US DoD Naval Medical Research Center Reports Positive Immunological Responses to Vaccine

Key Points

- **NMRC demonstrated functional antibodies in new oral therapeutic targeting Campylobacter and ETEC**
- **Immuron executes a Research Agreement with PCI Clinical Services to manufacture drug product**
- **Two human phase II clinical trials to be conducted in 2021 by the US NMRC**
- **One trial will focus ETEC infections**
- **The second trial will focus on the ability of the hyperimmune product to protect volunteers against moderate to severe campylobacteriosis**

Melbourne, Australia, November 09, 2020: 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, today is pleased to announce that the Naval Medical Research Center (NMRC) has completed the characterisation of the colostrum harvested from cows immunized with the experimental vaccine developed to target Campylobacter and Enterotoxigenic E.coli (ETEC). The NMRC confirmed that the conjugated vaccine produced a robust immunological response in cows and reported that the new Hyper-immune therapeutic contains high levels of antibodies which specifically target *Campylobacter jejuni* capsule and *Enterotoxigenic Escherichia coli* (ETEC) colonization factor antigen 1 (CFA/1). These are key antigenic targets predicted to be protective against diarrhea induced by both pathogens. The US DoD noted that the colostrum contained high levels of specific immunoglobulins against the target antigens in the vaccine and furthermore, was shown to contain functional antibodies capable of inducing hemoglutination inhibition of the CFA/1 specific ETEC strain to be used in one of the two planned controlled human infection-model clinical trials scheduled for next year.

PCI Clinical Services has been contracted to manufacture the drug product against *Campylobacter* and ETEC for clinical evaluation by the US Department of Defense. The manufacturing campaign is scheduled to commence this month and be completed by the end of 2020.

Work on the Investigational New Drug (IND) application and the clinical protocols for evaluating the safety and efficacy of the product in moderate to severe campylobacteriosis and Enterotoxigenic Escherichia coli (ETEC) infections is progressing well. The NMRC plans to file the IND application with the U.S. Food and Drug administration (FDA) in Q1 2021. The ability of the new hyperimmune product to protect volunteers from moderate to severe campylobacteriosis and ETEC disease will be assessed during two inpatient clinical trials planned for Q2 and Q3 2021. A total of 60 volunteers

divided into two inpatient cohorts will be enrolled in the study and randomly assigned to either Cohort 1 *C. jejuni* or Cohort 2 ETEC controlled human infection models.

Infectious diarrhea is the most common illness reported by military personnel deployed overseas and by travelers visiting developing countries. Diarrhea morbidity decreases daily performance, affects judgment, decreases morale and declines operational readiness. In addition, travelers' diarrhea is now also recognized by the medical community to result in post-infectious sequalae, including post-infectious Irritable Bowel Syndrome and several post-infectious autoimmune diseases. The US Department of Defense has recognized the burden of infectious diarrhea and has heavily invested in the development of effective vaccines for their prevention. However, despite robust research efforts made to develop vaccines against major enteric pathogens, there are currently no licensed vaccines available. Development of an effective, safe, and affordable prophylactic agent to control infectious diarrhea would offer a useful product for travelers and military personnel going to high-risk areas in Latin America, Africa, the Middle East, and Asia.

The major goal of this research effort is to lay the scientific foundation for development of a multi-pathogen anti-diarrheal colostrum supplement that confers protection against *Campylobacter jejuni* and ETEC, the predominant causes of infectious diarrhea in travelers visiting developing countries and among military personnel deployed overseas. Ultimately, the data resulting from these studies will provide military policymakers with information needed to make decisions on product acquisition and stocking.

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 inflammatory mediated and infectious diseases. Immuron has a novel and safe technology platform with one commercial asset generating revenue. In Australia, Travelan® is a listed medicine on the Australian Register of Therapeutic Goods (AUST L 106709) and is indicated to reduce the risk of Travellers' Diarrhea, reduce the risk of minor gastro-intestinal disorders and is antimicrobial. In Canada, Travelan® is a licenced natural health product (NPN 80046016) and is indicated to reduce the risk of Travellers' Diarrhea. In the U.S., Travelan® is sold as a dietary supplement for digestive tract protection in accordance with section 403 (r)(6) of the Federal Drug Administration (FDA).

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 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.