ASX Announcement Paradigm Biopharmaceuticals Ltd (ASX:PAR)

**ABN: 94 169 346 963**

**Date: 3 December, 2015**

# Elite athlete from a major sporting code treated with Paradigm's ZILOSUL® under the Therapeutic Goods Administration's Special Access Scheme.

## Highlights

- Elite athlete, with an unresolved orthopaedic condition, from a major sporting code treated with Paradigm's ZILOSUL®, Bone Marrow Edema (BME) pharmaceutical formulation;
- ZILOSUL® administered via six intramuscular injections across a three week period which commenced early November 2015, under the Therapeutic Goods Administration's (TGA's) Special Access Scheme;
- No adverse events were recorded during treatment, ZILOSUL® safe and well tolerated;
- Initial clinical response to the ZILOSUL® therapy has shown encouraging results – detailed results to follow in coming months.

**3 December 2015, Melbourne Australia:** Paradigm Biopharmaceuticals Ltd (ASX: PAR) is pleased to announce that the first patient has completed treatment for Bone Marrow Edema (BME or bone bruising) using the Company's proprietary pharmaceutical formulation, ZILOSUL®. Treatment was approved under the Therapeutic Goods Administration's (TGA's) Special Access Scheme (SAS).

The patient is an elite athlete with an un-resolving bone marrow lesion (an orthopaedic condition) refractory to multiple therapeutic and surgical interventions.

During the treatment which involved a total of 6 intramuscular injections of ZILOSUL®, and commenced early November 2015, no adverse events were observed and the product was well tolerated. The prescribing doctor has advised Paradigm that the initial clinical response to the ZILOSUL®, been very positive/encouraging, particularly given the refractory nature of symptoms in this patient. Detailed results of effect of the ZILOSUL® treatment on the athlete's condition are expected in coming months.

Mr Paul Rennie, CEO of Paradigm commented, "To date we are very pleased with the feedback that we have received following the dosing of this first athlete with ZILOSUL®. Bone Marrow Edema is a serious and painful condition which can hamper the ability of sportspeople to return to training and competitive sports. BME has also been associated with cartilage breakdown. Paradigm is hopeful ZILOSUL® will resolve the acute pain symptoms and protect the cartilage in the long term. The upcoming clinical trial will explore the effects of ZILOSUL® treatment in more detail, but the early result in the TGA-approved Special Access treatment is very encouraging".

### Accessing ZILOSUL® under the Special Access Scheme and drug registration status

Injectable ZILOSUL® is not currently registered in Australia. To obtain access to ZILOSUL® for the treatment of a patient, doctors need to submit a request to the TGA under the SAS (Category B).

The TGA approved the SAS Category B application for the patient noted in this announcement. Approval to treat the patient takes into account the safety of the drug (ZILOSUL®), as well as existing preclinical and clinical evidence that the drug may assist the patient, along with the failure of current therapies. Approval is obtained on a case-by-case basis.

The patient is an elite athlete with an un-resolving bone marrow lesion (an orthopaedic condition) refractory to multiple therapeutic and surgical interventions. The patient has not recently ruptured his anterior crucicate ligament and therefore is not eligible to enter the Paradigm sponsored clinical trial for BME for which the Company received ethics approval on 23 November 2015. The patient is being treated under the SAS Category B program because (i) the drug, in the injectable form, is not currently registered for human use in Australia, (ii) the patient does not meet the eligibility criteria for the Paradigm sponsored clinical trial and (iii) current therapies have not been effective.

**Elite athlete's use of ZILOSUL® in sport**

The governing sporting body under which the athlete competes has determined ZILOSUL® (Injectable Pentosan Polysulfate Sodium) is NOT a performance enhancing drug.

**ZILOSUL® trial**

In addition to treatments under the TGA's SAS, Paradigm is also sponsoring an open labelled, BME pilot clinical trial investigating the role of ZILOSUL® in treating patients who have bone marrow lesions arising from a recent anterior crucicate ligament injury. More detail on that trial can be viewed in the Company's announcement of 23 November 2015 re the successful Human Research Ethics Committee approval. For further details about the upcoming clinical trial, and for any extra detail on Paradigm Biopharmaceuticals please visit: www.paradigmbiopharma.com.

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***About Paradigm Biopharmaceuticals:*** Paradigm Biopharmaceuticals Ltd (ASX:PAR) is an Australian-based biopharmaceutical company. It is a drug repurposing company which seeks to find new uses for old drugs, thereby reducing the cost and time to bring therapeutics to market.

***About* ZILOSUL®:** ZILOSUL® is a registered trademark of Paradigm Biopharmaceuticals Ltd. ZILOSUL® is an injectable form of pentosan polysulphate produced by bene pharmaChem GmbH. This form of Pentosan Polysulphate, which is a sulphated extract of a polysaccharide obtained from the bark of the European beech tree, has been approved by the FDA for oral treatment of bladder pain associated with interstitial cystitis for more than 30 years. Injectable PPS, for human use, is a pharmaceutical product registered in 4 of the 7 major global markets as a thrombolytic therapy (clot busting) but it is not currently registered in Australia. Injectable PPS as a therapy for the treatment of Bone Marrow Edema (BME) is not currently registered in any markets. Paradigm plans to undertake the necessary clinical development of injectable PPS. Paradigm will file for the registration, in all major markets, of injectable PPS for the treatment of BME if its clinical trials meet the necessary safety and efficacy endpoints.

***About TGA Special Access Scheme (SAS) Category B***: The SAS refers to arrangements which provide for supply of an unapproved therapeutic good for a single patient on a case by case basis. Category B patients are those who are not seriously ill and unlikely to die within a matter of months. Doctors submitting SAS applications are required to provide clinical justification for the use of the drug. The name of the patient is de-identified under the SAS approval.