



ASX RELEASE

Hay Fever Trial Update

Melbourne 16 June 2017 Paradigm Biopharmaceuticals Ltd (ASX:PAR) today announced that its Phase 2a allergic rhinitis (hay fever) clinical trial did not meet its primary endpoints (total nasal symptom score and peak nasal respiratory flow) using the current nasal formulation.

The Company was verbally informed by its Contract Research Organisation ("CRO") of the top-line outcomes and anticipates receiving the final report shortly.

The Phase 2a trial investigated the intra-nasal effect of Pentosan Polysulfate Sodium (PPS) on post-challenge nasal symptoms using the allergen challenge model in subjects with seasonal Allergic Rhinitis.

Paul Rennie, Paradigm's Chief Executive Officer said: "Whilst this is an unexpected outcome, it should be noted that Paradigm conducted the Phase 2a clinical trial to the highest possible quality standards and was professionally executed on budget and on time."

"As part of the protocol, extensive clinical and laboratory data was collected and the analysis of this data will provide valuable insights into the effects of PPS and guide our future directions. In the coming weeks, Paradigm will receive the final report and the drug master file, allowing for an independent expert to conduct an in-depth investigation, in order to determine the next steps for our allergic rhinitis program. Early indications suggest that the formulation used in the allergic rhinitis clinical trial may need to be optimised."

Paradigm's other PPS-related programs proceeding as planned

It is important to note that Paradigm's other programs (bone marrow lesions and viral arthritis - following alpha virus infection) are proceeding as planned. These trials are investigating the well-established Mechanism of Action (MoA) (anti-inflammatory, mild anti-coagulant and anti-cartilage remodeling properties) and utilizing the well-established route of administration (subcutaneous or intra-muscular injection) of the drug. As the injectable form of the drug has been used for over 60 years, its safety and efficacy has already been established. The MoA are also well established and Paradigm has treated, under the Therapeutic Goods Administration's Special Access Scheme (TGA SAS), more than 40 people with either unresolved bone marrow lesions, osteoarthritis associated with bone marrow lesions or polyarthritis following Ross River infection. These human cases have demonstrated the safety, tolerability and clinical effect in these indications.

Thus, while the formulation and dose of the allergic rhinitis product may potentially need to be optimised, these factors are not required for Paradigm's other clinical programs which utilise the established and proven doses and delivery routes of administration and are supported by positive clinical outcomes in humans.

The Company's rationale for the Allergic Rhinitis Phase 2a clinical trial was based on the successful preclinical study, which was peer-reviewed and published in the medical journal *Immunity, Inflammation and Disease*. The preclinical data demonstrated the drug PPS was a potent Th2 antagonist (IL-4, IL-5 and IL-13) and the effect of PPS was compared to the corticosteroid budesonide. Both PPS and budesonide demonstrated a statistically significant outcome in that study.

The Phase 2a bone marrow lesion clinical trial continues to recruit and is scheduled to read-out in Q3 CY2017.

The Phase 2a Ross River clinical trial has received ethics approval and is scheduled to enroll its first subjects in Q3 CY2017.

In addition, the upcoming peer-reviewed publication of a TGA SAS case-study demonstrating PPS's clinical effect in osteoarthritis associated with bone marrow edema is due in Q3 CY2017.

As stated earlier, the outcome of the Phase 2a allergic rhinitis trial was unexpected however it has demonstrated that Paradigm has the resources to execute on its clinical trials in a professional, timely and cost-efficient manner (the Phase 2a AR trial cost ~\$2 million and was completed in approximately six months and is subject to the 45% R&D tax rebate).

Human data on bone marrow lesions and Ross River cases provides Paradigm with important efficacy signals for our next two clinical trials and the Company believes these will be significant value creating milestones for the Company.

FOR FURTHER INFORMATION PLEASE CONTACT:

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