



## PARADIGM EXTENDS TERM, INDICATIONS AND TERRITORIES UNDER EXCLUSIVE SUPPLY AGREEMENT WITH BENE PHARMACHEM

---

**Paradigm Biopharmaceuticals Ltd (ASX: PAR)** is pleased to announce that its exclusive license and supply agreement with bene pharmaChem of 11 November 2014 has been amended with positive and material commercial outcomes for Paradigm. This is an important development for Paradigm as bene pharmaChem remains the only FDA approved manufacturer/supplier of Pentosan Polysulphate Sodium (PPS). This major upgrade in arrangements for the long-term supply of bene PPS is very important to Paradigm's commercial plans and represents a further significant de-risking for Paradigm's investors.

### Amended Agreement with bene pharmaChem

Under the amended exclusive license and supply agreement, Paradigm receives the following:

#### Expansion of the Territories

- ✓ Territories now includes all major pharmaceutical markets (excluding Japan which is covered under a separate arrangement).

#### Expansion of the clinical indications

- ✓ Paradigm has been able to expand the number of indications under this agreement.

#### Extension of the term for the exclusive supply of PPS.

- ✓ Paradigm now has a term of 25 years from the date of marketing approval. As Paradigm moves towards commercialization, the exclusive supply of PPS for 25 years following marketing approval provides a greatly elevated level of commercial protection. Bene product exclusivity, along with regulatory exclusivity and patents combine to provide Paradigm with a multitiered protective moat around our business.

#### Dr Harald Benend, co-Managing Director of bene pharmaChem said:

*"Bene and Paradigm have developed a very solid commercial partnership over the past 7 years. Bene is impressed with the speed and professionalism of Paradigm as they move pentosan polysulfate sodium through clinical trials and regulatory submissions. We are excited to see Paradigm commencing its Phase 3 clinical trials in Europe, the USA and Australia in the near future. Bene has great confidence in Paradigm to execute on its Phase 3 clinical trials and we are pleased to be able to extend our exclusive supply of PPS to Paradigm for a period of 25 years post marketing approval. The bene PPS continues to be the only FDA approved PPS available worldwide and we are happy to support Paradigm with the long-term supply of our drug".*

---

**Paul Rennie, CEO and MD of Paradigm says, “there are no generic versions of bene PPS on the market and this makes the exclusive supply of bene PPS so valuable to our commercial plans. Paradigm is focussed on executing on our pivotal clinical trials in the USA and Europe and moving onto registration of Zilosul® in the major pharmaceutical markets. We are very grateful for the support that Dr Harald Benend and his Bene colleagues have provided to Paradigm and we are very excited about the additional territories, clinical indications and the 25-year exclusive supply of bene PPS post registration”.**

### **About bene pharmaChem**

In 1947, Dr W. Benend succeeded in developing a standardised process for manufacturing a type of sulphated polysaccharides, pentosan polysulphate sodium, which has an anticoagulant, fibrinolytic and thrombolytic quality with comparatively limited side effects. As a medicinal product, pentosan polysulphate sodium was first authorised and marketed in Germany in 1949, and afterwards in other European countries, primarily for thromboembolism. In the following years, pentosan polysulphate sodium was investigated on a global scale by research groups and its anti-inflammatory, antiviral and anti-carcinogenic effects, as well as its use for prion diseases, osteoarthritis, nephropathy, sickle cell anaemia, mucopolysaccharidoses and HTLV associated myelopathies, were qualified in numerous scientific articles.

As manufacturers and suppliers of high-quality medicinal substances, bene pharmaChem represents a high technological standard and technological competence in the manufacturing of pharmaceutical agents. Bene pharmaChem invests socially and in an environmentally responsible manner for the future. Contemporary research, longstanding medical and pharmaceutical experience as well as a network of excellent partners characterise bene pharmaChem.

The name bene has stood for high quality and innovative medicine manufacturing since its foundation in 1949.

### **About Paradigm Biopharmaceuticals**

Paradigm Biopharmaceuticals LTD (ASX: PAR) is a late stage drug development company with the mission to develop and commercialise pentosan polysulphate sodium for the treatment of pain associated with musculoskeletal disorders driven by injury, inflammation, aging, degenerative disease, infection or genetic predisposition.

Authorised for release by Paul Rennie, CEO & Interim Executive Chairman.

#### **FOR FURTHER INFORMATION PLEASE CONTACT:**

Simon White  
Director of Investor Relations  
Tel: +61 (0) 404 216 467

Paradigm Biopharmaceuticals Ltd  
ABN: 94 169 346 963  
Level 15, 500 Collins St, Melbourne, VIC, 3000, AUSTRALIA  
Email : [investorrelations@paradigmbiopharma.com](mailto:investorrelations@paradigmbiopharma.com)  
Web: <http://paradigmbiopharma.com/>

For personal use only