

# PARADIGM BIOPHARMACEUTICALS LIMITED



ASX RELEASE

21<sup>st</sup> February 2020

## Paradigm reports Positive Pre-IND meeting with US FDA

### KEY HIGHLIGHTS

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- Paradigm reports it had a positive and informative Pre-IND meeting to discuss the development and market authorisation plans for injectable Pentosan Polysulfate Sodium (iPPS) (Zilosul) for the treatment of symptomatic osteoarthritis.
  - Paradigm will provide further information to the market by receipt of final minutes from the US FDA.
  - Development plans are proceeding toward an IND filing by Q4 CY2020.
  - The company is fully funded for the proposed Phase 3 Clinical Trial.
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**Paradigm Biopharmaceuticals Ltd (ASX: PAR) 21 February 2020:** ASX listed biotechnology company Paradigm Pharmaceuticals Limited (ASX: PAR, “Paradigm” or the “Company”) is pleased to announce a positive and informative pre-IND meeting with the US FDA. The meeting took place at the FDA offices in Washington and was attended by several of the Paradigm team and consultants.

In the Pre-IND meeting Paradigm discussed its clinical, pre-clinical and CMC (Manufacturing) data with the US FDA.

Paradigm will provide further information from the Pre-IND meeting to the market by receipt of final minutes from the US FDA.

**Mr. Paul Rennie, Paradigm’s Chief Executive Officer said:**

*“The team and I are pleased with the positive feedback from the FDA at the Pre-IND meeting that took place yesterday. Paradigm looks forward to providing a more detailed update to the market once the final minutes of the meeting have been received.”*

**About injectable PPS (iPPS)**

Injectable PPS (iPPS) is not currently registered in Australia, but it was previously registered in four of the seven major global pharmaceutical markets. In those European markets, iPPS is registered as an antithrombotic agent. In Australia, iPPS for human use is not currently available for sale.

**Zilosul® is a registered Trademark of Paradigm Biopharmaceuticals Ltd (ASX: PAR).**

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