ASX RELEASE

Paradigm's Phase 2 Hay Fever Trial gets approval from Swedish MPA

Participant screening and recruitment has commenced !

Key Highlights:

- Ethics approval obtained for Rhinosul® Trial to treat allergic rhinitis (Hay Fever);
- Regulatory approval to proceed with Phase2a trial design from Swedish Medical Products Authority (MPA);
- Participant screening and recruitment has commenced and first participant scheduled to be treated Mid-December 2016;

Melbourne: 22 November 2016 Paradigm Biopharmaceuticals Ltd (ASX:PAR) announces both ethics committee and Swedish MPA approval to commence Phase 2a allergic rhinitis trial in Lund, Sweden.

PHASE 2a CLINICAL TRIAL: The Company is delighted to announce it has received approval from the Independent Ethics Committee, Lund, and regulatory approval from the Swedish MPA to proceed with a Phase 2a clinical trial in Lund, Sweden. Participant screening and recruitment has now commenced. The Phase 2a trial will be a challenge study in participants with allergic rhinitis. It will be a double blind, placebo controlled, cross over design, conducted in 40 participants. The trial will commence in December 2016. The treatment of trial participants will take between 2-3 months, with readout of results anticipated in Q3 CY2017. The trial will be conducted under the leadership of Professor Lennart Greiff at Skane University Hospital who has previously conducted similar clinical trials using the established clinical model for allergic rhinitis by Big Pharma including Astra Zeneca.

Paradigm's Operations manager, Dr Claire Kaufman who was involved in coordinating the preparation for this trial said "This is a very exciting opportunity to work with Dr Greiff. The challenge study will enable us to assess the nasal formulation of PPS for the treatment of this disease in a controlled setting".

Paradigm's CEO Mr Paul Rennie said "The commencement of the Phase 2a clinical trial is the next step in the clinical development of Rhinosul® following:

- the successful non-clinical (animal studies) comparing Astra Zeneca's Rhinocort® with Paradigm's Rhinosul® (Mori et al. Internal Medicine Journal 2016),
- intranasal toxicology study and
- the safety data from the Phase 1 clinical trial.

We expect to report the Phase 2a clinical trial results in Q3 of CY2017".

Mr Rennie also remarked "The novelty of Rhinosul® in comparison to current Allergic Rhinitis medications on the market is that it is a potential first-in-class product with both mast cell stabilizing activity (which controls histamine release) and also non-steroidal anti-inflammatory properties in one nasal spray pharmaceutical product. The initiation of the Phase 2a study within a short period following Paradigm's IPO will allow Paradigm to expeditiously progress its clinical development plans in line with its business model of drug repurposing".

ADDRESSABLE MARKET: The current market for Allergic Rhinitis is about USD 11 Billion[x] and is dominated by anti-histamines and corticosteroids with market surveys highlighting patient dissatisfaction and the need for effective therapy. Rhinosul® has unique properties consisting of both histamine stabilising and non-steroidal anti-inflammatory properties without the known side-effects of anti-histamines and steroids. The company believes its product can meet market needs that are not effectively managed by current nasal sprays.

About Paradigm Biopharmaceuticals Ltd: (ABN: 94 169 346 963) Paradigm Biopharmaceuticals Ltd (ASX: PAR) is an Australian biopharmaceutical company focused on repurposing the historic drug PPS (Pentosan Polysulfate Sodium) as a potential new treatment for Bone Marrow Edema (BME) lesions following traumatic injury. Paradigm Biopharmaceuticals is also repurposing PPS for respiratory diseases including Allergic Rhinitis (AR) also known as hay fever. Paradigm is also investigating the use of PPS to treat viral arthritis following mosquito born alphavirus infections such as Ross River and Chikungunya. Repurposing an existing drug diminishes early developmental risks associated with traditional new drug development and usually means shorter development times, lower development costs and less safety risk.

http://paradigmbiopharma.com or email enquiries to: info@paradigmbiopharma.com

[x] Visiongain: Allergic Rhinitis Drugs Market Forecast 2015-2025