Paradigm Biopharmaceuticals Ltd

22:36 09 Sep 2019

Paradigm Biopharmaceuticals gets FDA clearance for investigational new drug application

Paradigm Biopharmaceuticals Ltd (ASX:PAR) has confirmed that its first Investigational New Drug (IND) application (filed in August 2019) has been cleared by the US FDA within the 30-day review period.

The company submitted an Expanded Access IND for pentosan polysulfate sodium (PPS) for the treatment of about 10 patients with pain associated with knee osteoarthritis (OA) with concurrent bone marrow lesions where patients have failed to respond to standard of care.

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.

Knee osteoarthritis pain

The physician treating the patients, under the IND, is an ex-NFL player with the Green Bay Packers.

Since his retirement from the NFL, Dr Michels, has worked primarily with sportspeople such as retired NLF players.

A major risk factor for osteoarthritis is joint injury. Knee injury is a common injury amongst NFL players.

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

Potential treatment for a serious chronic disease

Paradigm chief executive officer Paul Rennie said: "We are very pleased to announce that Paradigm's Expanded Access IND has been cleared by the US

Price: 3.36

Market Cap: $653.44 m

1 Year Share Price Graph

Share Information

Code:	PAR	
Listing:	ASX	
52 week	**High**	**Low**
	3.38	**0.839883**

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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FDA within the 30-day review period.

"This clearance demonstrates the need for effective and safe therapies for the serious chronic disease of osteoarthritis. It also provides validation of the Paradigm dossier which contained information about our non-clinical and toxicology, our manufacturing and our clinical data and data about the previous human experience with the drug".

Rennie added: "FDA clearance means validation of Paradigm's

- safety data;
- the finished product's quality; and
- confirmation of an unmet medical need".

"Paradigm has also been able to demonstrate it now has very experienced staff with regulatory, manufacturing and clinical expertise, which is important as we plan to have an additional two pre-IND submissions with the US FDA before the end of CY 2019".

"Dr Michels will be treating people with osteoarthritis who have failed to respond to standard of care medications. Paradigm now looks forward to the completion of the Expanded Access Programme and reporting on those results in the months ahead".