**ASX RELEASE**

# Paradigm Biopharmaceuticals secures key European patent

***Highlights:***

- ***European Patent Office grants Paradigm key respiratory patent.***
- ***Patent to use Pentosan Polysulfate Sodium (PPS) to treat respiratory diseases.***
- ***Patent claims the use of PPS over allergic rhinitis, allergic asthma and COPD.***
- ***Allergic rhinitis (AR) or as it is more commonly referred to "hay fever" is a very common disease, affecting 10% to 30% of the world's population.***

**15 December 2015, Melbourne Australia:** Paradigm Biopharmaceuticals Limited (ASX:PAR) is pleased to advise it has been issued with a 71(3) communication, notice of intention to grant a patent by the European Patent Office (EPO).

Paradigm's patent attorney Paul Whenman from the firm FB Rice & Co said "the EPO 71(3) communication, notice of intention to grant a patent means that prosecution of the patent application has been finalized and the EPO will grant a patent once Paradigm has provided the requisite translations and paid the official grant fees. Upon grant of the patent, Paradigm will have market exclusivity under the patent until 30 May 2028. Since the patent claims the use of PPS for the treatment of allergic rhinitis, allergic asthma and COPD, Paradigm will have exclusivity for these indications while the patent is in force.

The granting of this respiratory patent in Europe adds to Paradigm's growing intellectual property portfolio. Paradigm's bone marrow edema (BME) patent is already granted in the USA, Australia and New Zealand. In addition Paradigm's PPS respiratory patent is already granted in China, Australia and New Zealand.

Mr Whenman also said "the prosecution of Paradigm's BME and respiratory patents continues in other major markets, such as Japan, Canada & China, where it is expected that more Paradigm patents will be granted in 2016".

In addition to patents, Paradigm has registered trademarks for the BME product, ZILOSUL® and respiratory product RHINOSUL® for Allergic Rhinitis.

**Enquiries:**


Paul Rennie
Managing Director and CEO
0437 778 300

Rudi Michelson
Monsoon Communications
03 9620 3333 or 0411 402 737

**About Allergic Rhinitis:** Allergic rhinitis (AR) or, as it is more commonly referred to, hay fever, is a very common disease, affecting 10% to 30% of the world's population and 7.8% of adults in the US (or, approximately, 25 million Americans) according to figures quoted by the American Academy of Allergy, Asthma and Immunology. AR is the result of the immune system over-reacting to allergens, such as pollen, dust and/or pet hair, in the air. Two common therapies for treating AR include antihistamines and intranasal corticosteroids.

**About Paradigm Biopharmaceuticals:** Paradigm Biopharmaceuticals (ASX:PAR) is an Australian biopharmaceutical company focused on repurposing historic drug PPS (Pentosan Polysulphate Sodium) as a potential new treatment for Bone Marrow Edema (BME) lesions arising from sporting injuries as well as for respiratory diseases including Allergic Rhinitis (AR), or hay fever.

PPS is a well-established anti-clotting and anti-inflammatory agent that has been used for over 60 years to treat interstitial cystitis and the prevention and treatment of deep vein thrombosis. It has a solid safety and efficacy profile.

BME is also known as bone bruising and is an extremely painful and debilitating injury. It typically affects sportspeople but can also result from a range of injuries including car accidents and falls. BME is caused by fluid build-up and micro-fractures inside the bone, causing severe pain. There is no approved pharmaceutical product to treat this condition. Current treatment of BME includes the use of steroidal and non-steroidal anti-inflammatory drugs, which can have serious side effects. Paradigm will launch an Open Label clinical trial of PPS in BME trial subjects at sites in Australia from early 2016.

Paradigm has also acquired patents over the use of PPS as a new treatment for respiratory diseases including Allergic Rhinitis (AR), Allergic Asthma (AA) and Chronic Obstructive Pulmonary Disease (COPD). Paradigm also acquired pre-clinical data, nasal formulation and other data from the previous developer Glycan BioSciences LLC, allowing Paradigm to fast-track its treatment for AR into clinical trials in Q4 2016.

Antihistamines and corticosteroid nasal sprays are standard existing treatments for AR. Long-term use of corticosteroids is associated with adverse side effects whereas Paradigm's AR product is not a steroid-based pharmaceutical. Paradigm's preclinical data demonstrates PPS is both a mast cell stabilizer (reduces mast cell degranulation and therefore PPS acts like an anti-histamine) and an anti-inflammatory (like a corticosteroid but PPS is not a steroid-based drug). Therefore and very importantly, PPS is potentially the first dual-acting (effective in both the early and late AR responses) product that could enter the very large market of AR.

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.

Paradigm has also acquired intellectual property over exosomes; a new technology in stem-cells and regenerative medicine fields. This technology offers the company the potential to participate in the development of new generation regenerative medicine products.