



Immuron Announces First Patients Enrolled in Travelan® Clinical Study

Highlights:

- **First cohort of 30 healthy volunteers enrolled in the Travelan® Clinical Trial**
- **Clinical Trial to examine a dosing regimen for Travelan® more suited to the US military has commenced**
- **Final 30 participants anticipated to be enrolled and commence the study in October 2023**
- **Travelan® is known to protect against the onset of Travelers diarrhea (TD), the most common illness reported by travelers**

Melbourne, Australia, July 25, 2023: Immuron Limited (ASX: IMC; NASDAQ: IMRN), an Australian based and globally integrated biopharmaceutical company is pleased to announce the first cohort of 30 participants have been enrolled into the clinical trial to evaluate the efficacy of Travelan® to prevent infectious diarrhea caused by enterotoxigenic *Escherichia coli* (ETEC).

The clinical study is being led by Principal Investigator Dr Mohamed Al-Ibrahim at the Pharmaron CPC FDA inspected Clinical Research Facility Inpatient Unit located in Baltimore, Maryland US. The Phase 2 clinical trial is designed to evaluate the safety and protective efficacy of Travelan® 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: [NCT05933525](https://clinicaltrials.gov/ct2/show/study/NCT05933525).

The first cohort of 30 participants is anticipated to complete dosing and the in-patient stage of the study by the first week of August 2023. The final 30 participants are anticipated to be enrolled into the study and complete the in-patient stage of the study by the end of October 2023. Headline results from the clinical trial expected to be reported in 1H 2024.

The U.S. Department of Defense Uniformed Services University is also running a randomized clinical trial with Travelan® in up to 868 participants (ASX announcement January 18, 2023). ClinicalTrials.gov Identifier: [NCT04605783](https://clinicaltrials.gov/ct2/show/study/NCT04605783). The USU has reported that to date it has successfully enrolled 347 participants into the clinical study following the initiation of enrolment and approximately 260 have completed the study. USU has extended the enrolment period and now expects to complete clinical trial enrolment in Q2 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, travelers' 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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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.