**ASX RELEASE**

# SHAREHOLDER UPDATE

**25 May 2016, Melbourne, Australia:** Paradigm Biopharmaceuticals Limited (ASX: PAR) (**Paradigm** or **Company**) is pleased to report that members of the management team were in Europe last week to visit the Company's key suppliers for the hay fever (allergic rhinitis) clinical trial programs.

The visit was very successful and the Company is pleased to report that plans for the Phase I and Phase II trials are on schedule. The Phase I Clinical Trial will commence in July 2016 in Perth and the Phase II Clinical Trial will commence in December 2016 in Sweden.

## UPCOMING NEWSFLOW

Over the next 6 months, Paradigm's focus will be on:

- Reporting on the intra-nasal hay fever toxicology trial;
- Commencing the Phase I and Phase II hay fever clinical trials;
- Submitting for publication the pre-clinical trial comparing Paradigm's drug (Rhinosul® / pentosan polysulfate sodium) to AstraZeneca's drug (Rhinocort® / budesonide) which is the number 1 selling intra-nasal corticosteroid to treat hay fever.

## HAY FEVER PROGRAM

Hay fever is a very large addressable market that is poorly treated at present:

- **600 million people** worldwide suffer from hay fever;
- The therapeutic market for treating hay fever is **USD$11+ billion**;
- **Rhinosul®** (pentosan polysulfate sodium) has been shown, in a preclinical model, **to have both anti-histamine and anti-inflammatory effects** making it a potential first in class non-steroid based treatment for hay fever.

The following image shows the Rhinosul® nasal spray product which has been manufactured for the upcoming clinical trials. The nasal spray will be used in the Phase I Clinical Trial (July – August 2016) and Phase II Clinical Trial (Dec 2016 – May 2017).

**Phase I Clinical Trial:**

Phase I clinical trial has been designed to evaluate the safety and tolerability of single and multiple doses of intranasal pentosan polysulfate sodium (Rhinosul®) in healthy subjects. A randomised, double blind, placebo-controlled trial in healthy subjects. The trial will be structured as 18 randomised subjects, with 9 subjects per dose level cohort and 2 dose level cohorts.

**Phase IIa Clinical Trial:**

Phase IIa clinical trial challenge study which will be a randomised, double blind, cross-over with placebo control design. This is the same clinical trial model for hay fever that was used by AstraZeneca to screen for its hay fever drugs including Rhinocort®. This is a significant advantage for Paradigm as the study model is well-known to big pharma companies and regulatory authorities.

**Peer Reviewed Scientific Publication:**

In Q4 2016, Paradigm plans to submit for publication pre-clinical research which investigated our drug's (Rhinosul® / pentosan polysulfate sodium) performance compared to the number 1 selling intranasal corticosteroid (AstraZeneca's Rhinocort® / budesonide).

Paul Rennie, Managing Director and CEO, commented: "We are very pleased with the rapid progress we have made on the hay fever clinical trial program. The next 6 months represents an exciting time for the Company and we look forward to being able to report further clinical outcomes. Hay fever represents a very large addressable market for the Company and we look forward to progressing our hay fever clinical program to potentially provide a superior and safer treatment."

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