PARADIGM BIOPHARMACEUTICALS LIMITED

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Paradigm Receives Written Response from Type-C Meeting with FDA Regarding Development of Zilosul® for OA

KEY HIGHLIGHTS

- **Paradigm has received written feedback from the Type-C meeting with the FDA and Paradigm confirms it will proceed to an Investigational New Drug (IND) submission in Q1 CY 2021.**
- **Paradigm confirms the same clinical trial protocol will be used in the USA, Europe and Australia potentially enabling registrations in multiple jurisdictions saving time and money.**
- **To achieve regulatory harmonization across the FDA and EMA, Paradigm will increase the proposed number of clinical trial study participants in its OA Clinical Program.**
- **Details of all clinical studies and study participant numbers will be presented at Paradigm's Inaugural R&D Day.**
- **FDA provided guidance regarding the pivotal study design for Zilosul® and expectations for a future New Drug Application (NDA) submission.**

Paradigm Biopharmaceuticals Ltd (ASX: PAR) is pleased to advise the Company has received the written response from the Type-C meeting with the US Food and Drug Administration (FDA) regarding Zilosul® for the treatment of Osteoarthritis. As previously reported, Paradigm submitted a request for a Type-C meeting in July 2020 with the briefing pack submitted to the US FDA on the 23rd of October. Paradigm's goal has been to gather and consolidate feedback from the US FDA, EMA, and TGA to have a pivotal protocol acceptable to all major jurisdictions and streamline the approval process in multiple key markets.

The FDA provided guidance with regard to the overall program for Zilosul® for the treatment of OA. The Agency reviewed and provided written responses to the following areas of Paradigm's pivotal clinical trial program:

- Primary Endpoint,
- Patient Population,
- Statistical Analysis Plan (SAP),
- Safety Population,
- Non-Clinical Studies, and

- Retreatment Schedule, which would support a future NDA submission and registration once the program is successfully concluded.

As a result of the feedback received from the Type-C meeting, Paradigm is finalising its IND for submission to the FDA in Q1, CY2021. The Company has already begun the planning and start-up phase for Zilosul® and once the IND is open clinical trial participants from the USA and Australia will be enrolled into Paradigm's pivotal Phase 3 randomised double-blind, placebo controlled, multicentre, multinational clinical trial (PARA002). PARA002 will firstly determine the minimally effective dose and then investigate the safety and efficacy of Zilosul in subjects with osteoarthritis (Kellgren Lawrence Grade 2-4). Paradigm is targeting enrolling the first patient for its clinical program in mid CY2021. Based on this timetable, the Company would expect top-line efficacy results in Q1 CY2023. The proposed number of sites in the USA will be up to 55, with up to an additional 10 sites in Australia.

PARA003 is the confirmatory study for PARA002 and will confirm the safety and efficacy in clinical trial subjects from Europe. Like PARA002, PARA003 will be a randomised double-blind placebo controlled, multicentre, clinical trial and has a proposed top-line readout timeline of Q3 CY 2023.

To maximise the commercial value of the OA asset, Paradigm will undertake additional clinical studies which will run concurrently with the pivotal Phase 3 clinical trials. Further detail will be shared at the inaugural R&D Day on the 21st December at 11:00am (AEDT).

Paradigm CEO and Interim Chairman, Paul Rennie said: *"Paradigm is grateful to the US FDA for their feedback. Paradigm is confident that it has all the necessary information and clarity for a pivotal Phase 3 program to now make an IND application in Q1 CY 2021. Paradigm has appointed its CRO in the USA and Australia. Paradigm can confirm preparatory work on its pivotal Phase 3 clinical trial has commenced but obviously no clinical trial subjects can be treated, with the investigational product (Zilosul®), until the FDA IND is open."*

Dr Skerrett Paradigm's Chief Medical Officer and executive director said: *"the FDA feedback to the Type C meeting was very valuable for Paradigm's Phase 3 clinical development plans for Zilosul (PPS) in the treatment of subjects with osteoarthritis. The feedback confirmed the FDA's views on the primary endpoint, patient population, statistical analysis plan, the safety population, re-treatment of patients with Zilosul (a re-treatment plan is expected as osteoarthritis is a chronic condition) and other general aspects of the clinical trial design including the use of placebo (saline)". Given this feedback, Paradigm is confident it can submit its Investigational New Drug (IND) application in Q1 CY 2021 and can continue with our harmonised global registration plans".*

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.

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 guarantees or predictions of 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. The rate and timing of enrolment of our clinical trials and the timing of top-line results of our clinical trials should be regarded as forward-looking statements and the actual dates could differ materially from the expectations and projections set forth in Company presentations or statements especially during a pandemic.

Approved for Release by Paul Rennie, CEO and Interim Chair

To learn more please visit: www.paradigmbiopharma.com

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