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Paradigm Shift Gives Old Drug New Life

BY JAMES DUNN - 20/01/2016 | VIEW MORE ARTICLES BY JAMES DUNN

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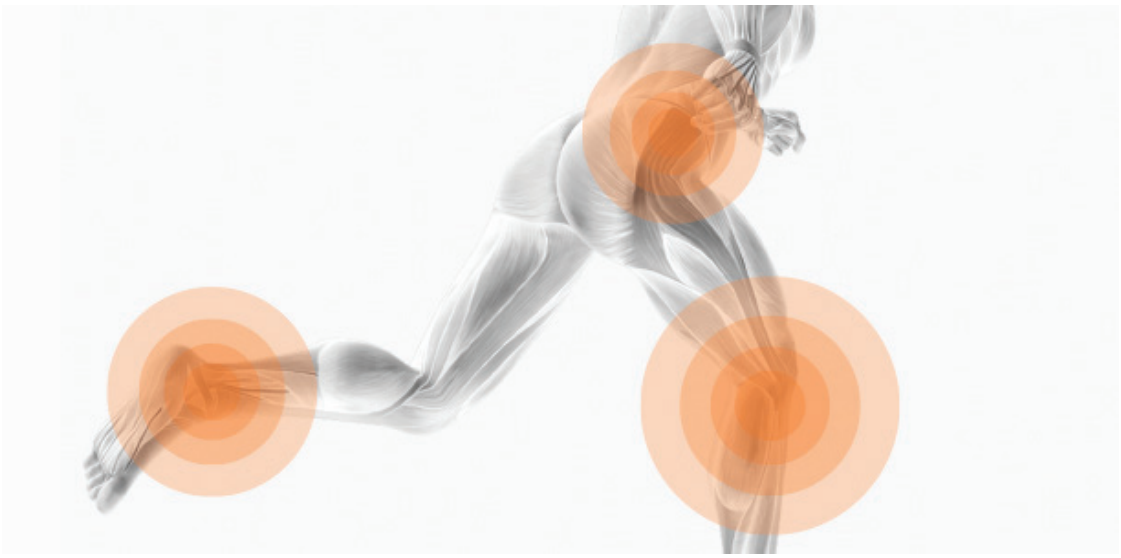
• PAR - PARADIGM BIOPHARMACEUTICALS LIMITED



Paradigm Biopharmaceuticals is a specialist drug repurposing company, formed to re-configure a compound called pentosan polysulphate sodium into new applications, starting with a treatment for bone marrow edema.

Recycling and re-using things efficiently are simply part of the modern world, so it should come as no surprise that a similar approach is being used in the pharmaceutical industry.

It's called "repurposing," and it involves taking an existing approved drug, which has demonstrated safety in the use for which it is approved, and re-directing it to a new, patented therapeutic application. Repurposing an existing drug lowers the developmental risks associated with typical new drug development, and usually means shorter development times, lower development costs and less safety risk. More than 30 per cent of drug approvals or launches represent drugs repurposed for new indications, reformulations or new combinations of existing drugs.

Paradigm Biopharmaceuticals Limited (PAR), which joined the Australian Securities Exchange in August 2015, is a specialist drug repurposing company, formed to re-configure a compound called pentosan polysulphate sodium (PPS) into new applications, starting with a treatment for bone marrow edema (BME), which is a painful bruising within the bone, most commonly arising from sporting injuries, but can also be caused by car (and other) accidents and minor falls.

BME – or "bone bruising" – is the result of fluid build-up and micro-fractures inside the bone. If untreated, BME can be associated with long-term health problems, including pain, disability, cartilage breakdown, and a greater likelihood of progression to osteo-arthritis, but there is no

approved pharmaceutical product for it at the moment. Current treatment of BME includes the use of steroidal and non-steroidal anti-inflammatory drugs, which can have serious side effects.

Enter PPS, a well-established anti-clotting and anti-inflammatory agent that has been used for more than 60 years. First developed in Germany in 1949 to treat blood clots, PPS has also been used to treat interstitial cystitis, and for the prevention and treatment of deep vein thrombosis. This form of PPS, which comes from a polysaccharide obtained from the bark of the beech tree, was first approved by the US Food & Drug Administration (FDA) 30 years ago, and has a strong safety and efficacy profile. Paradigm has signed an exclusive supply agreement with the original German manufacturer of PPS, bene pharmaChem.

