Immuron Announces FDA Removed Clinical Hold on New Campylobacter ETEC Therapeutic Paves way for Clinical Trial Initiation

Highlights:

- **U.S. Food and Drug administration (FDA) remove clinical hold on New Campylobacter ETEC Therapeutic IND application**
- **US Naval Medical Research Centre (NMRC) satisfactorily addressed all clinical hold issues identified by the FDA**
- **IND to evaluate the efficacy of new Campylobacter ETEC Therapeutic in two human Phase 2 clinical trials is now active**
- **One trial will focus on the ability of the hyperimmune product to prevent infectious diarrhoea caused by ETEC**
- **The second trial will focus on protecting volunteers against moderate to severe campylobacteriosis**

Melbourne, Australia, May 08, 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, is pleased to announce that the US Naval Medical Research Center (NMRC) has received approval from the US Food and Drug Administration (FDA) to proceed with the clinical evaluation of a new oral therapeutic targeting Campylobacter and Enterotoxigenic *Escherichia coli* (ETEC) developed in collaboration with Immuron. The FDA has removed a clinical hold on the Investigational New Drug (IND) application allowing the NMRC to proceed with its plans to evaluate the efficacy of the hyperimmune product to prevent infectious diarrhoea caused by Campylobacter and ETEC which is now active.

The safety and protective efficacy of the product will be tested utilising two controlled human infection-model clinical trials, with one trial focusing on the ability of the hyperimmune product to protect volunteers against ETEC infections, and the second trial focusing on moderate to severe campylobacteriosis. A total of 60 volunteers divided into two inpatient cohorts will be enrolled in the randomized, placebo-controlled trials and randomly assigned to either Cohort 1 ETEC or Cohort 2 *C. jejuni* controlled human infection models (https://www.who.int/publications/i/item/9789240037816).

The first clinical study will be conducted at the Johns Hopkins University (JHU) Center for Immunization Research (CIR) Inpatient Unit, located at the Johns Hopkins Bayview Medical Campus. The study

population will include 30 healthy participants (males or non-pregnant, non-nursing females), aged 18-50 years. Commencement is subject to ethics approval from the Institutional Review Board.

Infectious diarrhoea is the most common illness reported by travellers visiting developing countries and among US troops deployed overseas. The morbidity and associated discomfort stemming from diarrhoea decreases daily performance, affects judgment, decreases morale and declines operational readiness. The first line of treatment for infectious diarrhoea is the prescription of antibiotics. Unfortunately, in the last decade, several enteric pathogens have had an increasing resistance to commonly prescribed antibiotics. In addition, traveller's diarrhoea is now recognised 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 Travelan®

Travelan® is an orally administered passive immunotherapy that prophylactically reduces the likelihood of contracting traveller's diarrhoea, a digestive tract disorder that is commonly caused by pathogenic bacteria and the toxins they produce. Travelan® is a highly purified tabletised preparation of hyperimmune bovine antibodies and other factors, which when taken with meals bind to diarrhoea-causing bacteria and prevent colonisation and the pathology associated with traveller's diarrhoea. 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 Traveller's Diarrhoea, reduce the risk of minor gastrointestinal disorders and is antimicrobial. In Canada, Travelan® is a licensed natural health product (NPN 80046016) and is indicated to reduce the risk of Traveller's Diarrhoea. In the U.S., Travelan® is sold as a dietary supplement for digestive tract protection.

About Traveller's Diarrhoea

Traveller's Diarrhoea 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 Traveller's Diarrhoea 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 commercialising 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.