

Paradigm Biopharmaceuticals Ltd

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Paradigm Biopharmaceuticals higher on reporting 65% pain reduction in OA patients treated under US FDA EAP

Paradigm Biopharmaceuticals Ltd (ASX:PAR) (OTCMKTS:PBIGF) shares were more than 9% higher in early trade to \$3.55 following encouraging results received across 10 patients treated with Zilosul® under the FDA approved Expanded Access Program (EAP) in the US.

There has been a 65% mean reduction in WOMAC pain from baseline across total patient population using the WOMAC Pain Subscale 12 weeks after initiating Zilosul® treatment.

The company believes these FDA EAP results if replicated in a confirmatory Phase-3 clinical study, would provide a compelling product alternative to the use of current treatments of moderate to severe OA pain (NSAIDs and Opioids).

Paradigm considers the combined pain-reducing effects and tolerance of Zilosul® would allow it to become front-line OA therapy for patients with moderate to severe OA pain that have not responded to initial oral pain therapy.

"A fantastic outcome"

Interim executive chairman and CEO Paul Rennie said: "This is a fantastic outcome not only for Paradigm as our first treatment of a cohort of patients in the US under an FDA approved program, but also for all patients that have participated in the program.

"We are very encouraged with the EAP results which were reported, at 12 weeks, with the same pain scoring system Paradigm will use in its Phase 3 clinical trial (ie WOMAC).

"Paradigm would like to thank Dr East and all his staff in Dallas, for all their work and assistance with this program.

"We would also like to thank the 10 participants in the program and wish them all the best in returning to many activities that had previously been limited by the pain associated with OA".

The expanded access program 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.

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

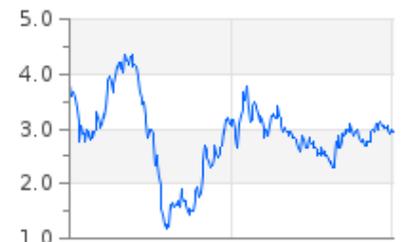
US FDA expanded access program

Each patient enrolled in the program was screened to measure their baseline pain scores under the WOMAC

Price: 2.99

Market Cap: \$679.5 m

1 Year Share Price Graph



December 2019 June 2020 November 20

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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osteoarthritis index and evaluated with MRI scans to determine the presence of Bone Marrow Edema Lesions (BMEL) within the knee joint.

The EAP started on February 18 with the treatment of the first patient and the last patient completing treatment on April 30.

All patients taking part in the study completed regular evaluations with the treating physician (Dr East).

Follow-up scan and pain measurements were then recorded at six weeks post-treatment completion.

Results video

Paradigm has released a results presentation to accompany this announcement detailing the EAP protocol and subsequent results achieved across the patient population.

The company has also produced a video detailing the patients under the EAP and their experiences with OA caused by joint issues sustained during professional sport careers.

This includes testimonials from some of the ex-NFL players who participated in the trial.

These players presented with significant pain associated with knee osteoarthritis and had failed other current standards of treatment.

The video presenters are Dr Donna Skerrett (Paradigm CMO), Dr John East (Regenerative Medicine Specialist and treating Physician) and Dr Ravi Krishnan (Paradigm CSO).

Results are presented through outcomes data and patient testimonials of their experiences with Zilosul® treatment are also included in the video.

To watch the video and view the presentation follow this [link](#).

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