



## Immuron Awarded AU \$6.2 Million to Clinically Evaluate a Military Strength Dosing Regimen for Travelan

### **Key Highlights:**

- **Immuron Awarded AU \$4.8 (USD \$3.43) million funding by the U.S. Department of Defense for Travelan**
- **U.S Naval Medical Research Center Received AU \$1.4 (USD \$1.02) million funding to support the Travelan clinical development effort**
- **Total Award AU \$6.2 (USD \$4.45) million to examine a dosing regimen for Travelan more suited for use by the military**
- **Plans in place to conduct a controlled human infection model (CHIM) clinical trial in 60 healthy volunteers in the USA**

Melbourne, Australia, January 12, 2022: Immuron Limited (ASX: IMC; NASDAQ: IMRN), an Australian biopharmaceutical company focused on developing and commercializing oral immunotherapeutics for the prevention and treatment of gut mediated pathogens, is pleased to announce the funding of a new research agreement with the U.S Department of Defense.

The focus of this new agreement, entitled “Biologics License Application (BLA) of a therapeutic Bovine Immunoglobulin supplement targeting Travelers’ Diarrhea caused by Enterotoxigenic Escherichia Coli (ETEC)”, is aimed at testing and confirming the efficacy of a single larger dose regimen of Travelan® in a controlled human infection model (CHIM) clinical study using the enterotoxigenic *Escherichia coli* (ETEC) strain H10407. This single larger dosing regime is potentially more amenable for use in military populations. Up to 60 volunteers will be enrolled in the clinical study and will be randomly assigned to receive either a once-daily dose of 1200 mg of Travelan® or placebo. This study will occur across two cohorts (n=15 Travelan® subjects and n=15 placebo subjects per cohort), as the inpatient unit can accommodate up to 30 study participants at a time. Results of the proposed clinical study will also inform on dosing in the pivotal Phase 3 registration trials for BLA licensure. A project kickoff meeting for this award has been scheduled for the end of January with the U.S Government sponsors.

The proposed development program is based on the past commercial and clinical trial experience with Travelan®. Two company sponsored clinical studies have demonstrated that Travelan® conferred 84% to over 90% protective efficacy against moderate to severe diarrhea upon challenge with ETEC in comparison to a placebo. These clinical studies were performed using two different doses of Travelan® (200 mg and 400 mg), administered 3 times a day. Ongoing discussions with Army and Navy leadership have highlighted that such a regimen is cumbersome for military personnel deployed in austere environments and military field studies have shown that compliance is low with products dosed more than once per day.

“This new project expands our clinical development program and represents the first of several significant clinical trials which the company expects to undertake with the US Military in 2022. The NMRC plans to clinically evaluate the protective efficacy of our new oral therapeutic targeting Campylobacter and ETEC this year in two controlled human infection-model clinical trials, with one trial focusing on the ability of the hyperimmune product to protect volunteers against moderate to severe campylobacteriosis, and the second trial focusing on ETEC infections” **said Dr. Jerry Kanellos, CEO of Immuron.** “The new funding is testament to the value proposition our hyperimmune bovine polyclonal colostrum technology offers to benefit the U.S. Military as well as the civilian international travelling population.”

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 an 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 and several post-infectious autoimmune diseases. A preventative treatment that protects against 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 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.

**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

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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.

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