

PARADIGM BIOPHARMACEUTICALS LIMITED



ASX RELEASE

14th December 2020

Phase 3 OA Clinical Program Update

Paradigm Biopharmaceuticals Ltd (ASX: PAR) is pleased to provide clarification to the market on the timeline for the proposed Phase 3 OA clinical program.

Timelines

Paradigm can confirm that Phase 3 data will be generated by Q1 CY 2023 and the market will be informed of the top-line results once the clinical data has been analysed. This is a slight delay, from the previously reported Q4 2022, which resulted from the Covid-19 based delays in the written response from the FDA Type C meeting. Paradigm submitted its briefing documents to the US FDA Type C meeting on 20 July, 2020.

Numbers in the trial

Over the past 12 months Paradigm has been in regular contact with both the EMA and FDA regarding the Phase 3 clinical trial design and the number of clinical trial subjects may be increased to reflect the feedback from the FDA Type C response.

Full details of the timing of the Phase 3 data and the numbers in each study will be presented at the Company's R&D day, 21st December 2020, which is as soon as possible after we anticipate receiving the Type C meeting feedback.

About Paradigm Biopharmaceuticals

Paradigm Biopharmaceuticals LTD (ASX: PAR) is a late-stage drug development company with the mission to develop and commercialise pentosan polysulphate sodium for the treatment of pain associated with musculoskeletal disorders driven by injury, inflammation, aging, degenerative disease, infection or genetic predisposition.

Authorised for release by Paul Rennie, CEO & Interim Executive Chairman.

To learn more about Paradigm Biopharmaceuticals please visit: www.paradigmbiopharma.com

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