





PharmAust Develops GMP Method for Monepantel Analogues

29 October 2018 – Perth, Australia: PharmAust Limited (ASX:PAA), a clinical-stage oncology company, in collaboration with Syngene International Ltd, has completed the development of a prototype Good Manufacturing Practice (GMP) method suitable for the scale up manufacture of monepantel and its analogues for use in clinical trials.

Monepantel is PharmAust's human and veterinary cancer drug candidate. Success of treatment in Phase 1 was observed in the significant reduction of cancer biomarkers in both human and dog clinical trials.

The method validated by Syngene is applicable to the aminoacetonitrile analogues produced by PharmAust's subsidiary Epichem (announced 23 November 2017) to have significantly improved monepantel anticancer activity. It is also applicable to molecules in the drug library secured from Nihon Nohyaku (announced 4 September 2017).

GMP is a globally recognised standard that requires rigorous, controlled and continually documented processes to provide fully characterised drugs with very high levels of purity for safe and effective use when administered to patients. This level of manufacture can be challenging for many drug classes. PharmAust now possesses the technology to manufacture a range of drugs in its portfolio at an economical cost and to standards required for clinical trials in Australia, the US and Europe.

PharmAust's Chief Scientific Officer Dr Richard Mollard commented, "The development of this GMP technology is a significant achievement. It means that PharmAust has in principle secured a manufacturing capability of its aminoacetonitrile drug development pipeline. PharmAust can confidently move forward with its preclinical programs knowing that in the future it can scale up and advance its novel anticancer candidates."

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About PharmAust (PAA):

PAA is a clinical-stage company developing therapeutics for both humans and animals. The company specialises in repurposing marketed drugs lowering the risks and costs of development. These efforts are supported by PAA's subsidiary, Epichem, a highly successful contract medicinal chemistry company which generated ~Aus\$3.02m in revenues in the 2018 FY.

About Syngene International:

Syngene International Ltd. (BSE: 539268, NSE: SYNGENE, ISIN: INE398R01022), an innovation focused global discovery, development and manufacturing organisation provides integrated services to the pharmaceutical, biotechnology, nutrition, animal health, consumer goods and specialty chemical industries across the world. Syngene's clientele include market leaders such as Bristol-Myers Squibb, Baxter, Amgen, GSK, Zoetis, Merck KGaA and Herbalife. Its innovative culture is driven by a strong team of over 3500 scientists working with clients around the world to improve R&D productivity, while reducing development time and cost. For more details, visit www.syngeneintl.com.