NMRC Reports Results for Campylobacter Controlled Human Infection Model Study

Melbourne, Australia, October 4, 2024: Immuron Limited (ASX: IMC; NASDAQ: IMRN), is an Australian based and globally integrated biopharmaceutical company that has developed two commercially available oral immunotherapeutic products for the treatment of gut mediated diseases. Following discussion with the US Naval Medical Research Command (NMRC), today the Company can announce that the NMRC has completed the interim analysis for the clinical evaluation of a new oral therapeutic targeting Campylobacter and Enterotoxigenic Escherichia coli (ETEC).

The results of this clinical trial are unrelated to Travelan® and do not impact Immuron's plans to hold an end of Phase 2 meeting with the U.S. Food and Drug Administration (FDA) with a view to initiating Phase 3 clinical trial(s) of Travelan® in 2H 2025. Nor does this NMRC trial impact on Immuron's commercialization strategy for Travelan®. This commercialization strategy also includes the results of the Uniformed Services University clinical study (n=866) of Travelan® which is 85% recruited with topline results anticipated in April 2025 (NCT04605783).

The details of the trial are available at clinicaltrials.gov/study/NCT06122870 . The trial was funded by the NMRC. Immuron's involvement in the study was to produce a hyperimmune bovine colostrum product using the NMRC developed campylobacter/ETEC vaccine which was tested in a controlled human infection model study.

Campylobacter jejuni is among the most common causes of diarrheal disease worldwide. Relatively little is known regarding what constitutes protective immunity against *Campylobacter* and there is currently no licensed vaccine to prevent disease caused by C. jejuni. *C. jejuni* is considered an invasive enteric pathogen, but the molecular details of its pathogenesis remain difficult to interpret or understand largely due to the lack of reliable, non-primate animal models of disease. To address this unmet medical need, the NMRC developed a conjugated vaccine using the *Campylobacter jejuni* capsule crosslinked to the colonization factor antigen 1 (CFA/1) of *Enterotoxigenic Escherichia coli* (ETEC). These key antigenic targets are predicted to be protective against diarrhea induced by both pathogens. Immuron used the conjugated vaccine to produce a new hyperimmune anti-microbial for clinical evaluation by the NMRC. 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 CFA/1 (ASX Announcement 9 November 2020).

Immuron has been advised by NMRC that the safety and protective efficacy of the product was tested in a controlled human infection-model clinical trial focusing on the ability of the hyperimmune product to protect volunteers against moderate to severe campylobacteriosis. A total of 27 volunteers were enrolled in the randomized, placebo-controlled trial and randomly assigned to either the active or placebo arm of the study. The interim results demonstrated **10.4% protective efficacy** against moderate to severe campylobacteriosis following challenge with Campylobacter compared to the placebo group. Data analysis by the NRMC continues, including secondary and exploratory endpoints, which may provide insights as to why protective efficacy for CampETEC for was lower than that achieved in similar studies with Travelan®. Immuron is not privy to any further details of the study at this time, pending the presentation of findings described below.

Dr Frédéric Poly, the principal Investigator of the study, will present the findings for the NMRC CampETEC clinical study at the 22nd International Workshop on Campylobacter, Helicobacter & Related Organisms (CHRO 2024) which commences on 7 October 2024 at the Perth Convention and Exhibition Centre. A copy of the presentation will be made available on the Company website once it is made available to the Company.

Travelan® demonstrated clinical efficacy in preventing ETEC-attributable diarrhea in two previous CHIM studies. These studies showed dosing 400 mg three times daily, resulted in **76.7% to 90.9%** protection (Otto et al., 2011) and more recently **36.4% protective efficacy** in a single daily dose Phase 2 study designed to compare the preventative effects of once daily dosing to the current standard recommended treatment of three times daily dosing (ASX Announcement 7 March 2024). This Phase 2 single dose trial also produced clinically relevant secondary endpoints (ASX Announcement 8 August 2024).

The vaccine used in CampETEC was a conjugated vaccine for both campylobacter and ETEC. The NMRC recently received U.S. Department of Defense funding to develop a new campylobacter vaccine not conjugated with ETEC as well as new vaccines for shigella and different strains of E.coli. The plan is to develop new hyperimmune products which specifically target each of these pathogens in collaboration with Immuron. NRMC and Walter Reed Army Institute of Research (WRAIR) are now developing an enhanced formulation of Travelan potentially expanding the coverage of the product as a therapeutic measure against endemic military relevant diarrheal pathogens (ASX announcement 16 August 2024).

Infectious diarrhea is the most common illness reported by travelers visiting developing countries and among 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 had an increasing resistance to commonly prescribed antibiotics. In addition, traveler's 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 authorized 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 traveler's diarrhea, a digestive tract disorder that is commonly caused by pathogenic bacteria and the toxins they produce. Travelan® is a highly purified tableted preparation of hyperimmune bovine antibodies and other factors, which when taken with meals bind to diarrhea-causing bacteria and prevent colonization and the pathology associated with traveler's 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 Traveler's Diarrhea, 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 Traveler's Diarrhea. In the U.S., Travelan® is sold as a dietary supplement for digestive tract protection.

About Traveler's Diarrhea

Traveler's 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 Traveler's 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.