



ASX RELEASE

**Preclinical study underpins efficacy of Paradigm's Rhinosul® for hay fever treatment**

**Key Highlights:**

- Leading Immunologist Professor Jonas Erjefalt (Lund University, Sweden) presents preclinical efficacy data on Rhinosul® (PPS) for allergic rhinitis (hay fever) treatment at the Australian Society of Clinical Immunology and Allergy;
- In an industry standard validated animal model, PPS in comparison with the steroid budesonide (Rhinocort®) showed profound reduction in inflammatory cell numbers in the nasal lavage fluid following allergen challenge;
- PPS represents a potential novel competitive therapeutic agent for the treatment of allergic rhinitis compared to the current nasal steroid budesonide;
- Based on compelling animal efficacy data and the safety profile in the Phase 1 clinical trial with Rhinosul®, Paradigm is preparing for a Phase 2 clinical trial in subjects with allergic rhinitis in Sweden in December 2016.

**Melbourne Friday, September 16, 2016 Paradigm Biopharmaceuticals Ltd (ASX:PAR) announces key preclinical data showing pentosan polysulfate sodium (PPS) as an effective treatment for allergic rhinitis / hay fever.**

Paradigm Biopharmaceuticals Ltd (Paradigm) is delighted to report the presentation of crucial preclinical data highlighting the efficacy of PPS in a translational model of allergic rhinitis.

Preclinical trials conducted by Professor Jonas Erjefalt's Lund University team in an industry standard validated animal model have shown that PPS is as effective as the industry leading treatment, an intra-nasal corticosteroid, budesonide. The research was unveiled today at the Australian Society of

Clinical Immunology and Allergy's (ASCI) annual conference on the Gold Coast (Queensland, Australia).

Professor Erjefalt said, "Our research showed that the drug, PPS, blocked the TH2 cytokines, such as IL-4, IL-5 and IL-13 which are known to be responsible for the late stage of the disease causing nasal congestion. Our data showed that the anti-inflammatory properties of PPS were as effective as well-known intra-nasal corticosteroid-based treatments". Corticosteroids are known to have undesirable side effects so treatment with this drug represents a potential breakthrough for those people wanting a steroid-free treatment for hay fever.

Paradigm's Chief Scientific Officer Dr Ravi Krishnan stated "Independent and peer-reviewed experimental data has also demonstrated that PPS is an effective mast cell stabiliser (reduces histamine release)." He also stated "Anti-histamines are important in the early phase of the allergic response and combined with the anti-inflammatory activity would suggest that Rhinosul® has the hallmark of a first-in-class drug for the treatment of hay fever symptoms".

Dr Claire Kaufman, Paradigm's Operations Manager said, "Given these very encouraging preclinical results, Paradigm will now proceed with plans to test PPS in human hay fever patients in a randomised double-blind, placebo-controlled crossover study in Sweden in December 2016.

Respiratory Physician, Assoc. Prof. Janet Rimmer, of the University of Sydney, said, "Recently conducted surveys on the use of nasal sprays for the treatment of hay fever have shown patient dissatisfaction and poor compliance. Current nasal corticosteroids have anti-inflammatory activity but do not have the other effects shown by Rhinosul®. An effective, non-steroid-based therapy such as PPS with anti-inflammatory properties as well as the prevention of histamine release would represent a major global advance in the treatment of what is a distressing and debilitating condition."

Mr Paul Rennie, CEO of Paradigm said, "Repurposing PPS for hay fever represents a breakthrough in the treatment of hay fever i.e. one drug (PPS) which is steroid independent and has the potential to attenuate the symptoms of both the early and late phases of the disease. The global market for hay fever therapeutics is US\$11bn. With a potential first-in-class drug for this massive market, the treatment of hay fever represents a major commercial opportunity for Paradigm".

#### **ANY QUESTIONS OR ADDITIONAL INFORMATION PLEASE CONTACT:**

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