ASX RELEASE

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

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2nd March 2016, Melbourne Australia: Paradigm Biopharmaceuticals Limited (ASX:PAR) is sponsoring an open label clinical trial at Southern Orthopaedics in Adelaide, South Australia. 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 at the Southern Orthopaedics clinic, Professor Jegan Krishnan announced the clinical trial has commenced and he and his colleagues are now actively recruiting participants.

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 Southern Orthopaedics clinic in Adelaide is the second site that Paradigm has initiated following the initiation of Box Hill's Sportsmed Biologic medical clinic. Both centres are now actively involved in recruiting subjects 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. ZILOSUL® will be administered twice weekly for a period of three weeks in participants exhibiting a BME lesion identified by MRI in association with bone pain and reduced joint function following an Anterior Cruciate Ligament (ACL) injury.

Leading Orthopaedic surgeon, Professor Jegan Krishnan is heading the clinical trial at Southern Orthopaedics clinic. Professor Krishnan was concerned about some patients waiting for surgery after a knee injury. "Some patients are waiting for surgery for six to twelve months and during this time inflammatory changes in the injured joint are building up and setting the scene for a long term disease process as a result of the BME lesions that may lead to post-traumatic osteoarthritis" and "Therefore I am very interested to assess in this pilot open label trial the effectiveness of ZILOSUL® as an early interventional agent that will target the BME lesions which occur as a result of the ACL rupture in these participants as identified by MRI"

Paradigm's CEO, Mr Paul Rennie remarked that in addition to the primary end point of safety and tolerability to ZILOSUL® therapy, outcomes of pain, function, BME lesions and disease biomarkers are being investigated. Mr Rennie also explained "This open-label study design will allow us to "road test" the efficacy parameters of ZILOSUL® before undertaking a randomised double-blind placebo-controlled Phase 2b clinical trial".

Mr Rennie said “Paradigm’s team of scientists, nurses and other specialists assisted in preparing the clinical trial site at Southern Orthopaedics clinic to enable the launching of the clinical trial”.

Professor Krishnan said clinical trial subjects are being recruited from people across the community, including subjects involved in sporting activity who have played at both the elite and amateur levels.

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: krishnanadmin@sahi.org.au or info@sahi.org.au web: http://www.sahi.org.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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