ASX RELEASE

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Paradigm's Phase 2a Ross River Virus Clinical Trial Recruitment Finalised

Key Highlights:

- Paradigm has finalised the recruitment of its Phase 2a randomised, double-blinded placebo-controlled pilot clinical trial in participants with persistent Ross River virus (RRV) induced arthralgia (painful joints) treated with injectable pentosan polysulfate sodium (iPPS).
- Paradigm has decided to cap recruitment at 20 instead of 24 participants due to the significantly lower RRV incidence in 2018 compared to the 2017 outbreak.
- Paradigm's key objective of safety in the target population with RRV-induced arthralgia is expected to be met despite the shortfall of 4 participants.
- Paradigm's safety and efficacy signals with the RRV trial will support the design of future clinical trials for the viral induced arthralgia caused by the related Chikungunya virus (CHIKV).
- Paradigm will be continuing strategic discussions with the United States Department of Defence for the treatment of Chikungunya virus (CHIKV) induced arthralgia following data read-out of the current RRV Phase 2a clinical trial late Q4 CY2018.

Paradigm Biopharmaceuticals Ltd (ASX: PAR) is pleased to announce the finalisation of recruitment of its Phase 2a randomised, double-blinded placebo-controlled clinical trial in participants with persistent Ross River virus (RRV) induced arthralgia (painful joints) treated with injectable pentosan polysulfate sodium (iPPS).

Clinical trial sites initiated for subject recruitment by Paradigm in central and regional areas of Victoria and Queensland demonstrated good recruitment rates in 2017 and in early 2018. Inconsistent with the high RRV infection rates observed in CY2017, there has been a significantly lower than average incidence of RRV infection rates reported throughout CY2018. The low incidence of RRV infection has been associated with the lack of rainfall in the eastern states of Australia in CY2018 and parallels the significant reduction in reported mosquito outbreaks. This has slowed recruitment of participants that satisfy the trial's inclusion criteria. The seasonal and epidemiological challenge was particularly evident in Victoria (rural and remote), where the number of notified cases were nearly 20-fold lower in 2018 (98 notifications)[1] compared to 2017 (1921 notifications)[1].

As a result of the seasonal and epidemiological factors on recruitment and the low RRV infection incidence predicted for the rest of 2018, Paradigm's clinical development team rationalized that capping of participant recruitment to 20 instead of 24 would effectively meet the clinical milestones without escalating trial maintenance costs or delaying trial read-out.

Paradigm is satisfied that 20 participants will meet the outcome objectives for the pilot Phase 2a study, and will provide valuable clinical data demonstrating safety (primary endpoint) and effects on disease symptoms (secondary endpoint) in participants with recent Ross River virus infection treated with iPPS.

Paradigm's CEO, Paul Rennie remarked that "Strategically, this pilot study is aimed at providing the clinical evidence for the design of a larger clinical trial in Chikungunya Virus (CHIKV) induced arthralgia".

Paradigm looks forward to the results from this Phase 2a study, due to be reported by late Q4 CY2018.

About Chikungunga Virus:
CHIKV is closely related to the Ross River virus (both of the alphavirus genera) and causes similar debilitating symptoms of joint pain, fever, headache, conjunctivitis, and rash. The disease course is divided into an acute stage, lasting approximately one week, and a chronic stage, also known as the persistent stage, which can last from months to years. Acute fever and polyarthralgia are highly indicative of an infection, with arthralgia (joint pain) appearing in 30–90% of cases. This joint pain is often bilateral, symmetric, and debilitating. There are occasional ophthalmic, neurological, and cardiac symptoms[2].

Causing more than 3 million[3] infections worldwide, CHIKV outbreaks have been reported in parts of Africa, Europe, South east Asia, and islands in the Indian and Pacific Oceans. In 2013, CHIKV was found for the first time in the Americas and has spread to the Caribbean, South and Central America and North America[4]. The expanding incidence and the lack of anti-viral agents, vaccines or effective pharmaceutical agents to treat the debilitating effects of CHIKV make iPPS a valuable product for this unmet medical need. In addition, to the clinical data from the RRV Phase2a clinical trial, Paradigm is in collaboration with the Institute of Glycomics at Griffith University to investigate the effects of iPPS in animal models of CHIKV infection which would further support future clinical trial design.

References:

1. http://www.health.vic.gov.au/ideas/downloads/daily_reports/rptRS_SNIDSRegionalYTDComparisons_GR.pdf
2. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5744143/
3. https://www.sciencenews.org/article/chikungunya-move
4. https://www.cdc.gov/chikungunya/pdfs/factsheet_chikungunya-what-you-need-to-know.pdf

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