



Letter to Shareholders

Highlights:

- **Immuron Board approves IMM-529 cGMP manufacturing and to proceed with FDA pre-IND submission**
- **Recruitment and screening update for Travelan® Controlled Human Infection Model (CHIM) Clinical Trial**

Melbourne, Australia, June 22, 2023

Dear Immuron Limited Shareholders (ASX: IMC; NASDAQ: IMRN),

Immuron is pleased to announce that it has approved proceeding with IMM-529 cGMP manufacturing and to proceed with FDA pre-IND submission.

IMM-529 was developed for treatment of *Clostridioides difficile* (*C. difficile*) which is an anaerobic, spore-forming, gram-positive bacillus typically associated with gastrointestinal disease. Transmission of *C. difficile* occurs by ingestion of spores either through person-to-person contact, animal-to-person contact or environment-to-person contact. *C. difficile* infection (CDI) can cause life-threatening diarrhoea and is the leading healthcare-related gastrointestinal infection in the world.¹

Lumanity, a leading lifescience consulting company conducted an opportunity assessment of IMM-529. Infectious disease experts reacted favourably to the IMM-529 mechanism of action, and its unique ability to target three elements of the CDI infection – the spores, vegetative cells, and Toxin B. Base case yearly revenue in USA for IMM-529 was estimated at US\$92M for the target patient population (limited to second recurrence and later). Positioning IMM-529 earlier than second recurrence could lead to higher uptake. The global CDI market was estimated to increase to \$1.7B by 2026, according to a report by GlobalData.²

Pharmaron have scheduled 96 telehealth screening interviews since recruitment for the planned Travelan clinical study was initiated at the end of May 2023 (ASX announcement 30 May 2023). To date 81 potential candidates have been selected for in-person screening visits which are anticipated to commence on the 28 June 2023 at Pharmaron's Clinical Research Facility Inpatient Unit located in Baltimore, Maryland US. The Phase II clinical trial is designed to evaluate the safety and protective efficacy of Travelan® compared to a placebo in a controlled human infection model (CHIM) in up to 60 healthy participants (males or non-pregnant, non-nursing females), aged 18-50 years.

Thank you for your support.

A handwritten signature in black ink, appearing to read "S. Lydeamore".

Steven Lydeamore
Chief Executive Officer



1. Australian Commission on Safety and Quality in Health Care
2. GlobalData via Pharmaceutical Technology

This release has been authorised by the directors of Immuron Limited.

Contact Information:

Steven Lydeamore

Chief Executive Officer

Ph: +61 (0)3 9824 5254

info@immuron.com

<https://www.immuron.com.au/form/contact-us/>

About Travelan®

Travelan® is an orally administered passive immunotherapy that prophylactically reduces the likelihood of contracting travelers' diarrhea, a digestive tract disorder that is commonly caused by pathogenic bacteria and the toxins they produce. Travelan® is a highly purified tabletized preparation of hyper immune bovine antibodies and other factors, which when taken with meals bind to diarrhea-causing bacteria and prevent colonization and the pathology associated with travelers' diarrhea. In Australia, Travelan® is a listed medicine on the Australian Register for Therapeutic Goods (AUST L 106709) and is indicated to reduce the risk of Travelers' Diarrhea, reduce the risk of minor gastro-intestinal disorders and is antimicrobial. In Canada, Travelan® is a licensed natural health product (NPN 80046016) and is indicated to reduce the risk of Travelers' Diarrhea. In the U.S., Travelan® is sold as a dietary supplement for digestive tract protection.

About Travelers' diarrhea

Travelers' diarrhea is a gastrointestinal infection with symptoms that include loose, watery (and occasionally bloody) stools, abdominal cramping, bloating, and fever. Enteropathogenic bacteria are responsible for most cases, with enterotoxigenic *Escherichia coli* (ETEC) playing a dominant causative role. *Campylobacter* spp. are also responsible for a significant proportion of cases. The more serious infections with *Salmonella* spp. the bacillary dysentery organisms belonging to *Shigella* spp. and *Vibrio* spp. (the causative agent of cholera) are often confused with travelers' diarrhea as they may be contracted while travelling and initial symptoms are often indistinguishable.

About Immuron

Immuron Limited (ASX: IMC, NASDAQ: IMRN), is an Australian biopharmaceutical company focused on developing and commercializing orally delivered targeted polyclonal antibodies for the treatment of inflammatory mediated and infectious diseases.

For more information visit: <http://www.immuron.com>

FORWARD-LOOKING STATEMENTS:

This press release may contain "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, each as amended. Such statements include, but are not limited to, any statements relating to our growth strategy and product development programs and any other statements that are not historical facts. Forward-looking statements are based on management's current expectations and are subject to risks and uncertainties that could negatively affect our business, operating results, financial condition and stock value. Factors that could cause actual results to differ materially from those currently anticipated include: risks relating to our growth strategy; our ability to obtain, perform under and maintain financing and strategic agreements and relationships; risks relating to the results of research and development activities; risks relating to the timing of starting and completing clinical trials; uncertainties relating to preclinical and clinical testing; our dependence on third-party suppliers; our ability to attract, integrate and retain key personnel; the early stage of products under development; our need for substantial additional funds; government regulation; patent and intellectual property matters; competition; as well as other risks described in our SEC filings. We expressly disclaim any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in our expectations or any changes in events, conditions or circumstances on which any such statement is based, except as required by law.