Immuron Receives FDA Approval for Travelan IND Application

Highlights:

- **Immuron receives U.S. Food and Drug administration (FDA) approval for Travelan Investigational New Drug (IND) application**
- **IND to evaluate the efficacy of a single dose of Travelan to prevent infectious diarrhea caused by ETEC is now active**
- **Plans in place to initiate a Human clinical trial in 60 healthy volunteers in the USA**
- **Clinical Trial to examine a dosing regimen for Travelan more suited for use by the US military**
- **Infectious diarrhea is the most common illness reported by travelers**

Melbourne, Australia, December 23, 2022: 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 announce that it has received approval from the US Food and Drug Administration to proceed with the clinical evaluation of Travelan. The Investigational New Drug (IND) application to evaluate the efficacy of a single dose of Travelan to prevent infectious diarrhea caused by ETEC is now active.

As a result of this approval the company will proceed with the planned clinical trial in the United States. The safety and protective efficacy of Travelan will be tested utilizing a controlled human infection-model clinical trial design.

Immuron is the sponsor of the IND, and the clinical study will be conducted by the Contract Research Organisation Pharmaron CPC, Inc (ASX announcement October 4, 2022) at its FDA inspected clinical research facility located in Baltimore, Maryland in the USA.

The Phase II clinical trial will evaluate the efficacy of a single dose regimen of Travelan® in a controlled human infection model (CHIM) using the enterotoxigenic *Escherichia coli* (ETEC) strain H10407. The clinical study aims to enrol up to 60 healthy adult subjects each will be randomly assigned to receive either a once-daily dose of 1200 mg of Travelan® (30 subjects) or placebo (30 subjects). Recruitment is planned to be initiated in 1H 2023 with headline results from the clinical trial expected to be reported by year end 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 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.

- - - END - - -

COMPANY CONTACT:

Steven Lydeamore
Chief Executive Officer
Ph: +61 (0)3 9824 5254
info@immuron.com

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.