ASX RELEASE 14 March 2023

Paradigm receives parallel European regulatory and ethics approvals for the pivotal PARA_OA_002 global clinical trial.

Key Highlights

- Regulatory and ethics approvals have been received via Europe's Clinical Trial Information System (**CTIS**) for Paradigm's pivotal PARA_OA_002 clinical trial.
- Paradigm now has all required approvals in place to commence clinical trial site start-up activities in Belgium, Poland, and the Czech Republic for the PARA_OA_002 clinical trial.
- The CTIS is a recently implemented system for the evaluation of clinical trial applications and harmonises regulatory and ethics committee reviews by European countries.
- Paradigm is in the process of activating up to seven sites across the three countries to enrol participants with knee osteoarthritis (**OA**) into the PARA_OA_002 study.

Paradigm Biopharmaceuticals Ltd (ASX:PAR) ("Paradigm" or "the Company"), a late-stage drug development company focused on delivering new therapies to address unmet medical needs, is pleased to announce it has received parallel regulatory and ethics approvals for the pivotal PARA_OA_002 clinical trial in Belgium, Poland, and the Czech Republic.

The phase 3 pivotal PARA_OA_002 clinical trial is a randomised, double-blind, placebo-controlled, multicentre (US/AU/UK/EU/CA) study that will evaluate the dose and treatment effect of injectable pentosan polysulphate sodium (**iPPS**) in participants with knee osteoarthritis pain.

Paradigm's PARA_OA_002 application was submitted via Europe's recently implemented the CTIS for evaluation in these three European countries. As such, Paradigm's iPPS dossier underwent harmonised review by the three countries' regulatory and ethics committees, resulting in a single decision to authorise the trial to proceed. Paradigm now has all the required approvals in place to commence clinical trial site start-up activities in these countries for the pivotal PARA_OA_002 global clinical trial. Paradigm has identified sites and is in the process of activating up to seven sites across the three countries to enrol participants with knee OA into the PARA_OA_002 study.

The CTIS has been established in Europe to support the Implementation of Clinical Trial Regulation No 536/2014. The CTIS portal facilitates communication between clinical trial sponsors, European Union (**EU**) Member States, European Economic Area (**EEA**) countries, and the European Commission throughout the lifecycle of a clinical trial. The CTIS portal went live on 31 January 2022 and became mandatory for all clinical trial submissions from 31 January 2023.

Paradigm's Managing Director, Paul Rennie, commented: *"Paradigm's pivotal PARA_OA_002 global clinical protocol continues to gain acceptance and approval by key regulatory bodies. The Company has focused on gaining approval in Poland, Belgium, and the Czech Republic due to the large pool of OA sufferers and number of experienced clinical trial sites with proven recruitment capabilities. This harmonised approval paves the way for further regulatory and ethics applications in additional European countries for the upcoming confirmatory phase 3 clinical trial, PARA_OA_003."*

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About Paradigm Biopharmaceuticals

Paradigm Biopharmaceuticals Ltd. (ASX:PAR) is a late-stage drug development company driven by a purpose to improve patients' health and quality of life by discovering, developing, and delivering pharmaceutical therapies. Paradigm's current focus is developing iPPS for the treatment of diseases where inflammation plays a major pathogenic role, indicating a need for the anti-inflammatory and tissue regenerative properties of PPS, such as in osteoarthritis (phase 3 clinical trial) and mucopolysaccharidosis (phase 2 clinical trial).

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.

Authorised for release by the Paradigm Board of Directors.

To learn more please visit: www.paradigmbiopharma.com

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