



ASX RELEASE

First participant in Paradigm's clinical trial starts ZILOSUL[®] treatment for bone bruising following Anterior Cruciate Ligament (ACL) injury.

25 February 2016, Melbourne Australia: Paradigm Biopharmaceuticals Limited (ASX:PAR) is pleased to announce the recruitment of its first participant with ACL injury in the open label clinical trial at Box Hill Sportsmed Biologic medical clinic. The clinical trial is seeking to investigate if ZILOSUL[®] can resolve bone marrow edema (BME) lesions (bone bruising) arising from sporting or accidental injuries to the knee such as a ruptured Anterior Cruciate Ligament (ACL). The Principal Investigator of the Box Hill site, Dr Ruben Branson announced that the first participant who has had a recent ACL injury has fulfilled eligibility criteria for the trial and has started ZILOSUL[®] treatment.

Unresolved bone marrow edema or bone bruising is considered to be a potent risk factor for osteoarthritis following injury. The use of the drug (ZILOSUL[®]) shortly after the injury may resolve the bone bruise and potentially improve the long-term health of the knee cartilage.

Dr Nick Van Wetering who is a co-investigator in the trial with Dr Ruben Branson said "The patient had sustained an ACL injury recently in a Netball match and became aware of the Paradigm trial during a consultation with me". "After the patient had consented to participating in the trial we initiated the screening process which included a pain and functional test and an MRI to determine the presence of the BME lesion". "The patient was a suitable trial candidate since she exhibited a BME lesion identified by MRI in association with bone pain and reduced joint function following her ACL injury". "The patient has received her first intramuscular injection of ZILOSUL[®] today and will be administered a course of intramuscular injections twice weekly for a period of three weeks".

The trial at Box Hill's Sportsmed Biologic medical clinic is one of two clinical centres involved in this 40 participant open-label pilot clinical trial to determine the safety and tolerability of Paradigm's proprietary formulation of Pentosan Polysulphate Sodium (PPS), ZILOSUL[®] in participants with a BME lesion.

Paradigm's Chief Scientific Officer, Dr Ravi Krishnan said "We are very keen to see the outcome of ZILOSUL[®] therapy in ACL injury since it will provide valuable data for the clinical evaluation for the treatment of BME lesions which are strongly associated with pain and functional deficit experienced in these participants". "Paradigm is also preparing its second clinical trial site in Adelaide and Paradigm will advise the commencement of this site which is imminent".

Call to action!! What should I do if I am interested in the clinical trial?

For those interested in knowing more about the clinical trial they can email Dr Ruben Branson email: ruben@sportsmedbiologic.com.au or info@sportsmedbiologic.com.au web: <http://www.sportsmedbiologic.com.au/> or call the clinic directly on the number below.

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About Paradigm Biopharmaceuticals: Paradigm Biopharmaceuticals Ltd (ASX:PAR) is an Australian biopharmaceutical company focused on repurposing historic drug PPS (Pentosan Polysulphate Sodium), under the Paradigm trademark ZILOSUL®, as a potential new treatment for Bone Marrow Edema (BME) lesions following traumatic injury. Paradigm Biopharmaceuticals is at the same time repurposing PPS for respiratory diseases including Allergic Rhinitis (AR) also known as hay fever under the Paradigm trademark RHINOSUL®.

PPS is a well-established mild anticoagulant and anti-inflammatory agent that has been used for over 60 years to treat interstitial cystitis and to prevent and treat deep vein thrombosis. It has a solid safety and efficacy profile.

Traumatic BME lesions also known as bone bruising, can be a painful and debilitating injury. Traumatic BME normally affects sportspeople. There is no approved pharmaceutical product to treat this condition. Current treatment of BME includes the use of non-steroidal and steroidal anti-inflammatory drugs, which can have serious side effects. Paradigm is sponsoring a pilot Phase 2 clinical study of PPS in BME trial subjects at sites in Australia from February 2016. ZILOSUL®, will be administered to the study subjects shortly after the Anterior Cruciate Ligament (ACL) injury. It is hoped the early intervention of the drug will delay or even stop the progression of post traumatic osteoarthritis.

Paradigm has also acquired patents over the use of PPS as a new treatment for respiratory diseases including Allergic Rhinitis (AR), Allergic Asthma (AA) and Chronic Obstructive Pulmonary Disease (COPD). Paradigm also acquired pre-clinical data, nasal formulation and other data from the previous developer Glycan Biosciences LLC, allowing Paradigm to fast-track its treatment for AR, RHINOSUL®, into clinical trials in mid-2016.

Antihistamines and corticosteroid nasal sprays are standard existing treatments for AR. Long-term use of nasal corticosteroids is associated with adverse side effects whereas Paradigm's AR product is a non-steroidal pharmaceutical.

Repurposing an existing drug diminishes early developmental risks associated with traditional new drug development and usually means shorter development times, lower development costs and lower safety risk.

Paradigm has also acquired intellectual property over exosomes. The exosomes are an in-house R&D project and product development has commenced but is still at an early stage.

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