

PARADIGM DOSES FIRST PARTICIPANT IN PARA_OA_008 CLINICAL TRIAL EXPLORING SYNOVIAL BIOMARKERS

KEY HIGHLIGHTS

- First participant in the PARA_OA_008 study has been dosed at Sportsmed Biologic in Box Hill, Victoria.
 - The study will investigate changes in knee synovial fluid biomarkers associated with pain, inflammation and disease progression of knee OA.
 - This is a randomised, double-blind, placebo-controlled phase 2 study to investigate PPS or placebo treatment in a total of 60 (n=60) participants.
 - Additional patients have commenced screening and may proceed to dose randomisation once this process has been completed.
 - Paradigm will update investors on key study milestones throughout the PARA_OA_008 study as they are achieved.
 - This study is designed to generate clinical data which will inform Paradigm of the potential Zilosul® has as the first in class Disease Modifying Drug for Osteoarthritis (DMOAD).
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Paradigm Biopharmaceuticals Ltd (ASX: PAR) ("Paradigm" or "the Company") is pleased to announce it has enrolled the first patient in the exploratory PARA_OA_008 knee OA Biomarker study. The participant has been randomized and has begun study procedures, including joint aspiration to collect baseline biomarker synovial fluid Information, at Sportsmed Biologic in Box Hill, Victoria. The treatment phase has now commenced with the participant receiving the first dose of injectable Pentosan Polysulfate Sodium (iPPS) or Placebo and will continue at two injections a week subcutaneously for a six-week period.

Paradigm previously reported ethics approval¹ and trial design for the knee OA Biomarker study with the primary purpose of this Phase 2b study to measure the change in synovial fluid biomarkers associated with pain, inflammation and osteoarthritis disease progression following treatment with subcutaneous injections of pentosan polysulfate sodium compared with subcutaneous injections of placebo in participants with knee OA. Sixty (n=60) participants with Kellgren-Lawrence grade 2, 3 or 4 and have OA pain will be enrolled and randomised 1:1 to receive either PPS (n=30) or placebo (n=30). Participants will receive twice weekly subcutaneous injections for six weeks.

Paradigm can report that additional participants have commenced the screening process and may begin the treatment phase over the next few weeks, subject to meeting inclusion criteria. The company intends to update investors on key study milestones as they are achieved. The primary endpoint data is expected to read out in 2H CY2021.

Paradigm CEO and Chairman, Paul Rennie, commented: *"We are very pleased to have progressed to the treatment phase of the knee synovial fluid Biomarker study, by dosing of the first participant. This study has been designed to generate clinical data which will inform of the potential of Zilosul® as the first in class disease modifying OA*

drug (DMOAD). Additionally, the data generated will form part of Paradigm's submission package to the TGA for the next step of the provisional approval application".

About Osteoarthritis

Osteoarthritis (OA) is the most common joint disorder in the United States. Symptomatic knee OA occurs in 10% men and 13% in women aged 60 years or older. The number of people affected with symptomatic OA is likely to increase due to the aging of the population and the obesity epidemic. Current estimates indicate that there are 14 million U.S. adults with symptomatic knee osteoarthritis². The overall number of U.S. adults affected by OA in any joint has increased during recent decades and is estimated to affect over 30 million U.S. adults today, primarily due to an aging population and an ever-increasing prevalence of obesity³.

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 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.

¹ASX Announcement 18th February: https://asx.api.markitdigital.com/asx-research/1.0/file/2924-02343035-3A561598?access_token=83ff96335c2d45a094df02a206a39ff4

² Deshpande BR, Katz JN, Solomon DH, et al. Number of persons with symptomatic knee osteoarthritis in the US: impact of race and ethnicity, age, sex, and obesity. *Arthritis Care Res (Hoboken)*. 2016;68(12):1743-50.

³ Centers for Disease Control and Prevention. Osteoarthritis. Available at <https://www.cdc.gov/arthritis/basics/osteoarthritis.htm>

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

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