PARADIGM BIOPHARMACEUTICALS LIMITED

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Paradigm reports: All 10 patients have commenced treatment in the USA under FDA approved Expanded Access Program.

KEY HIGHLIGHTS

- **Total Patient population (n=10) have commenced dosing with Zilosul® (iPPS) in the US under the FDA approved Expanded Access Program (EAP).**
- **First patient dosed is due to complete full treatment course Monday 23rd March.**
- **Strong feedback and testimonials on effect of Zilosul® from patients as they progress through course of treatment.**
- **The Extended Access Program remains on-track with Paradigm expecting to report results to the market Q3 CY2020. Pain reduction will be measured using the WOMAC pain scoring questionnaire. WOMAC is used in assessing pain, stiffness, and function in patients with OA of the hip or knee.**
- **Paradigm's Board and Management have implemented strict protocols across its team both in Australia and the US to keep staff safe, productive and to minimize any interruptions to the business and FDA submission timelines in wake of COVID-19.**

Paradigm Biopharmaceuticals Ltd (ASX: PAR) Paradigm is pleased to announce it has commenced dosing of all ten patients with Zilosul® under the FDA approved Expanded Access Program (EAP) in the US.

Patients being treated are at different stages of the treatment cycle, with one patient in the program due to receive final dosing on Monday 23rd March (US). Paradigm's staff in the US have monitored the progression of each patient and note consistent positive feedback from patients as they progress through the treatment course. The ten patients being treated under the EAP have all failed many of the other current standards of treatments for Knee Osteoarthritis and thus far have provided positive feedback about the early effects of treatment with Zilosul®.

Thomas Everett, former NFL Safety, Two-Time Super Bowl Champion and currently undergoing treatment under the EAP said:

"As a former professional of The National Football League and now active Alumnus, I've suffered with OA since later in my playing days and understand firsthand the debilitating effects of how it can affect a person's life.

I have tried pretty much all traditional treatment available without a ton of success, so I am absolutely thrilled and very excited to be part of a study that could actually treat the underlying ailment and not just the symptoms".

Richard Van Druten formerly of the Kansas City Chiefs and another patient being treated with Zilosul® under the EAP said:

"I have recently started walking comfortably and even jogging for the first time in many years. Not bad for 318lbs, knees have handled it a lot better since I have been on the treatment and I also seem to be losing weight. I feel more energetic in a way where my body seems to be firing on all cylinders a lot better than ever before".

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. Paradigm expects to report the results of this data in Q3 of 2020.

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

"Paradigm is pleased that the treatment of the ten patients has been unaffected by the current COVID-19 pandemic and we thank all participants in the EAP for their commitment to the treatment regime.

We continue to be encouraged by the anecdotal feedback from each patient as they progress through the treatment cycle and look forward to presenting the results to the market once available. "The conclusion of the enrollment and commencement of treatment by all 10 participants is an example of how Paradigm continues to drive its business forward even in the face of the challenges of the COVID-19 pandemic. "I would like to thank all the medical staff involved in the treatment of the 10 participants and of course thank the participants and Paradigm staff who have worked hard to achieve this milestone. I look forward to our ongoing dialogue with the NFL and the NFL Past Players Association".

COVID-19 Update

The Paradigm Board and staff are observing all recommendations issued by the Australian Federal Government, States and Territories. All Paradigm staff are working from home and have been for the past 3 weeks, so no shutdowns are expected to adversely affect our business. All operational meetings have been conducted by video or teleconference. The work-from-home systems have been in place since 2015.

The Paradigm Board and Management have implemented strict protocols across its team both in Australia and the US to keep everyone safe, productive and focused on our milestones and timelines. Focus has also been on identifying any risks to minimize any interruptions to the business especially the current FDA submission timelines in wake of COVID-19. Risk mitigations strategies are in place across our business and we continue to move forward to our key FDA submissions.

Paradigm will continue to monitor and adhere to government notices in particular around travel restrictions. Apart from this disruption, the company does not believe the impact from COVID-19 is material to the overall business operations at this time due to the fact no clinical trials are being undertaken and the majority of Paradigms staff already work remotely. The

company continues to work on the data and submissions to the FDA and regulators post the recent meetings and will use the opportunity to focus on these submissions in the months ahead.

The company has a strong balance sheet with over A$70m cash. While the COVID-19 pandemic is likely to cause some minor delays, the company is well positioned and believes overall it is unlikely to have a material long term impact on the business.

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).

What is the US FDA Expanded Access Program (EAP)?

Sometimes called "compassionate use", expanded access is a potential pathway for a patient with an immediately life-threatening condition or serious disease or condition to gain access to an investigational medical product (drug, biologic, or medical device) for treatment outside of clinical trials when no comparable or satisfactory alternative therapy options are available[3].

Did you Know?

Paradigm patents.

Paradigm has filed many patents including, but not limited to, iPPS to treat bone marrow edema lesions, osteoarthritis with concurrent bone marrow edema lesions, viral arthritis, respiratory diseases, heart failure, pain and many more.

The patent claims where treatment is administered by an injection that includes the intra-

muscular (IM) or subcutaneous (SC) routes, intra-venously (IV), intra-articularly (IA), peri-articularly but also includes topical or **oral administration**. Oral use of PPS, for the indications which Paradigm has patented, is covered under Paradigm's patents and any oral use thereof would be an infringement of Paradigm's patent.

[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

[3] https://www.fda.gov/news-events/expanded-access/expanded-access-information-industry

To learn more please visit: www.paradigmbiopharma.com

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