarification on one remaining question. The question is directed at the non-clinical interpretation and clinical mitigation relating to one of Paradigm's recently completed GLP non-clinical toxicology studies. Paradigm conducted 26 non-clinical studies in 2020 at the request of the US FDA, to provide a GLP non-clinical portfolio of injectable PPS. Of the 26 non-clinical studies conducted, the FDA is seeking clarification on only one rat GLP study.

Based on the response received from the Agency, Paradigm will undertake the following:

1. Complete the response with the assistance of expert clinical and non-clinical consultants. The response will include clarification on the non-clinical question and mitigation plan in the protocol.
2. Continue its global phase 3 clinical trial start-up activities in Europe and Australia.

The Company anticipates submitting the requested information to the FDA within the month. Paradigm will notify the market once feedback from the Agency is received.

Plans to open the pivotal Para_OA_002 OA clinical trial in Australia is continuing. Eight sites have been selected and the protocol has ethics approval. The market will be informed once clinical trial sites have been initiated and screening of participants begin. Paradigm is on schedule to commence screening participants in Australia during Q4 CY 2021. Site selection activities are currently underway in Europe.

Dr Donna Skerrett, Paradigm Chief Medical Officer:
"For new indications that impact large populations, such as osteoarthritis, a thorough and iterative process with the FDA for initiating the pivotal registration studies is common practice. Even though the pace of progressing the clearance process has been slowed due to COVID-19 resulting in all communications being written, we are confident that we can address the FDA's one remaining question. We look forward to resolving the one outstanding question with the FDA and moving froward with our pivotal program in the US, Europe and Australia."

Conference Call for Investors

Paradigm will be hosting a conference call for investors via the Lumi platform to discuss the response from the US FDA. Current and potential investors will be able to participate online via https://web.lumiagm.com on your smartphone, tablet or computer.

Meeting Details:

Event: Paradigm Biopharmaceuticals (PAR) Investor Call

Time: AUS: Tuesday 3rd August, 11:00am (AEST)
US: Monday 2nd August, 9:00pm (Eastern)

Meeting Link: https://web.lumiagm.com/m#/300830238

Meeting ID: 300 830 238

About injectable PPS

Pentosan polysulfate sodium (PPS) is a medication that has been used in humans for over 60 years. Injectable PPS has previously been approved in European markets, where it is registered as an antithrombotic agent. In Australia, injectable PPS for human use is not currently available for sale. Injectable PPS is available via a Paradigm sponsored clinical trial or under the TGA Special Access Scheme to physicians for individual patients who satisfy strict criteria and is subject to approval from the TGA. Elmiron (the oral formulation utilised for interstitial cystitis) is the only PPS product approved in the US, with the injectable form of PPS currently being evaluated by Paradigm for potential registration for the treatment of osteoarthritis and other inflammatory diseases in the US and other major global markets.

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 the Paradigm Board of Directors.

To learn more please visit: www.paradigmbiopharma.com

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