Paradigm's proprietary pharmaceutical formulation of PPS, called ZILOSUL, aimed at treating BME lesions. This year, the company is taking ZILOSUL into an open-label Phase 2a clinical trial (an 'open-label' trial has no placebo controls and no 'blinding,' meaning that both the researchers and participants know which treatment is being administered.) The trial, which will take up to 12 months, will be carried out in two medical centres, Southern Orthopaedics in Adelaide, South Australia, and Sportsmed Biologic Medical Centre at Box Hill, in Melbourne.

The patients will be up to 40 people who have suffered an anterior cruciate ligament (ACL) injury, and subsequently experienced bone pain and reduced joint function, and had a BME lesion identified by MRI. The patients will receive ZILOSUL twice weekly for a period of three weeks. PPS is known to protect cartilage, having anti-inflammatory and blood-clot-clearing properties — which are considered to be vital in quickly resolving BME. The aim of the trial from PAR's perspective is to see if the ZILOSUL, when used shortly after the anterior cruciate ligament injury, can preserve the knee cartilage and therefore delay – or even prevent – the onset of osteoarthritis in the injured knee, and improve the functional knee joint capacity.

Other objectives of the study are to evaluate the effect of IZILOSUL on the patient's pain levels following their ACL injury and its effect on the biomarkers of inflammation, bone and tissue remodelling.

Prior to the commencement of the trial, an un-named Australian "elite athlete" began treatment (in November 2015) with ZILOSUL on an unresolved BME lesion that had resisted multiple therapeutic and surgical interventions. Although ZILOSUL is not yet registered in Australia, the Therapeutic Goods Administration (TGA) allowed Paradigm to supply the drug under its Special Access Scheme (SAS). The athlete received six intra-muscular injections of ZILOSUL.

Announcing this treatment to the ASX in December, PAR said that no adverse events were observed and the product was well tolerated. “The prescribing doctor has advised Paradigm that the initial clinical response to the ZILOSUL has been very positive/encouraging, particularly given the refractory nature of symptoms in this patient. Detailed results of effect of the ZILOSUL treatment on the athlete’s condition are expected in coming months,” said the announcement.

Further down the track, PAR holds patents covering the use of PPS to treat respiratory diseases including allergic rhinitis (AR), allergic asthma (AA) and chronic obstructive pulmonary disease (COPD). Better known as hayfever, allergic rhinitis, which is the result of the immune system over-reacting to allergens – such as pollen, dust and/or pet hair – in the air, is a very common disease, estimated to affect 10 per cent–30 per cent of the world’s population. In the US, the American Academy of Allergy, Asthma and Immunology estimates that 7.8 per cent of adults (approximately 25 million Americans) suffer from AR.

Two common therapies for treating AR include anti-histamines and intra-nasal cortico-steroids. Long-term use of cortico-steroids is associated with adverse side effects whereas Paradigm’s AR product is not steroid-based. Paradigm plans to develop a nasally inhaled product to treat AR, as a substitute for steroid-based treatments. PPS is potentially a dual-acting product – meaning it acts like an anti-histamine and an anti-inflammatory, and thus could be effective in both the early and late AR responses. As such, PPS could be the first dual-acting product to enter the very large market of AR. After an AR product has been developed, Paradigm plans to turn its attention to an inhalable product for allergic asthma.

This week, Paradigm announced that it had received a notice of intention to grant a patent by the European Patent Office (EPO). 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 the company's growing intellectual property portfolio. PAR’s bone marrow edema patent is already granted in the USA, Australia and NZ: in addition, its PPS respiratory patent is already granted in China, Australia and NZ. Paradigm’s BME and respiratory patents continues in other major markets, such as Japan, Canada and China, where it is expected that more Paradigm patents will be granted in 2016.

In addition to patents, Paradigm has registered trademarks ZILOSUL and the respiratory product for allergic rhinitis, RHINOSUL. Paradigm has also acquired intellectual property over exosomes, which is a new technology in stem-cells and regenerative medicine fields. This technology gives the company the potential to participate in the development of new-generation regenerative medicine products.

PAR hit the ASX screens in August 2015. Issued through the prospectus at 35 cents, the shares opened at 41 cents — a 12.5 per cent premium — and closed at 37 cents. The shares have traded as low as 28 cents, but have moved back to 32 cents, which capitalises Paradigm at $28 million. At this price, which is cheaper than issue, Paradigm represents a very interesting play on

the drug repurposing market, with several clear targets identified for its PPS-based IP portfolio. As with all biotechs, news flow will be a the major driver for share price movements.

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