PharmAust prepares for commercialisation with Head of Manufacturing appointment

Highlights:

- **PharmAust has strengthened its management team with the appointment of Dr Herbert Brinkman as Head of Manufacturing**
- **Dr Brinkman has over 30 years of product development and manufacturing experience in the pharmaceutical industry and has successfully launched nine products in the US**
- **Manufacturing process development agreements have been executed with leading global pharmaceutical manufacturers Syngene International to supply GMP monepantel and Catalent Pharma Solutions to supply GMP tablets in bulk for clinical studies**
- **Successful completion of process development will position monepantel for regulatory approval and commercialisation**

18 April 2024 – Perth, Australia: PharmAust Limited (ASX: PAA & PAAOA) ("PharmAust" or "the Company"), a clinical-stage biotechnology company, is pleased to announce the appointment of Dr Herbert Brinkman as Head of Manufacturing. Dr Brinkman's appointment comes at a pivotal time in the fast-track development of monepantel (MPL) for the treatment of patients with Motor Neurone Disease (MND)/Amyotrophic Lateral Sclerosis (ALS). The manufacturing process development agreements have been executed with global leaders Syngene International and Catalent Pharma Solutions to commence validation and registration batches at scale to support regulatory approval and commercialisation.

Dr Herbert Brinkman's Biography

Dr Brinkman, based in Denver, Colorado, has over 30 years of experience in the pharmaceutical industry. Dr. Brinkman has prepared over 25 Chemistry Manufacturing and Control (CMC) sections and updates for multiple Investigational New Drug (IND), New Drug Application (NDA), supplementary NDA (sNDA), Investigational Medicinal Product Dossier (IMPD), and Abbreviated NDA (ANDA) filings for United States Food and Drug Administration (FDA) and European regulatory agencies. Dr Brinkman has filed and commercially launched nine products encompassing oncology, metabolic, dermatology, and endocrinology therapeutic areas and contributed to filing 21 ANDAs for various semi-solid and parenteral products. He is also an inventor on 14 patents. His expertise includes current Good Manufacturing Practice (cGMP) systems applied to API manufacture / Drug Product manufacture and addressing regulatory issues. Dr Brinkman's previous position was Executive Director of Product Development at NASDAQ-listed company Arcutis Biotherapeutics, Inc. (NASDAQ: ARQT), where he was responsible for the successful commercial launch of ZORYVE (roflumilast).

PharmAust Chief Executive Officer Dr Michael Thurn commented:

"This is a significant appointment for PharmAust. Herb has considerable expertise in product development, manufacturing, and launching pharmaceutical products. PharmAust is only one clinical study away from potentially receiving either accelerated or full approval of monepantel for the treatment of MND/ALS. Our GMP manufacturing capabilities must be appropriately scaled and robust to support accelerated approval and the rapid rollout of products once approved.

I very much look forward to working with Herb as the Company positions itself as a leading developer of neurodegenerative medicines."

Manufacturing Process Development Agreements
Manufacturing process development agreements have been executed with Syngene International and Catalent Pharma Solutions, global leaders in GMP manufacture and commercial supply of pharmaceutical products. Under these agreements, Syngene will manufacture 60 kgs of GMP monepantel consisting of 1 x 15 kg engineering batch followed by 3 x 15 kg process validation batches designed to validate the GMP manufacturing process, support product registration and prepare the Company for commercial supply. Catalent Pharma Solutions will be responsible for the GMP manufacture of 3 registration batches, totalling more than a million tablets, which will be required to support product registration and facilitate commercial scale-up activities. The product manufactured will be used to support the upcoming pivotal registration Phase 2/3 clinical study.

The manufacturing process development agreements are anticipated to be followed by a commercial supply agreement.

PharmAust Chief Operating Officer John Clark commented:
"We are delighted to have partnered with Syngene and Catalent to meet our GMP manufacturing requirements. Syngene has successfully developed a new scalable and reproducible GMP manufacturing process for monepantel that will be the subject of future patent applications. Catalent was responsible for successfully reformulating monepantel into a solid tablet dosage form, and we look forward to continuing our longstanding relationship with them both".

