Immuron Initiates Recruitment of Travelan® Clinical Study

Highlights:

- **Immuron receives approval from U.S. Army Medical Research and Development Command**
- **Recruitment and screening of healthy volunteers for Travelan® Controlled Human Infection Model (CHIM) Clinical Trial is in progress**
- **Clinical Trial to examine a dosing regimen for Travelan® more suited to the US military will commence shortly**
- **Travelan® is known to protect against the onset of Travelers diarrhea (TD), the most common illness reported by travelers**
- **This is one of three Phase 2 studies with FDA IND approval to proceed; in addition to a clinical trial of Travelan® in progress by the Uniformed Services University**

Melbourne, Australia, May 30, 2023: Immuron Limited (ASX: IMC; NASDAQ: IMRN), an Australian based and globally integrated biopharmaceutical company is pleased to announce that it has received approval from the U.S. Army Medical Research and Development Command (USAMRDC) Office of Human and Animal Research Oversight (OHRO) to proceed with the clinical trial to evaluate the efficacy of Travelan® to prevent infectious diarrhea caused by enterotoxigenic *Escherichia coli* (ETEC).

The study has also been granted Institutional Review Board (IRB) human ethics and US Food and Drug Administration (FDA) approvals (ASX announcement December 23, 2022).

Immuron is now proceeding with the planned clinical trial in the United States and has initiated recruitment.

The clinical study will be conducted by Pharmaron CPC at its FDA inspected Clinical Research Facility Inpatient Unit located in Baltimore, Maryland US. The Phase II 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.

This week Pharmaron initiated recruitment of up to 60 healthy participants (males or non-pregnant, non-nursing females), aged 18-50 years on the Pharmaron Website.

https://www.pharmaron.com/clinical-trials/current-trials

The first cohort of 30 participants is anticipated to be enrolled and dosed by the end of July 2023. The final 30 participants are anticipated to be enrolled into the study in October 2023. Headline results from the clinical trial expected to be reported in 1H 2024.

This is one of four clinical trials Immuron has, or is soon to, initiate. The U.S. Department of Defense Uniformed Services University is running a randomized clinical trial of Travelan® in up to 868 participants (ASX announcement January 18, 2023). ClinicalTrials.gov Identifier: NCT04605783.

https://clinicaltrials.gov/ct2/show/NCT04605783?term=NCT04605783&draw=2&rank=1

The FDA recently removed a clinical hold on two planned Phase 2 trials of Campylobacter ETEC therapeutic paving way for initiation (ASX announcement May 8, 2023).

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.