

US Department of Defense Uniformed Services University Clinical Evaluation of Travelan™ Achieves 150 Recruitment Milestone

Highlights:

- First participants enrolled in USU Travelan Clinical Trial Field Study
- 157 participants successfully randomized into the Clinical Study
- Plans in place to enrol in 1302 healthy volunteers in total
- Infectious diarrhea is the most common illness reported by travelers & military personnel

Melbourne, Australia, January 18, 2023: Immuron Limited (ASX: IMC; NASDAQ: IMRN), an Australian based and globally integrated biopharmaceutical company that has developed two commercially available oral immunotherapeutic products for the treatment of gut mediated diseases, is pleased to provide shareholders and the market with a progress update on the US Department of Defense Uniformed Services University (USU) Clinical Evaluation of Travelan.

After overcoming significant challenges due to the COVID-19 pandemic and international travel restrictions and COVID-19 related quarantine period enforced by many countries the USU has reported that to date it has successfully recruited 157 participants into the clinical study following the initiation of enrolment (ASX announcement 9 May 2022). USU expect to complete clinical trial enrolment in approximately 18 months.

USU's Infectious Diseases Clinical Research Program (IDCRP), the UK Ministry of Defense and the New York City Travel Clinic are jointly conducting the randomized clinical trial to evaluate the efficacy of Travelan and a commercially available probiotic nutraceutical product in Travelers' Diarrhea. The P3TD study is a randomized, double-blind, placebo controlled multicenter clinical trial designed to evaluate the effectiveness of IMM-124E (Travelan®) passive immunoprophylaxis and Florastor® verses a placebo, during deployment or travel to a high-TD risk region (ClinicalTrials.gov Identifier: NCT04605783). All study participants (1302 in total) will be randomized to Travelan®, Florastor® or placebo (434 per arm).

The Problem: Travelers' diarrhea (TD) remains a highly prevalent disease that impacts operational readiness of military personnel and is also debilitating civilian travel. In addition to its acute morbidity, TD is associated with acquisition of antimicrobial resistance genes and long-term sequelae. Current mitigation strategies including pre-travel counseling and antibiotics for prevention and treatment have important limitations, and there are currently no licensed, pathogen-specific vaccines for TD prevention.

The Approach: Prebiotics, probiotics and passive immunotherapy may offer safe and relatively inexpensive preventive strategies by promoting gut resistance to enteropathogens, and potentially lessening the use of antibiotics. USU's Infectious Diseases Clinical Research Program (IDCRP), the UK Ministry of Defense and the New York City Travel Clinic are jointly conducting a randomized clinical trial





to evaluate the efficacy of these nutraceutical products for TD prevention and inform strategies for Force Health Protection.

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 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.

