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Australian Patent Application Acceptance by IP Australia

Paradigm Biopharmaceuticals Ltd (ASX: PAR) ("Paradigm" or "the Company"), a clinical stage biopharmaceutical company focussed on repurposing existing molecules for new indications with unmet clinical needs, is pleased to provide an update to the market that it has received official acceptance of the Australian patent application "Treatment of bone marrow pathologies with polysulfated polysaccharides (Australian application number (2021201198). The expiry date of the Australian patent (2021201198) is 6th August 2038.

The first claim of the accepted patent (2021201198) refers to "a method of improving knee function where the subject has a bone marrow lesion and osteoarthritis in a knee by administering pentosan polysulfate sodium".

Paradigm clarified in an ASX Announcement 9th March 2022, that a pending patent application with the US Patent and Trademark Office (the USPTO), had received a final rejection notice for the patent application titled "Treatment of bone marrow pathologies with polysulfated polysaccharides" (US application number 16/636,545). This is the same patent as the recently issued Australian patent (above). Paradigm clarified that a final rejection is not final, and the prosecution of this patent continues with Paradigm expected to file its response, to the US patent and trademark office (USPTO), by the end of July 2022.

Paradigm Chairman, Mr Paul Rennie commented, "It is very exciting for the Company's strategic plans to have a patent which claims the treatment of people with osteoarthritis and bone marrow lesions with pentosan polysulphate sodium (PPS) and we expect further acceptance and grants in other territories in the coming months. We continue to work in partnership with our patent attorneys to proactively prosecute new patents to extend our protection on the use of PPS in disease indications with unmet medical needs."

Summary of IP

Paradigm's PPS has a multi-faceted protection consistent with composition of matter encompassing manufacturing, patents, and exclusive in-licensing and supply for new indications with unmet clinical needs.

There is only one FDA approved manufacturer of Pentosan Polysulfate Sodium (PPS), bene pharmaChem GmbH (bene), with whom Paradigm has an exclusive, sublicensable, global supply agreement for the manufacture and commercial use of PPS for multiple indications extending for 25 years post first marketing approval. In addition, Paradigm has an ongoing collaboration agreement with bene for product related development support for meeting regulatory milestones and development of PPS for new indications and second-generation molecules.

PPS is a highly complex molecular platform technology; a highly sulphated semisynthetic

xylan-based polysaccharide that structurally resembles glycosaminoglycans, which is derived from beechwood hemicellulose. The manufacture and composition of PPS is a trade secret tightly held by bene for over 60 years.

A generic manufacturer would be required to develop an identical molecular fingerprint of the bene PPS. The complex molecular structure of PPS means generic manufacturers face a task of similar difficulty to that of developing a copy of a biosimilar. Potential generic entrants must provide GPC (gas permeable chromatography) data demonstrating identical structure and purity for each of the multiple moieties.

A generic copy is highly unlikely to be identical as described above. Therefore, a full clinical development program to demonstrate equivalent pharmacokinetic, pharmacodynamic, clinical safety and efficacy profiles will be required. Paradigm has a broad patent portfolio covering multiple indications in all key jurisdictions. Paradigm's primary and foundational patents (US10,610,542, US9,861,657 and US9,101,650) which have been granted in the US and several other jurisdictions are for the use of PPS to treat bone marrow edema (BME). Since BME is associated with painful knee OA our patent protection blocks any generic use to treat knee OA in the absence of BME.

Paradigm is proactively prosecuting new patents to extend its protection on the use of PPS in disease indications with unmet medical needs where the actions of PPS have been scientifically (in preclinical proof-of concept models) and/or clinically (population of patients) been ascertained to be therapeutically effective. For example, a patent related to the action of PPS in pain mediated by NGF is currently being prosecuted in key jurisdictions.

Currently registered oral formulations of PPS are not suitable for conditions requiring systemic distribution for treatment effect. The bioavailability of oral formulations of PPS is 3.3 -3.5%.[1]

In summary, Paradigm's injectable PPS is well protected with

- a 25-year post-marketing exclusive supply agreement with the only FDA approved manufacturer of the API,
- trade-secret and complex manufacturing processes of the API from the extracted biological starting material and,
- method of use patents covering multiple disease indications in key jurisdictions globally.

With no FDA approved generics of injectable PPS, the barrier to entry for potential competitors is high.[2]

About Paradigm Biopharmaceuticals

Paradigm Biopharmaceuticals LTD (ASX: PAR) is a late-stage drug development company with the mission to develop and commercialise Pentosan Polysulfate Sodium for the treatment of pain associated with musculoskeletal disorders driven by injury, inflammation, aging, degenerative disease, infection, or genetic predisposition. Paradigm is also exploring proof-of-concept studies for the use of PPS in respiratory and heart failure indications.

Forward Looking Statements

This Company announcement contains forward-looking statements, including statements regarding anticipated commencement dates or completions dates of preclinical or clinical trials, regulatory developments, and regulatory approval. These forward-looking

statements are not guarantees or predictions of future performance, and involve known and unknown risks, uncertainties, and other factors, many of which are beyond our control, and which may cause actual results to differ materially from those expressed in the statements contained in this presentation. Readers are cautioned not to put undue reliance on forward-looking statements.

References

1. Greenslade D, Vickers J, Hopkins R. (3H)-Sodium Pentosan Polysulfate: A Pharmacokinetic Study in Man after Oral Administration. Hazleton Laboratories; 1983.
2. Smith RB. Repositioned drugs: integrating intellectual property and regulatory strategies. Drug Discov Today Ther Strateg. 2011;8(3-4):131-137. doi:10.1016/j.ddstr.2011.06.008

Authorised for release by the Paradigm Board of Directors.

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FOR FURTHER INFORMATION PLEASE CONTACT:
Simon White
Director of Investor Relations
Tel: +61 404 216 467
Paradigm Biopharmaceuticals Ltd
ABN: 94 169 346 963
Level 15, 500 Collins St, Melbourne, VIC, 3000, AUSTRALIA
Email: investorrelations@paradigmbiopharma.com