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ASX RELEASE

Paradigm To Commence Phase 2 Ross River Virus Clinical Trial

Key Highlights:

- Phase 2 Alphavirus clinical trial of the drug Pentosan Polysulfate Sodium (PPS) for the treatment of Ross River virus (RRV) now ready to commence
- Participant dosing expected in the coming weeks; trial will recruit 24 participants with Ross River virus in Queensland and Victoria
- Trial subjects will be evaluated for safety, tolerability and effects on disease symptoms, with results anticipated in Q2 CY2018
- Opportunity for Accelerated Approval as there are currently no therapeutic agents to treat the disease
- Trial commencement will signify strong momentum and depth in Paradigm's clinical trial pipeline, making it the Company's fourth active clinical trial

Melbourne, 10 July 2017, Paradigm Biopharmaceuticals Ltd (ASX:PAR) announces that it has initiated its two trial sites for its Phase 2 Alphavirus clinical trial of the drug Pentosan Polysulfate Sodium (PPS) for the treatment of Ross River virus.

Ethics approval and site initiation of the two sites at Mater Research in Brisbane, Queensland and Barwon Health in Geelong, Victoria, means the Company can commence participant recruitment for the trial. The dosing of the first participant is expected in the coming weeks. Other sites in Queensland are being evaluated for this clinical trial.

The randomised, double-blinded placebo-controlled clinical trial will treat a total of 24 subjects across both trial sites. People with RRV-induced arthralgia (painful joints) will be evaluated for safety, tolerability and effects on disease symptoms of PPS subcutaneous injections, with results anticipated in mid 2018.

Mr Paul Rennie, Paradigm's CEO said: "We look forward to recruiting participants and to commence dosing over the coming weeks. We hope that PPS can prove effective through this Phase 2 trial, especially as there are no effective pharmaceutical treatments available to RRV sufferers, making this a true unmet medical need."

Paradigm partnered with Griffith University who conducted the preclinical studies of RRV and Chikungunya virus infections. These data were peer-reviewed and published in the Journal of Virology. Subsequent Phase 2 trial design work was completed by Paradigm in consultation with experts in alphaviral disease. The regulatory documents were approved by the Ethics Committee and the sites initiated. The next steps are to recruit and then treat the clinical trial participants with current RRV infection.

There were 9,549 cases of Ross River fever notified in 2015 - more than double the previous year - and 21 per cent of them were from NSW, Victoria, Tasmania, South Australia and the ACT (Source: Federal Department of Health). Closely related to RRV is the Chikungunya virus (CHIKV). PPS was also tested in the preclinical model of CHIKV and proven to be successful in treating the disease. CHIKV is more widespread compared to RRV and the Pan American Health Organisation and the World Health Organisation reported for the first six months of CY2017 over 1 million cases of CHIKV just in the Americas.

Post a successful Phase 2 clinical trial for RRV, Paradigm plans to apply to the Regulators for Accelerated Approval for the treatment of the disease. While many RRV sufferers use over-the-counter pain medication to treat the symptoms, there are currently no therapeutic agents to treat the disease.

Clinical Trial Update:
Phase 2a Open Label Bone Marrow Edema Lesion trial due to read-out end of Q3 CY2017. Phase 1 and Phase 2 Hay Fever clinical trials complete and waiting on analysis of data before announcing next steps. The Ross River clinical trial is the fourth clinical trial commenced in under two years. Paradigm has demonstrated the operational discipline to execute on its clinical development plans.

FOR FURTHER INFORMATION PLEASE CONTACT:

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