



# Immuron Announces First Patients Enrolled in Campylobacter Challenge Clinical Study

## Highlights:

- **First participants enrolled in the US Naval Medical Research Command Clinical Trial**
- **Clinical Study initiated to evaluate the efficacy of a new Immuron clinical product to protecting volunteers against moderate to severe campylobacteriosis**
- **New CampETEC product is a prophylactic therapeutic designed to protect against Campylobacter and Enterotoxigenic *Escherichia coli* (ETEC) infections, two of the major causes of Travelers' diarrhea**
- **The in-patient stage of the study is anticipated to be completed by the end of December 2023**

Melbourne, Australia, December 04, 2023: Immuron Limited (ASX: IMC; NASDAQ: IMRN), an Australian based and globally integrated biopharmaceutical company is pleased to announce that the US Naval Medical Research Command (NMRC) has initiated the clinical evaluation of a new oral therapeutic targeting Campylobacter and Enterotoxigenic *Escherichia coli* (ETEC) developed in collaboration with Immuron. The NMRC has prioritized the clinical development of the study to evaluate the efficacy of the new therapeutic product to prevent infectious diarrhea caused by Campylobacter.

The clinical study is being led by Principal Investigator Dr Kawsar Talaat, MD at the Johns Hopkins University (JHU) Center for Immunization Research (CIR) Inpatient Unit, located at the JHU Bayview Medical Campus, Baltimore, Maryland, U.S. The Phase 2 clinical trial is designed to evaluate the safety and protective efficacy of the new product compared to a placebo in a controlled human infection model (CHIM). The primary efficacy outcome is prevention and/or reduction of moderate to severe diarrhea. ClinicalTrials.gov Identifier: [NCT06122870](https://clinicaltrials.gov/ct2/show/study/NCT06122870).

The dosing, challenge and the in-patient stage of the study is anticipated to be completed by the third week of December 2023. The estimated study completion date (last participant, last visit) is June 2024 with headline results from the clinical trial expected to be reported in 2H 2024.

Infectious diarrhea is the most common illness reported by travelers visiting developing countries and among US troops deployed overseas. The morbidity and associated discomfort stemming from diarrhea decreases daily performance, affects judgment, decreases morale and declines operational readiness. The first line of treatment for infectious diarrhea is the prescription of antibiotics. Unfortunately, in the last decade, several enteric pathogens have demonstrated increasing resistance to commonly prescribed antibiotics. In addition, traveler's diarrhea is now recognized by the medical community to result in post-infectious sequelae, including post-infectious irritable bowel syndrome (IBS) and several



post-infectious autoimmune diseases. A preventative treatment that defends against infectious enteric diseases is a high priority objective for the US Military.

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

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**COMPANY CONTACT:**

**Steven Lydeamore**  
Chief Executive Officer  
Ph: +61 (0)3 9824 5254  
info@immuron.com

**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 tabletised 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.