



ASX RELEASE

### **Significant momentum with Phase 2 Ross River Virus Clinical Trial**

#### **Key Highlights:**

- Significant momentum in Phase 2 Ross River virus clinical trial: 25% of the 24-participant total have now been dosed across the initial two trial sites in Geelong, Victoria and Brisbane Queensland following the commencement of the trial in August 2017.
- In addition, a third trial site has been initiated in Echuca, Victoria following the receipt of ethics approval.
- A fourth trial site on the Gold Coast, Queensland is planned to be initiated over the coming weeks.
- Clinical trial will treat a total of 24 participants; trial participants will be evaluated for safety, tolerability and effects on disease symptoms, with results anticipated in Q2 CY2018.

**Melbourne, 14 September 2017, Paradigm Biopharmaceuticals Ltd (ASX:PAR) is pleased to announce strong momentum with its Phase 2 Ross River virus clinical trial, with 25% of the 24-participant total now treated in the trial.**

The Phase 2 clinical trial is of the drug Pentosan Polysulfate Sodium (PPS) for the treatment of Ross River virus (RRv).

A total of six participants have now been dosed across the initial two trial sites in Geelong, Victoria and Brisbane, Queensland following the trial's commencement in August 2017.

In addition, a third trial site has now been initiated in Echuca, Victoria following the receipt of ethics approval last month. The first participant is expected to be dosed at the site over the next few weeks. It is anticipated that a fourth trial site on the Gold Coast will also be initiated over the coming weeks.

Mr Paul Rennie, Paradigm's CEO said: *"We are very pleased to have such strong momentum in this trial so far, with a quarter of the 24-participant total now dosed following the trial's commencement just last month. This strong start in recruiting eligible patients follows the outbreak of RRv seen earlier in 2017. Given RRv outbreaks are seasonal, we need to add more sites to keep our recruitment rates as high as possible. We look forward to initiating our fourth trial site in the Gold Coast over the coming weeks and recruiting more participants over the coming months."*

*"Ross River virus is a disease with a significant unmet medical need and we hope that PPS can prove to be an effective treatment. Current therapeutics can help to manage the joint pain associated with the virus but they have not been shown to treat the detrimental effects on joint cartilage that are associated with the disease. Current treatment options are also often inadequate in providing*

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*symptom relief, or associated with significant gastrointestinal side effects in patients with symptoms of joint pain which persist beyond the acute phase.”*

The randomised, double-blinded placebo-controlled clinical trial will treat a total of 24 participants. Participants with persistent RRV-induced arthralgia (painful joints) will be treated with PPS subcutaneous injections and will be evaluated for safety, tolerability and effects on disease symptoms. The study period will be approximately three months per participant, from first dose to final visit. Taking this into account, Paradigm anticipates results readout in mid 2018.

The Phase 2 trial follows research conducted by Griffith University in RRV and Chikungunya disease models, and subsequent phase 2 trial design work completed by Paradigm in consultation with experts in alphaviral disease.

The trial is being conducted as a pilot study, and it is intended to provide important clinical signals which will guide the design of a subsequent larger study. In addition, given the similarity between RRV and Chikungunya virus, the readout of the pilot study will be important in our ongoing partnering discussions.

Paradigm also continues its discussions with the US Department of Defense in regard to the development of PPS for a treatment for Chikungunya virus infections.

**FOR FURTHER INFORMATION PLEASE CONTACT:**

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