

Paradigm Biopharmaceuticals Ltd

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Paradigm Biopharmaceuticals set to release results of FDA's IND expanded access program for Zilosul osteoarthritis treatment

Paradigm Biopharmaceuticals Ltd (ASX:PAR) expects to release results for its Zilosul treatment for osteoarthritis under the US Food and Drug Administration's (FDA) Investigational New Drug expanded access program (EAP) in early August.

The results will include a video detailing the patients under the EAP and their previous struggles with osteoarthritis caused by joint issues during their professional NFL careers and will highlight outcomes and results after completion of the Zilosul® treatment program.

All patients have completed their follow-up screenings and the EAP database has been locked for data cleaning and preparation of patient results.

The company said it remained focused on its IND submission to the FDA for the remainder of 2020.

The Paradigm team and its consultants continue to compile the necessary information and data for submission towards the end of the fourth quarter.

Shares have been as much as 13.5% higher to \$3.21.

TGA submission

Paradigm Biopharmaceuticals is continuing to prepare information requested by the Therapeutic Goods Administration (TGA) for the next stage of submission for the Provisional Approval determination for the use of Zilosul in the treatment of osteoarthritis.

It will update the market on the progress of this process in the fourth quarter this year.

There is additional new data on 67 patients treated under the Special Access Scheme (SAS) program and the company expects to report on 35 patients in the third quarter with the remaining patient data expected to be available in early fourth quarter this year.

The data will be presented, using the same endpoints and product identified for Paradigm's Phase 3 trials. This will take the total number of SAS patients reported on with the proposed Phase 3 endpoints to over 100 patients.

Commercial research deal

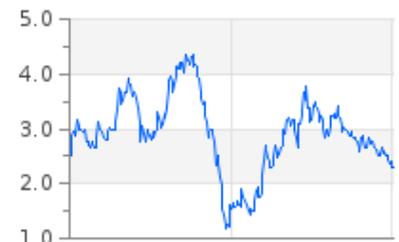
Paradigm Biopharmaceuticals is in the process of finalising a commercial research agreement with an unnamed Australian university.

The research program will investigate the safety and efficacy of injectable Pentosan Polysulfate Sulfate (iPPS) in a viral-induced respiratory disease model.

Price: 2.28

Market Cap: \$520.01 m

1 Year Share Price Graph



September 2019 March 2020 September 2020

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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Additional details on this agreement will be released to the market once this has been completed.

Proposed Phase III

The primary and secondary endpoints for Paradigm's proposed Phase 3 trial will be

? Reduced WOMAC (Western Ontario and McMaster Universities Arthritis Index) pain from baseline; and

? Improved Patient Global Impression of Change (PGIC).

Paradigm plans to conduct two randomized controlled Phase 3 clinical trials consisting of 750 patients in the first Phase 3 trial and 400 patients in the second Phase 3 trial (confirmatory study).

MPS-1

Paradigm expects to receive notification from the Ethics Committee on its MPS-1 (Mucopolysaccharidosis) clinical program in the current quarter.

It is also expecting feedback from the Joint Parallel Scientific Advice meeting with the US FDA and the European Medicines Agency (EMA) this quarter.

This will give Paradigm important information on the views of both agencies with regards to endpoints and overall trial design for Paradigm's proposed pivotal/registrational trial in MPS-VI.

Paradigm has also made a submission to the ethics board for a Phase 2a clinical program to evaluate iPPS in MPS-I subjects with residual symptoms following Enzyme Replacement Therapy or Bone Marrow Transplantation treatment.

Journal publications

Paradigm staff and the principal investigators have completed writing the Phase 2b osteoarthritis clinical trial and the Phase 2A Viral Arthritis clinical trial manuscripts, which will be sent to the chosen Journal Editor for peer-review and publication.

It expects both peer-reviewed publications to be released in the fourth quarter of 2020.

Virtual conferences

Paradigm is targeting to be present at several domestic and international virtual conferences in the financial year 2021 to promote the company to new investors as it progresses through its clinical development programs.

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