ASX RELEASE

Paradigm's ZILOSUL® approved for clinical trial

..Currently no effective treatment for this common orthopaedic condition
..Pilot study on 40 sufferers of Bone Marrow Edema (BME)
..12 month study to determine safety and tolerability

23 November 2015, Melbourne Australia: Paradigm Biopharmaceuticals Limited (ASX:PAR) has been granted approval by the Human Research Ethics Committee (HREC) to proceed with the open-label pilot clinical trial to determine the safety and tolerability of ZILOSUL® in patients with a BME lesion.

This study in 40 patients will administer ZILOSUL® 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

Paradigm's CEO, Mr Paul Rennie said that "the HREC approval enables commencement of the Company's clinical development program of ZILOSUL® in the orthopaedic indication." Mr Rennie highlighted that unresolved traumatic BME lesions may be the harbinger of post-traumatic osteoarthritis and he emphasised that there is currently no registered pharmaceutical agent approved to treat this unmet medical need. ZILOSUL® involves repurposing Pentosan Polysulphate (PPS) to treat BME lesions. PPS is a drug with long history of use and safety in humans.

The Pilot study will be carried out in two Medical Centres in Australia – Southern Orthopaedics in Adelaide, South Australia (Principal Investigator, Professor Jegan Krishnan) and Box Hill in Melbourne, Victoria (Principal Investigator, Dr Ruben Branson). Expected duration is 12 months subject to patient recruitment.

Dr Branson who is the Principal Investigator at Sportsmed Biologic Medical Centre, Box Hill, in Melbourne said that "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 also said: "We are excited to see if the ZILOSUL®, when used shortly after the anterior cruciate ligament injury, can preserve the knee cartilage and therefore delay or even prevent the onset of osteoarthritis in the injured knee. We are looking forward to reviewing the results of this initial pilot study in about 12 months' time".

About the Clinical Trial:

Study Centres:

Southern Orthopaedics: 13 Laffers Road, Belair SA 5052, Tel (08) 7231 8444 or email enquiries: admin@sahi.org.au or email Professor Jegan Krishnan: krishnanadmin@sahi.org.au

Sportsmed Biologic: 1G/116 -118 Thames St, Box Hill VIC 3128, Free Call 1300 858 860 or email enquiries: info@sportsmedbiologic.com.au or Dr Ruben Branson: ruben@sportsmedbiologic.com.au

PARA_001 is an open label pilot study investigating the short-term outcome of intramuscular administration of ZILOSUL® for the treatment of bone marrow lesions of the knee following acute anterior cruciate ligament injury (ACL).

Clinical Trial Objectives:

Primary study objectives are to evaluate the safety and tolerability of IM ZILOSUL® in subjects with bone marrow lesions following an ACL injury.

Secondary study objectives are to evaluate the:

- effect of IM ZILOSUL® on bone marrow lesions following an ACL injury as assessed by magnetic resonance imaging (MRI)
- effect of IM ZILOSUL® on functional knee joint capacity following an ACL injury.

Exploratory study objectives are to evaluate the:

- effect of IM ZILOSUL® on pain following an ACL injury and to evaluate the effect of IM ZILOSUL® on biomarkers of inflammation, bone and tissue remodelling
- relationships between changes in bone marrow lesions with changes in functional knee joint capacity and changes in pain intensity.

It is an open label study so there are no placebo controls and no blinding.

Key inclusion criteria:

1. Subjects who have experienced an acute anterior cruciate ligament (ACL) injury a minimum of 2 weeks and maximum of 8 weeks prior to Day 0, and have been managed conservatively with physical therapy and medications;
2. Subjects with bone marrow lesions of the femur or tibia on a least 2 consecutive sagittal or coronal MRI slices as confirmed by an independent reader.

About ZILOSUL®: ZILOSUL® is an injectable form of pentosan polysulphate produced by bene pharmaChem GmbH in an FDA audited facility in Germany and manufactured in accordance to cGMP standards. This form of Pentosan Polysulphate, which is a sulphated extract of a polysaccharide obtained from the bark of the beech tree, has been approved by the FDA for oral treatment of bladder pain associated with interstitial cystitis for more than 30 years. ZILOSUL® is a registered trademark of Paradigm Biopharmaceuticals Ltd.

For investor enquires contact:

Mr Rudi Michelson
Monsoon Communications
03 9620 3333 or 0411 402 737

Or

Mr Paul Rennie
CEO
Paradigm Biopharmaceuticals Ltd
Level 2, 517 Flinders Lane, Melb, VIC, 3000, AUSTRALIA
Email: prennie@paradigmbiopharma.com
Mobile International: +61 437 778 300
Mobile (Australia): 0437 778 300

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 preventing and treating deep vein thrombosis. It has a solid safety and efficacy profile.

Traumatic BME lesions also known as bone bruising and 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 less 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.

ABN: 94 169 346 963
Web: http://paradigmbiopharma.com/