

## Immuron US DoD Naval Medical Research Center responds to FDA Clinical Hold for New Campylobacter ETEC Therapeutic

Melbourne, Australia, January 25, 2023: 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 today announces that a response letter has been submitted to the US Food and Drug Administration (FDA). Immuron has previously reported feedback was received from the FDA following a review of the Investigational New Drug (IND) application (ASX announcement July 26, 2022) of a new oral therapeutic targeting Campylobacter and ETEC developed in collaboration with Immuron. The FDA informed the NMRC that based on its review of the nonclinical data, the agency was placing a clinical hold on the clinical trials of the new oral therapeutic under the IND application.

The Sponsor Investigator and Principal Investigator from Johns Hopkins University (JHU) Bloomberg School of Public Health and personnel from the Naval Medical Research Center (NMRC) and Immuron participated in a virtual meeting with the FDA on 2 December 2022 to discuss the clinical hold and advise on a path forward to address the safety concerns and supporting data associated with this new product. The FDA provided written guidance to the NMRC following a subsequent meeting on 20 December 2022. NMRC, JHU and Immuron have now addressed the specific concerns of the FDA clinical hold and a response letter has been submitted. The agency will provide feedback on the clinical hold in 30 calendar days from receipt of the NMRC information package.

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 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.