ASX RELEASE

Paradigm starts clinical trial to investigate ZILOSUL® as a treatment for bone bruising following Anterior Cruciate Ligament (ACL) injury

23 February 2016, Melbourne Australia: Paradigm Biopharmaceuticals Limited (ASX:PAR) is sponsoring an 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 the clinical trial has commenced and he and his colleagues are now actively recruiting patients.

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.

The trial at Box Hill's Sportsmed Biologic medical clinic is one of two clinical centres involved in this 40 patient open-label pilot clinical trial to determine the safety and tolerability of Paradigm's proprietary formulation of Pentosan Polysulphate Sodium (PPS), ZILOSUL® in patients with a BME lesion. ZILOSUL® will be administered twice weekly for a period of three weeks in patients exhibiting a BME lesion identified by MRI in association with bone pain and reduced joint function following an Anterior Cruciate Ligament (ACL) injury.

Box Hill's Sportsmed Biologic medical clinic is headed by leading sports physician Dr Ruben Branson. Dr Branson's involvement in the trial stems from his own experiences as a leading sports medicine physician that has included working with Collingwood in the AFL and the NRL's Melbourne Storm.

"People, especially athletes who have anterior cruciate ligament injuries, are more likely to develop osteoarthritis compared to people who haven't had an ACL injury" Dr Branson explained. Dr Branson said clinical trial subjects were being recruited from people across the community, including sports people who have played at both the elite and amateur levels. "We are excited to see if Paradigm's proprietary formulation of PPS, ZILOSUL® when used shortly after the anterior cruciate ligament injury, can reduce pain and resolve the bone marrow lesion and hopefully protect the cartilage in the long-term."

Paradigm's CEO Mr Paul Rennie said the Melbourne clinic is among Australia's leading specialist sports medicine centres and the trials were being led by exceptional medical experts who understand the importance of treating bone marrow lesions. Paradigm's team of scientists, nurses and other specialists assisted in preparing the clinical trial site at Box Hill

to enable the launching of the clinical trial. Mr Rennie said he was pleased that Paradigm was able to achieve a significant commercial milestone within six months of its ASX listing which highlights the advantage of the company's business model of drug repurposing PPS.

Chief Scientific Officer, Dr Ravi Krishnan said that "Many scientific publications have indicated that unresolved BME lesions as a consequence of acute traumatic injury to the knee may be the cause of post-traumatic osteoarthritis" and "The commencement of our sponsored trial will start to provide data in the clinical validation of ZILOSUL® for the early treatment of the disease process that leads to poor joint health and functional limitation". Dr Krishnan also remarked "Paradigm's strong patent for the treatment of BME lesions has placed the company in a strategic position internationally since there are currently no registered pharmaceutical agents approved to treat this unmet medical need".

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) 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.
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 will launch a pilot Phase 2 clinical study of PPS in BME trial subjects at sites in Australia from late 2015. The drug, PPS, 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 into clinical trials in early 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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