

ASX RELEASE 13 July 2022

# Paradigm Partners with NFL Alumni Health on Osteoarthritis Program

#### **KEY HIGHLIGHTS**

- Paradigm as an NFL Alumni Health member has entered into a research partnership to inform NFL Alumni members about osteoarthritis (OA) and potential clinical trial participation.
- NFL Alumni Health is a wholly owned subsidiary of NFL Alumni offering informational resources, programs, services, and other benefits to both NFL Alumni members (former NFL players, coaches, executives, spouses, cheerleaders, and associate members) and the general public.
- Paradigm was introduced to NFL Alumni Health by expanded access program (EAP) participants, who have become strong advocates of Zilosul® for knee osteoarthritis (KOA) treatment based on their positive experiences.
- Paradigm's designation by NFL Alumni Health as a research partner demonstrates Paradigm's leading role in developing a multi-modal nonaddictive treatment for the pain and dysfunction associated with KOA.
- Paradigm previously treated 10 former NFL players suffering from KOA via an FDA-cleared EAP with pentosan polysulfate sodium (**Zilosul**®). At the 12-week time point (6 weeks following final injection), participants experienced an average 65% reduction in pain as assessed with the WOMAC® index.

Paradigm Biopharmaceuticals Ltd (ASX:PAR) (Paradigm or the Company) a clinical stage biopharmaceutical company focussed on repurposing existing molecules for new indications with unmet clinical needs, is pleased to announce it has entered into a corporate partnership with NFL Alumni Health (NFLAH). This partnership will inform NFL Alumni Association (NFLAA) members about osteoarthritis disease onset and progression, current treatment options, and provide information about actively enrolling clinical trials throughout the U.S.

The NFLAA has over 10,000 members and represents former NFL players, coaches, executives, spouses, cheerleaders, and associate members through its 40 chapters across the U.S. NFL Alumni Health is a wholly owned subsidiary of NFLAA offering informational resources, programs, services, and other benefits to NFLAA members and the general public. This division of the NFLAA appraises corporate partners that may provide beneficial research opportunities in health areas relevant to their members. NFL Alumni Health oversee the vetting process to ensure they bring credible and meaningful health sector-related partnerships to their membership. Paradigm's designation as

NFLAH's newest corporate and research partner demonstrates its leading role in developing a safe and effective potential treatment for those suffering with OA.

Kyle Richardson, NFL Alumni Association Co-Director of Healthcare Initiatives, commented on the partnership: "The NFL Alumni Health division of the NFL Alumni Association are driven to provide initiatives that help its members learn more about and gain access to safe and effective treatments through clinical trials and other FDA-approved treatment options. In males under the age of 60, arthritis is over three times more prevalent in retired NFL players than in the general U.S. population. We are pleased to hear the positive experience several of our alumni members have had through working with Paradigm and we hope this partnership will inform a larger number of alumni on the disease of osteoarthritis and the available clinical trials that are currently enrolling participants".

Paradigm previously submitted an IND application for an expanded access program protocol to treat 10 patients for osteoarthritis-associated knee pain with Zilosul®. The US FDA provided clearance for this program to proceed in September 2019. On 30<sup>th</sup> July 2020, Paradigm released the results of this EAP demonstrating that at week 12, the 10 participants treated with Zilosul® achieved an average WOMAC® pain reduction of 65%. Zilosul® was well tolerated in this program.

Paradigm remained in close contact with the EAP physician and participants, leading to an introduction to NFL Alumni Health. The NFL endorsed this partnership following a review of Paradigm's clinical program results as well as the ongoing global registration clinical trial. Paradigm's introduction from such an enthusiastic group within their own membership made Paradigm an ideal partnering candidate to present to their constituency.

Paradigm CEO, Marco Polizzi commented, "Having followed the progress of the expanded access program participants and hearing first-hand the positive impact Zilosul® has had on their lives. Paradigm is honoured to be able to continue to work with NFL Alumni members to inform them of the onset and progression of osteoarthritis and Paradigm's clinical progress through phase 3 as we strive to bring Zilosul® to commercialisation for the millions suffering from the debilitating effects of OA".

Access EAP study results here: <a href="https://paradigmbiopharma.com/performance-progress/#announcements">https://paradigmbiopharma.com/performance-progress/#announcements</a>

NFL Alumni Health: https://nflalumnihealth.org

Osteoarthritis is the most prevalent form of joint disease, affecting up to 16% of the population in the developed world, with more than 72 million people in the US, EU5, Canada, and Australia suffering from it<sup>1</sup>. OA has a significant impact on day-to-day functioning. Although the levels of pain and disability may fluctuate, it has no known cure or spontaneous remission and is associated with irreversible structural damage and progression over time.

## **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 (PPS/Zilosul®) for the treatment of pain associated with musculoskeletal disorders driven by injury, inflammation, aging, degenerative disease, infection or genetic predisposition.

Paradigm is also exploring proof-of-concept studies for the use of PPS in respiratory and heart failure indications.

# **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.

#### References

<sup>1</sup> Global Health Data Exchange, Institute for Health and Metrics Evaluation, University of Washington. Accessed June 2021 http://ghdx.healthdata.org/gbd-results-tool.

Authorised for release by the Paradigm Board of Directors.

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

To learn more please visit: www.paradigmbiopharma.com

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