US Department of Defense Uniformed Services University Clinical Evaluation of Travelan™

UPDATE

Key Points

- **Manufacture Completed of investigational medical products to be clinically evaluated by the Uniformed Services University (USU). The clinical program aims to determine the comparative efficacy of Travelan® with two third party non-antibiotic OTC products in Travelers' Diarrhea**
- **The treatment period in the clinical protocol has been extended from 13 days to 22 days, to accommodate COVID-19 quarantine period requirements during travel**
- **Initial shipments of investigational medicinal products to clinical trial sites now dispatched**
- **USU are anticipating an enrolment start date of June 2022 and plan to enrol 1336 participants in total**

Melbourne, Australia, May 09, 2022: Immuron Limited (ASX: IMC; NASDAQ: IMRN), an Australian biopharmaceutical company focused on developing and commercializing oral immunotherapeutic products for the prevention and treatment of gut pathogens, today is pleased to provide shareholders and the market with a progress update on the planned clinical trial to evaluate the efficacy of Travelan® and two third party non-antibiotic products in Travelers' Diarrhea

USU's Infectious Diseases Clinical Research Program (IDCRP), the UK Ministry of Defense and the New York City Travel Clinic are jointly planning to conduct the randomized clinical trial to evaluate the efficacy of three commercially available nutraceutical products for TD and inform strategies for Defense Force Health Protection. The P4TD study is a randomized, double-blind, placebo controlled multicenter clinical trial designed to evaluate the effectiveness of 3 nutraceuticals: A prebiotic (Bimuno®), a probiotic (Florastor®) and IMM-124E (Travelan®) passive immunoprophylaxis verses a placebo, for prophylaxis during deployment or travel to a high-TD risk region (ClinicalTrials.gov Identifier: NCT04605783)All study participants (1336 in total) will be randomized to one of the three active products or placebo (334 per arm).

USU have completed the manufacture of the first batches of investigational medicinal products and shipment of these to the first clinical trial sites is now complete. USU are anticipating recruitment of study participants to commence in June 2022 and expect to complete clinical trial enrolment in approximately 18 months.

The clinical protocol has also been amended to extend the treatment period from 13 days to 22 days to cover the COVID-19 quarantine period still required by some countries. The extended time is necessary as those travelers required to quarantine upon arrival who may be still at risk of diarrhea symptoms during this period. The protocol amendment has now been submitted to the ethics board for approval and recruitment will commence once approval has been granted.

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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 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. Immuron has a novel and safe technology platform with one commercial asset generating revenue. In Australia, Travelan® is a listed medicine on the Australian Register of Therapeutic Goods (AUST L 106709) and is indicated to reduce the risk of Travellers' Diarrhea, reduce the risk of minor gastro-intestinal disorders and is antimicrobial. In Canada, Travelan® is a licenced natural health product (NPN 80046016) and is indicated to reduce the risk of Travellers' Diarrhea. In the U.S., Travelan® is sold as a dietary supplement for digestive tract protection in accordance with section 403 (r)(6) of the Federal Drug Administration (FDA).

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.

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.