ASX RELEASE

Market update Paradigm's PPS nasal spray to treat Allergic Rhinitis (Hay Fever)

Key Highlights:

- Intra-nasal PPS toxicology complete with no adverse events;
- 18 Phase 1 clinical trial participants treated with intra-nasal PPS spray;
- Paradigm proceeds with plans for phase 2 clinical trial December 2016.

Melbourne 19 August 2016 Paradigm Biopharmaceuticals Ltd (ASX:PAR) announces favourable intra-nasal pentosan polysulfate sodium (PPS) toxicology and Phase 1 clinical trial reports.



TOXICOLOGY: Paradigm is pleased to announce the results of the 28 Day intra-nasal toxicology study in rats. The 'bridging' toxicology study evaluated the nasal route of administration and included clinical observations, systemic haematology, biochemistry, coagulation, and histopathology of major organs and nasal tissue. The final toxicology report concluded no observed adverse effects at any tested dose of PPS, with results supporting a safety margin of up to 20 x the estimated human dose. Paradigm's Chief Scientific Officer, Dr Ravi Krishnan said "The delivery of a clean slate from our preclinical safety study conducted to Good Laboratory Practice (GLP) standards allows Paradigm to progress confidently towards the Clinical Development program to commercialise Rhinosul® as a treatment for Allergic Rhinitis".

PHASE 1 CLINICAL TRIAL: Following the successful toxicology study Paradigm undertook a Phase 1 safety study. The Company is delighted to announce the treatment of the 18 healthy volunteers in its Phase 1 study is complete. The study was conducted to Good Clinical Practice (GCP) standards in a dedicated Phase 1 Clinical Trial Unit. The study is the first ever to evaluate the new nasal route of administration for PPS, in a randomised double-blind, placebo-controlled design. Participants were enrolled in 2 cohorts of 2 dose levels, and monitored intensively with full blood analysis, daily clinical observations and a general and nasal examination. With the trial successfully completed, the Company has been able to collate valuable and comprehensive safety data for single and 7-day dosing periods.



With the database now locked and analysis underway, the final report from the Phase 1 study is due in October 2016. In the interim, the Company is delighted to announce that, in the absence of any significant safety concerns in any treated participant, the appointed Phase 1 Data and Safety Monitoring Committee has endorsed the Company's proposed dosing regime for a second clinical trial.

Paradigm's Operations Manager, Dr Claire Kaufman said the company was very pleased with the smooth running of the trial, and having met all recruitment and scheduling targets. "It's an exciting milestone for us at Paradigm to have progressed to this point in a short time frame". She says this has been made possible by the company's repurposing strategy, and a dedicated network of leading clinical, scientific and manufacturing partners

Dr Kaufman also said that preparation for the Phase 2 randomised double-blind placebo-controlled challenge study was well underway, targeting a start date in December 2016.

ADDRESSABLE MARKET: The current market for Allergic Rhinitis is about USD 11 Billion and is dominated by anti-histamines and corticosteroids with market surveys highlighting patient dissatisfaction and the need for effective therapy. Rhinosul® is unique having both anti-histamine and anti-inflammatory effects without the known side effects of anti-histamines and steroids. The company believes its product can meet market needs that are not effectively managed by current nasal sprays.

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ABOUT PARADIGM BIOPHARMACEUTICALS LTD: 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 also 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 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 shortly after the Anterior Cruciate Ligament (ACL) injury. It is hope 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.

Antihistamines and corticosteroid nasal sprays are standard existing treatments for AR. Long-term use of 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.

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