

Collaborative research article from bene pharmaChem, Kiel University, and Paradigm is accepted for publication.

Paradigm Biopharmaceuticals Ltd (ASX:PAR) (“Paradigm” or “the Company”), a late-stage drug development company focused on delivering new therapies to address unmet medical needs, is pleased to announce that a scientific article arising from a collaboration between bene pharmaChem, Kiel University, and Paradigm Biopharma scientists, has been accepted for publication in the scientific journal *Carbohydrate Polymers*. The article entitled “*Chemical and biological differences between original and mimetic pentosan polysulfates*” (1) is currently available as an open-access pre-print on the journal [website](#).

Carbohydrate Polymers, published by Elsevier, is a major journal within the field of glycoscience and is devoted to scientific and technological aspects of medically and industrially relevant polysaccharides.

The collaborative study has demonstrated that Paradigm's pentosan polysulfate sodium (**PPS**) drug substance is different from other available PPS drug substances, both with respect to their respective structure and biological characteristics. This finding is commercially impactful in that it validates that Paradigm can expect to command a regulatory moat around PPS which is in addition to its extensive patent portfolio. Having a regulatory moat means that would be generic PPS manufacturer must perform their own clinical efficacy and safety studies in order to attain approval to market their PPS products.

PPS was originally manufactured by bene pharmaChem and is a semisynthetic sulfated polysaccharide derived from European beech tree wood. The manufacturing undergoes a complex process to produce a final mixture comprising of a spectrum of sulfated glucuronoxylans which are very challenging to be characterised by structural analysis. Although attempts have been made by other competitive PPS manufacturers, the bene pharmaChem PPS is the only product that has been approved by FDA and EMA for clinical use. PPS is currently approved for oral treatment of interstitial cystitis in Australia, Canada, the European Union, and the USA.

Dr Christian Reiter, Paradigm’s Senior Principal Researcher, commented: “This collaborative study involving University of Kiel, bene pharmaChem and Paradigm for the first time has described multiple structural differences in the chemical composition of bene PPS compared to the other commercially available PPS products. Our study gives evidence that PPS is a complex drug and that products from different manufacturers are chemically and functionally not identical.”

Paradigm’s Chair and Managing Director, Mr Paul Rennie said, “I am pleased that this peer-reviewed publication in this highly regarded journal emphasis that the bene PPS

is unique structurally and functionally and furthermore, Paradigm has demonstrated the safety and clinically efficacy in its osteoarthritic and rare disease indications. It would appear to be a significant challenge by competitors to develop a convincingly similar or generic PPS by further investigations to meet the regulatory requirement for clinical use. Furthermore, Paradigm's patents cover the use of bene's PPS in a range of medical indications in musculoskeletal diseases".

About Paradigm Biopharmaceuticals

Paradigm Biopharmaceuticals Ltd. (ASX:PAR) is a late-stage drug development company driven by a purpose to improve patients' health and quality of life by discovering, developing, and delivering pharmaceutical therapies. Paradigm's current focus is developing injectable (subcutaneous) pentosan polysulfate sodium (**iPPS**) for the treatment of diseases where inflammation plays a major pathogenic role, indicating a need for the anti-inflammatory and tissue regenerative properties of iPPS, such as in osteoarthritis (phase 3) and mucopolysaccharidosis (phase 2).

To learn more please visit: www.paradigmbiopharma.com

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