Paradigm Biopharmaceuticals Ltd

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Paradigm Biopharmaceuticals files Investigational New Drug submission for ZilosulÒ with FDA

Paradigm Biopharmaceuticals Ltd (ASX:PAR) has filed its first IND (Investigational New Drug) submission to the US FDA for an Expanded Access Program under which ten people from the US may be treated with ZilosulÒ (iPPS).

ZilosulÒ (iPPS) is a potential first-line therapeutic treatment for osteoarthritis and other diseases affecting the musculoskeletal system.

The ten Americans are anticipated to include some retired NFL players who have early-onset osteoarthritis and have also failed standard of care.

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.

This excess of early-onset arthritis may be due to the high incidence of injury in football.

The unmet clinical need

Osteoarthritis is a disabling disease leading to chronic pain, disability and a decreased quality of life.

It is the most common joint disorder in the developed world, with the lifetime risk of developing symptomatic knee osteoarthritis before age 85 years estimated in one US study at 44.7%.

Expanded Access Program

Expanded access, also called 'compassionate use', provides a pathway for 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.

FDA recognizes that osteoarthritis 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.

READ: Paradigm Biopharmaceuticals Ltd fully funded as it advances iPPS development

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

Price: 1.595

Market Cap: $315.51 m

1 Year Share Price Graph

Share Information

Code:		PAR
Listing:		ASX
52 week	**High**	**Low**
	4.5	**1.08**

Sector: **Pharma & Biotech**

Website: **www.paradigmbiopharma.com**

Company Synopsis:

Paradigm Biopharmaceuticals Ltd (ASX:PAR) is listed on the Australian Securities Exchange.

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Paradigm plans to further its understanding of the potential utility of ZilosulÒ (PPS) for the treatment of BML (bone marrow edema lesions) associated pain and joint stiffness in a small group of knee OA patients while it prepares applications for a larger Phase 3 clinical trial.

READ: Paradigm Biopharmaceuticals receives positive results for Ross River clinical trial

Paradigm's clinical and regulatory teams are continuing to work on submissions to the US FDA for the Phase 2/3 clinical trial in the very rare lysosomal storage disease (MPS), the Phase 3 clinical trial in Osteoarthritis and the Australian Therapeutic Goods Administration for the provisional approval of ZilosulÒ (iPPS) to treat osteoarthritis.

Paradigm is planning to submit these within the next two quarters of CY 2019.

Meanwhile, commercial discussions are ongoing regarding potential partnership deals and commercial transactions.

Expected future market updates prior to the end of CY 2019:

- File Expanded Access Program for 10 patients with US FDA Q3 CY 2019;
- File initial submission with the TGA for Provisional Approval Application of ZilosulÒ (iPPS) for treatment of osteoarthritis, Q3 CY 2019;
- Pre-IND meeting with US FDA Orphan Indication (MPS) Phase 2/3 clinical Trial Q4 CY 2019;
- Pre-IND meeting with US FDA osteoarthritis Phase 3 clinical trial Q4 CY 2019; and
- Commercial discussions - ongoing.

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