ASX RELEASE

Clinical trial update

Highlights

- **PPS was safe and well tolerated in animal study, with no adverse effects**
- **Ethics approval has been received for the Phase I clinical trial**
- **Phase I trial to commence on 20 June 2016, expected completion on 30 August 2016**
- **Recruitment for the bone marrow edema trial continues, interim analysis expected December 2016**

9 June 2016, Melbourne, Australia: Paradigm Biopharmaceuticals Limited (ASX: PAR) (**Paradigm** or **Company**) is pleased to advise on the progress of its clinical trial programs.

Toxicology Report – Hay Fever

During Paradigm's upcoming hay fever clinical trial, Pentosan Polysulfate Sodium (PPS) will be delivered intranasally for the first time in human volunteers. Given this new route of administration, Paradigm has undertaken a bridging toxicology study at Charles River Laboratories in the USA. Three doses of PPS solution were given intranasally to rodents twice daily for 28 consecutive days. The study included comprehensive evaluation of in-life observations, haematology, biochemistry, coagulation, gross necropsy and complete systemic histopathology, including nasal histopathology.

The draft toxicology report concludes PPS was safe and well tolerated with a safety margin of up to 20 times the estimated dose that will be administered to humans. No adverse effects, nasal or systemic, were seen at any dose in the study.

Phase I Clinical Trial – Hay Fever

Clinical trial product

The developmental nasal spray product for the Phase I clinical trial has arrived into Australia. On the right is a picture of the Paradigm intranasal product for the Phase 1 Clinical Trial. The product is the culmination of prior developmental work on the formulation, quality and stability, in collaboration with our top quality European manufacturing Partners Bene PharmaChem GmbH, MoNo chem-pharm GmbH, and Aptar Pharma.

Ethics approval

Paradigm has received Ethics Approval for the Phase I clinical trial. Additionally, the trial is now successfully registered under the TGA's Clinical Trial Notification Scheme (CTN) and with the ANZCTR.

Trial composition

- Good Clinical Practice study in healthy volunteers
- Double blind, randomised, placebo controlled
- 2 cohorts/dose levels, 9 subjects per cohort (6:3)
- Single dose, followed by 7 day multiple dose
- Comprehensive safety monitoring, subjects remain in Clinical Trial Unit during dosing
- Full bloods, general + nasal exam, AEs, ECG, APTT surrogate PK, PK sampling

Key dates

- Commencement of trial 20 June 2016
- Last day of dosing 20 July 2016
- Last patient out 30 July 2016, and
- Site close-out 30 August 2016

Phase II Clinical Trial – Bone Marrow Edema

Recruitment for the Phase 2 Clinical Trial investigating the use of PPS in treating bone marrow lesions arising from acute injury, such as ruptured anterior cruciate ligaments (ACLs), is ongoing. Interim analysis is planned for December 2016.

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