# PARADIGM BIOPHARMACEUTICALS LIMITED

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## Paradigm reports: first patient dosed in USA under FDA approved Expanded Access Program

### KEY HIGHLIGHTS

- **First Participant dosed with Zilosul® (iPPS) in the US under the FDA approved Expanded Access Program (EAP).**
- **The Participants in the program will receive two Zilosul® injections per week over a 6-week period in line with the proposed protocol for the forthcoming Phase 3 Pivotal Study to be discussed with FDA in upcoming Pre-IND meeting on 19th February.**
- **Paradigm will treat 10 patients (comprised of Ex-NFL Players) under the EAP. In males under the age of 60, osteoarthritis is over 3 times more prevalent in retired NFL players than in the general U.S. population.**
- **The remaining nine patients to be treated under the EAP will be staggered to commence over the next 4 weeks, with Paradigm expecting last patient final dosing to occur mid – May. Paradigm expects to report results to the market early CY Q3.**

**Paradigm Biopharmaceuticals Ltd (ASX: PAR)** Paradigm is pleased to announce the first patient has been dosed under the US FDA approved EAP. This milestone marks the first patient treated with Zilosul® in the United States. Patients under the EAP will receive treatment in line with the proposed treatment protocol for Paradigms proposed Phase 3 Pivotal study. Each patient will receive two Zilosul® injections subcutaneously per week for a period of 6 weeks. Paradigm will stagger the commencement of the remaining patient's treatment over the next 4 weeks, with the final patient likely to receive their last injection towards the middle of May. Paradigm Expects to report data on patient outcomes around the beginning of Q3.



Mitch Marrow, the first former NFL Player (Carolina Panthers) to be treated with iPPS, in Australia under the special access program, said *"The treatment was so life changing in treating my years of pain and lack of mobility that I am thrilled more former NFL players will have access to this incredible drug in the US under the Expanded Access Program".*

Each patient in the program is first screened to measure their baseline pain scores under the WOMAC osteoarthritis index as well as MRI scans to determine the presence of Bone Marrow Edema Lesions (BMEL) within the knee joint. Follow-up scans and pain measurements will then be recorded at 6 weeks after completion of treatment.

**Mr. Paul Rennie, Paradigm's Chief Executive Officer said:**

"*This is an important milestone for Paradigm as we continue to progress toward the commencement of the Phase 3 Pivotal Study and commercialisation of Zilosul® as a potential first line treatment for Knee Osteoarthritis.*

*The data collected from the 10 patients in the Extended Access Program will add strength to the data already collected from the 600+ patients Paradigm has treated throughout its successful Phase 2b clinical trials and SAS program in Australia. We are looking forward to releasing more information in due course about the progress of the Pivotal Phase 3 Study and are hopeful that a positive experience under this EAP will help drive public interest in the forthcoming trials the company expects to conduct in 2020"*.

## What is The FDA Expanded Access Program?

"Expanded access", also called "compassionate use," provides a pathway for doctors and patients to gain access to investigational drugs, biologics, and medical devices used to diagnose, monitor, or treat patients with serious diseases or conditions for which there are no comparable or satisfactory therapy options available outside of clinical trials"[2].

FDA recognizes that osteoarthritis (OA) can be a serious disease with an unmet medical need for therapies that modify the underlying pathophysiology of the disease and potentially change its natural course to prevent long-term disability.

Through this Expanded Access Program (EAP), Paradigm (the Sponsor) seeks to provide Zilosul® (iPPS) to a limited number of patients who have failed other conservative therapies (standard of care), and for whom access is requested by the treating physician.

## Early Onset of Osteoarthritis in Retired NFL Footballers.

In males under the age of 60, arthritis is over 3 times more prevalent in retired NFL players than in the general U.S. population. This excess of early-onset arthritis may be due to the high incidence of injury in football[1].

**About injectable PPS (iPPS)**

Injectable PPS (iPPS) is not currently registered in Australia, but it is was previously registered in four of the seven major global pharmaceutical markets. In those European markets, iPPS is registered as an antithrombotic agent. In Australia, iPPS for human use is not currently available for sale.

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

[1] Golightly YM et al Early-onset arthritis in retired National Football League players, J Phys Act Health. 2009 Sep;6(5):638-43

[2] https://www.fda.gov/news-events/public-health-focus/expanded-access

To learn more please visit: www.paradigmbiopharma.com

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