About Syngene International Ltd
Syngene International Ltd. (BSE: 539268, NSE: SYNGENE, ISIN: INE398R01022) is an integrated research, development, and manufacturing services company serving the global pharmaceutical, biotechnology, nutrition, animal health, consumer goods, and specialty chemical sectors. Syngene's more than 6,000 scientists offer both skills and the capacity to deliver great science, robust data security, and world-class manufacturing at speed to improve time-to-market and lower the cost of innovation. With a combination of dedicated research facilities for Amgen, Baxter, and Bristol-Myers Squibb as well as 2 Mn sq. ft of specialist discovery, development and manufacturing facilities, Syngene works with biotech companies pursuing leading-edge science as well as multinationals, including GSK, Zoetis and Merck KGaA. For more details, visit www.syngeneintl.com. For the Company's latest Environmental, Social, and Governance (ESG)report, visit https://esgreport.syngeneintl.com/.

About Catalent Pharma Solutions
Catalent Pharma Solutions is a global leader in enabling pharma, biotech, and consumer health partners to optimise product development, launch, and full life-cycle supply for patients worldwide. With broad and deep scale and expertise in development sciences, delivery technologies, and multi-modality manufacturing, Catalent is a preferred industry partner for personalised medicines, consumer health brand extensions, and blockbuster drugs. Catalent helps accelerate over 1,500 partner programs and launches over 150 new products annually. Its flexible manufacturing platforms at over 50 global sites supply approximately 70 billion doses of nearly 8,000 products annually. Catalent's expert workforce of almost 18,000 includes more than 3,000 scientists and technicians. Headquartered in Somerset, New Jersey, the company generated nearly $4.3 billion in revenue in its 2023 fiscal year.

The Board authorises this announcement.

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About Motor Neurone Disease:

According to the International Alliance of ALS/MND Associations, MND affects over 350,000 people globally and kills more than 100,000 people yearly. The disease is invariably fatal, with the average life expectancy of someone with MND being around 27 months. The MND/ALS addressable market is US$3.6Bn per annum, with the standard of care treatment, Riluzole, only prolonging life on average by 2-3 months.

The disease is progressive, meaning the symptoms get worse over time. MND has no cure and no effective treatment to reverse its progression. Independent studies have shown that one-third of patients die within 12 months after the first diagnosis.

About PharmAust Limited:

PharmAust Limited is listed on the Australian Securities Exchange (ASX Code: PAA). PAA is a clinical-stage biotechnology company developing therapeutics for human and animal health applications. The company is focused on repurposing monepantel (MPL) for human neurodegenerative diseases.

MPL is a potent and safe inhibitor of the mTOR pathway. This pathway plays a central role in the growth and proliferation of cancer cells and degenerating neurons. The mTOR pathway regulates the cellular "cleaning process," where toxic protein is broken down into macromolecules to be reused. This autophagic process is disrupted in most neurodegenerative diseases, including motor neuron disease (MND/ALS).

PAA's lead MPL program is for the treatment of MND/ALS, a rare, incurable disease. The company recently announced positive top-line results for its Phase 1 study in patients with MND/ALS. PAA anticipates commencing enrolment in its pivotal registration adaptive Phase 2/3 clinical study in H2 CY 2024 that could lead to accelerated approval with the US Food and Drug Administration in 2026.

The Neurodegenerative Disease Market size is estimated at USD 55.12 billion in 2024, and is expected to reach USD 77.82 billion by 2029, growing at a CAGR of 7.14% during the forecast period (2024-2029).[1]

[1] https://www.mordorintelligence.com/industry-reports/neurodegenerative-disease-market

PharmAust Investor Hub:

We encourage you to utilise our Investor Hub for any enquiries regarding this announcement or other aspects concerning PharmAust. This platform offers an opportunity to submit questions, share comments, and view video summaries of key announcements.

Access the investor hub by scanning the QR code or visiting: https://investorhub.pharmaust.com/