Immuron new MTEC project proposal "Development of Oral Immunotherapy for the Prevention of Bacterial Diarrheal Disease"

Key Highlights:

- **Immuron's request for AU$5.4M (US$4M) additional funding from the U.S. Department of Defense for Travelan considered to be 'eligible for award'**
- **Travelan Investigational New Drug (IND) application advances**
- **Clinical trial Synopsis complete and plans in place to conduct a controlled human infection model (CHIM) clinical trial in 60 healthy volunteers in the USA**

Melbourne, Australia, April 19, 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 advise that a new request for funding has been considered to be eligible for award by the US Department of Defense funding body 'Medical Technology Enterprise Consortium' (MTEC).

Immuron is pursuing a regulatory pathway to license Travelan® with the Food and Drug Administration (FDA) via a Biologics License Application (BLA). The proposed indication is to reduce the risk of contracting travelers' diarrhea caused by bacterial pathogens.

The Company was recently awarded **AU$4.8M (US$3.43M)** by MTEC for the development of a Travelan® dosing regimen acceptable for use by the US military (ASX announcement 12 January 2022). In this new MTEC request for funding, Immuron is seeking an additional **US$4M** to fund the Investigational New Drug Application, CMC Assay Development and Validation, Nonclinical Safety Studies and Stability Studies required to support the BLA.

The focus of this new project proposal is to develop a self-administered non-vaccine oral immunotherapy to prevent endemic diarrheal disease by targeting multiple bacterial pathogens. The oral immunotherapy should mitigate symptoms, shorten the duration of illness, and/or reduce the risk of contracting bacterial diarrheal illnesses. The proposed immunotherapy product will target enterotoxigenic *Escherichia coli* (ETEC), and at least one other common bacterial diarrheal pathogen e.g., *Campylobacter spp* or *Shigella spp*.

Immuron was formally notified that no government funding is immediately available, however, this application has been deemed 'eligible for funding' and will be eligible for award for a period of up to two years. **Dr Jerry Kanellos, CEO of Immuron** said "The current **AU$4.8M** MTEC funded project

was reviewed similarly and was funded 6 months post eligibility notification. There is also the potential for additional noncompetitive funding for follow-on tasks from this RPP to partially support the planned phase III pivotal registration clinical studies depending on the success of the project".

The Company is also pleased to announce that work on the Investigational New Drug application to evaluate the efficacy of a single dose regimen of Travelan® in a controlled human infection model (CHIM) clinical study using the enterotoxigenic *Escherichia coli* (ETEC) strain H10407 is progressing well. The Company has been working with our regulatory consultants to address the FDA's guidance and feedback received following the Type B meeting with the agency and our Navy Medical Research Centre (NMRC) associates have completed the Travelan ETEC Clinical trial Synopsis. A mutual Confidentiality Disclosure Agreement has been executed with a qualified Contract Research Organization and discussions have been initiated to discuss costs and timelines for the proposed Travelan clinical study. Up to 60 volunteers will be enrolled in the CHIM clinical study and will be randomly assigned to receive either a once-daily dose of 1200 mg of Travelan® or placebo.

Infectious diarrhea is the most common illness reported by travelers visiting developing countries and amongst 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 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.