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# PARADIGM RECEIVES FEEDBACK FROM US FDA ON IND SUBMISSION

**Paradigm Biopharmaceuticals Ltd (ASX: PAR) (Paradigm or the Company),** wishes to inform the market it has received a written response from the US FDA in relation to its Investigation New Drug (IND) submission for pentosan polysulfate sodium (PPS) to treat pain in subjects with knee Osteoarthritis. In response to the FDA's one request, Paradigm will make an amendment to Its protocol.

## Response received from the US FDA

The one outstanding question regarding adrenal gland function related to a preclinical finding in the adrenal gland of rats only and was not seen in the adrenal gland of dogs. Adrenal gland malfunction has not previously been seen by Paradigm or bene pharmaChem in their ongoing pharmacovigilance. This one preclinical finding has been the focus of the ongoing US FDA review. Paradigm, working with external endocrinologists, presented changes to the clinical trial protocol, which included a comprehensive adrenal screening protocol and clinical monitoring as part of its mitigation plan. In the written communication, the FDA requested modifications to Paradigm's adrenal screening and mitigation plan. Paradigm plans to amend its clinical trial protocol, including all the FDA's requests, and respond to the FDA within the next week. Paradigm assumes the FDA may again take 30 days to respond.

**Mr Paul Rennie, Paradigm Chief Executive Officer:**
*"Although we understand the agency's obligations for thorough reviews which commenced in March of this year, I am confident that the FDA and Paradigm have now attained a pathway to commence our phase 3 clinical trial in the US".*

## 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.

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Authorised for release by the Paradigm Board of Directors.

To learn more please visit: www.paradigmbiopharma.com

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