

Paradigm Biopharmaceuticals Ltd

11:05 30 Jul 2020

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.

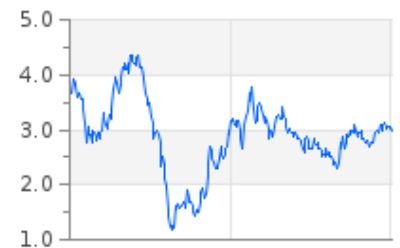
US FDA expanded access program

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

Price: 2.91

Market Cap: \$663.54 m

1 Year Share Price Graph



November 2019 May 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.

action@proactiveinvestors.com.au

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](#).

Proactive Investors facilitate the largest global investor network across 4 continents in 4 languages. With a team of analysts, journalists & professional investors Proactive produce independent coverage on 1000's of companies across every sector for private investors, private client brokers, fund managers and international investor communities.

Contact us +61 (0)2 9280 0700 action@proactiveinvestors.com.au

No investment advice

The Company is a publisher. You understand and agree that no content published on the Site constitutes a recommendation that any particular security, portfolio of securities, transaction, or investment strategy is suitable or advisable for any specific person. You understand that the Content on the Site is provided for information purposes only, and none of the information contained on the Site constitutes an offer, solicitation or recommendation to buy or sell a security. You understand that the Company receives either monetary or securities compensation for our services. We stand to benefit from any volume which any Content on the Site may generate.

You further understand that none of the information providers or their affiliates will advise you personally concerning the nature, potential, advisability, value, suitability or profitability of any particular security, portfolio of securities, transaction, investment, investment strategy, or other matter.

You understand that the Site may contain opinions from time to time with regard to securities mentioned in other products, including Company-related products, and that those opinions may be different from those obtained by using another product related to the Company. You understand and agree that contributors may write about securities in which they or their firms have a position, and that they may trade such securities for their own account. In cases where the position is held at the time of publication and such position is known to the Company, appropriate disclosure is made. However, you understand and agree that at the time of any transaction that you make, one or more contributors may have a position in the securities written about. You understand that price and other data is supplied by sources believed to be reliable, that the calculations herein are made using such data, and that neither such data nor such calculations are guaranteed by these sources, the Company, the information providers or any other person or entity, and may not be complete or accurate.

From time to time, reference may be made in our marketing materials to prior articles and opinions we have published. These references may be selective, may reference only a portion of an article or recommendation, and are likely not to be current. As markets change continuously, previously published information and data may not be current and should not be relied upon.

The Site does not, and is not intended to, provide investment, tax, accounting, legal or insurance advice, and is not and should not be construed as providing any of the foregoing. You should consult an attorney or other relevant professional regarding your specific legal, tax, investment or other needs as tailored to your specific situation.

In exchange for publishing services rendered by the Company on behalf of Paradigm Biopharmaceuticals Ltd named herein, including the promotion by the Company of Paradigm Biopharmaceuticals Ltd in any Content on the Site, the Company receives from said issuer annual aggregate cash compensation in the amount up to Twenty Five Thousand dollars (\$25,000).