

ASX Release

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JUNIPER PHARMA SERVICES APPOINTED TO REFORMULATE MONEPANTEL FOR PHASE II TRIALS

Juniper provides Science-Led Product Development Services to GMP Standards to Support Clinical Development of Pharmaceutical Products

PharmAust Limited (“PharmAust”) (ASX: PAA) is pleased to report that it has appointed Juniper Pharma Services, a subsidiary of Juniper Pharmaceuticals, Inc. (Nasdaq: JNP), to reformulate monepantel (MPL) for its Phase II studies currently in planning and preparation.

UK-based Juniper Pharma Services will also manufacture 20,000 capsules of the reformulated MPL solution under Good Manufacturing Practice (GMP), ensuring that the Phase II data are admissible to regulators as part of any subsequent submissions.

The primary need to reformulate MPL stems from the particularly unpleasant taste of the current MPL formulation, as used at the Royal Adelaide Hospital during the Phase I study. Despite showing significant activity of MPL on tumour markers such as p70S6K and p-4E-BP1, compliance by patients in taking the drug for 28 days was poor due to nausea associated with the exceptionally poor palatability of the drug.

PharmAust’s Chairman, Dr Roger Aston said: “We expect the reformulation process to take about 12-14 weeks which gives us time to prepare clinical trial submissions to regulatory bodies based on the capsule format. We have shown that oral MPL is effectively absorbed in humans and canines yielding blood levels of the drug which have shown both safety and activity against key tumour markers.”

With an established track record of helping pharmaceutical companies develop and produce drug products for clinical trials, Juniper Pharma Services is able to optimise formulation performance through its science-led approach to projects.

The contract development and manufacturing organisation (CDMO) has well-established GMP clinical manufacturing capabilities at its facilities in Nottingham, covering topical and oral dosage form products. The company’s approach is based around helping clients develop a robust and scalable process and focusing on viable commercial solutions.

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About Juniper Pharma Services

Juniper Pharma Services Ltd., a wholly owned subsidiary of Juniper Pharmaceuticals, Inc., is a contract development and manufacturing organisation (CDMO) that specializes in early phase pharmaceutical development. Its early phase services extend from pre-formulation and formulation development to clinical trial manufacturing, with specialist knowledge on developing challenging molecules and complex compounds. Juniper Pharma Services is also renowned for its expertise and toolkit to analytically resolve some of the toughest issues during development and relating to intellectual property issues. The company's services are dedicated to pharmaceutical, biopharmaceutical and healthcare companies across the globe. For more information please visit www.juniperpharma.com

About PharmAust Limited

PharmAust Limited specializes in the relaunch of existing marketed products for oncology applications making the whole development, regulatory, and commercialization process much faster. Its pipeline includes human and veterinary proprietary medicines to treat cancer. PharmAust has two key strategic alliances with major pharmaceutical companies and products about to enter Phase II trials. These products target substantial multi-billion dollar markets. In addition, PharmAust's wholly-owned subsidiary, Epichem Pty Ltd, generates sales of around US \$1.7M per annum from sales of products and contract research to the pharmaceutical industry. Epichem also facilitates the generation of new IP by synthesizing similar drug formulations for projects within the Company.