US DoD Naval Medical Research Center Clinical Update

Key Points

- **Manufacture of investigational medical products to support the US Naval Medical Research Centre (NMRC) clinical programs completed.**
- **IND submission to the U.S. Food and Drug administration (FDA) planned for Q1 CY2022 to support Two human phase II clinical trials.**
- **One trial will focus on the ability of the hyperimmune product to prevent infectious diarrhea caused by ETEC and scheduled to be initiated H1 CY2022.**
- **The second trial will focus on protecting volunteers against moderate to severe campylobacteriosis.**

Melbourne, Australia, November 10, 2021: Immuron Limited (ASX: IMC; NASDAQ: IMRN), an Australian biopharmaceutical company focused on developing and commercializing oral immunotherapeutic products for the prevention and treatment of gut pathogens, today is pleased to provide shareholders and the market with an update on the company's clinical development portfolio.

The company is pleased to inform shareholders that after facing over a 12-month hiatus due to the COVID-19 pandemic our clinical development programs are back on track. The NMRC has reported that most of the inpatient clinical trial sites in the USA are coming off COVID-19 based restrictions and the Company looks forward to the recommencement of the planned NMRC clinical development programs.

In this regard, the manufacturing campaign for the new drug product targeting *Campylobacter* and Enterotoxigenic *Escherichia coli* (ETEC) was completed in October 2021. The investigational medical products will be transferred to the Johns Hopkins Bloomberg School of Public Health (JHBSPH) in the USA, which is the clinical trial site to be used to conduct the two planned clinical studies. The safety and protective efficacy of the product will be tested utilizing 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 studies and randomly assigned to either Cohort 1 ETEC or Cohort 2 *C. jejuni* controlled human infection models. Immuron is also pleased to report that the NMRC is working on the Investigational New Drug (IND) application and the clinical protocols. The NMRC plans to file the IND application with the U.S. Food and Drug administration (FDA) early in CY2022. The first of these exciting trials is scheduled to commence in the first half of CY2022.

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 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.