Immuron Clinical Trials Update

Highlights:

- **US Naval Medical Research Command (NMRC) campylobacter clinical program completes in-patient phase**
- **Manufacture of IMM-529 drug substance to support the Pre-IND information package has been completed**
- **Pre-IND submission to the U.S. Food and Drug administration (FDA) planned for H1 2024**
- **Travelan® clinical study inpatient phase completed and 6 month follow up visits planned**

Melbourne, Australia, December 22, 2023: Immuron Limited (ASX: IMC; NASDAQ: IMRN), an Australian based and globally integrated biopharmaceutical company is pleased to provide shareholders and the market with an update on the company's clinical development portfolio.

The NMRC has recently completed the in-patient stage of the campylobacter challenge clinical study. The clinical study is being led by Principal Investigator Dr Kawsar Talaat, MD at the Johns Hopkins University (JHU) Center for Immunization Research (CIR) Inpatient Unit, located at the JHU Bayview Medical Campus, Baltimore, Maryland. U.S. A total of 30 participants were enrolled in the study, of which 27 participants were dosed with either the Investigational Medical Product or placebo and all subjects were challenged with Campylobacter. All study volunteers have now been treated with antibiotics and discharged from the clinic. The study participants will return as outpatients for several follow-up visits, with the last patient last visit scheduled to be completed in June 2024. Headline results from the clinical trial are anticipated to be reported in H2 2024. The Phase 2 clinical trial is designed to evaluate the safety and protective efficacy of the new product manufactured by Immuron compared to a placebo in a controlled human infection model (CHIM). The primary efficacy outcome is prevention and/or reduction of moderate to severe diarrhea. ClinicalTrials.gov Identifier: NCT06122870.

Immuron 's manufacturing campaign for a new therapeutic product which targets the *Clostridioides Difficile* (C. Diff) bacteria, IMM-529 drug substance was completed in December 2023 by CSIRO Agriculture and Food. IMM-529 is the second therapeutic drug candidate the company is planning to take into the clinic and has been specifically developed to target (i) toxin B, (ii) spores and (iii) vegetative cells of *Clostridioides Difficile* (C. Diff) which are thought to be the primary cause of C. Diff disease recurrences. A research services agreement has recently been executed with Monash University to assist with vaccine manufacture and stability testing of the Investigational Medical Product to support the pre-IND information package. A research services agreement has also been executed with VivoPharm Global Preclinical Services to conduct a GLP compliant toxicity study in rodents. The study protocol has been submitted and approved by the Animal Ethics Committee and the study is planned

to commence in Q1 2024. The company is working towards submitting a Pre-IND information package to the U.S. Food and Drug Administration (FDA) in H1 2024.

The inpatient challenge phase of the Travelan clinical study led by Principal Investigator Dr Mohamed Al-Ibrahim at the Pharmaron CPC FDA inspected Clinical Research Facility Inpatient Unit located in Baltimore, Maryland US, has been completed. The double-blind study was separated into two cohorts of approx. 30 subjects (60 in total) dosed with Travelan or placebo for two days prior to challenge continuing for a total of 7 days. All study participants were challenged with Escherichia coli, monitored for symptoms and treated with antibiotics. Safety data at two weeks and 4 weeks post challenge has been collected and the final 6 month follow up interviews will be initiated in January 2024 and are expected to be completed in April 2024. Headline results from the clinical trial are anticipated to be reported in June 2024. The Phase 2 clinical trial is designed to evaluate the safety and protective efficacy of Travelan® compared to a placebo in a controlled human infection model (CHIM). The primary efficacy outcome is prevention and/or reduction of moderate to severe diarrhea. ClinicalTrials.gov Identifier: NCT05933525.

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 inflammatory mediated and 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.