US Department of Defense Reports Final Results from Travelan® Shigellosis Challenge Study

Key Highlights:

- **Travelan® shigellosis challenge studies in non-human primates successfully completed**
- **Travelan® prevented clinical shigellosis (bacillary dysentery) in 75% of Travelan® treated animals compared to placebo and demonstrated a significant clinical benefit**
- **Prophylactic administration of Travelan® may provide an effective prevention alternative to antibiotics for gastrointestinal infections in humans**
- **Three new *Shigella* specific anti-microbial therapeutics under preclinical evaluation**
- **A preventative treatment that protects against enteric diseases, specifically *Shigella*, is a high priority objective for the US Army**

Melbourne, Australia, June 12, 2019: Immuron Limited (ASX: IMC; NASDQ: IMRN), an Australian biopharmaceutical company focused on developing and commercializing oral immunotherapeutics for the prevention and treatment of many gut mediated pathogens, today is pleased to provide shareholders with an update on the company's cooperative research and development agreements with the US Department of Defense (US DoD).

The *Shigella* challenge model was used to assess the therapeutic potential of Travelan® as a prevention treatment for shigellosis or dysentery. The placebo-controlled study was carried out in 12 juvenile rhesus monkeys segregated into 2 groups: a Travelan® treatment cohort of 8 and a placebo cohort of 4, which were treated twice daily for a total of 12 doses over a 6-day period. The animals received treatment for 3-days prior to oral challenge with ~3 x 10^9 viable *Shigella* organisms.

As reported in September last year, all (4 of 4 - 100%) placebo-treated animals displayed acute clinical signs of dysentery within 24 – 36 hours of *Shigella* challenge. Only two of the eight Travelan-treated group displayed any signs of dysentery. The remaining 6 of 8 (75%) of the Travelan-treated group remained healthy and without signs of dysentery post challenge. Recently completed histopathological analysis, which provides a comprehensive view of the clinical disease and its effect on tissues of gut, revealed that all animals in the placebo-treated group displayed severe inflammation in different parts of the gastrointestinal tract. These animals also had very high levels of inflammatory cytokines (IL-1b, IL-6 and IL-8) in fecal samples collected throughout the study. The inflammation seen in the gastrointestinal tract and the increase in inflammatory cytokines in the feces were closely associated with the observed clinical outcomes of dysentery. Only 3 of the 8 Travelan-treated animals had signs of inflammation in the gastrointestinal tract, and only 2 of those had high levels of inflammatory cytokines in fecal samples. All other animals in the Travelan-treated group were clinically healthy and did not

excrete any inflammatory cytokines. Overall the results suggest that Travelan® is functionally cross-reactive and may have some prophylactic activity against Shigellosis.

"The latest results reported by our colleagues at the US Armed Forces Research Institute of Medical Sciences (AFRIMS), an overseas laboratory of the Walter Reed Army Institute of Research (WRAIR), located in Bangkok, Thailand are very impressive indeed. The study results clearly demonstrated that animals with severe inflammation in the gastrointestinal tract and high inflammatory cytokines in fecal samples were associated with severe dysentery and that prophylactic administration of Travelan® significantly reduced the inflammatory response," **said Dr. Robert Kaminski, Chief, Subunit Enteric Vaccines and Immunology, Department of Enteric Infections, Bacterial Diseases Branch, WRAIR.**

The abstract of the study findings has been submitted for presentation at the 10th International conference on Vaccines for Enteric Diseases which will be held at the University of Lausanne Switzerland on the 16th to 18th October 2019.

"This is further validation of our technology platform," **said Dr. Gary Jacob, CEO of Immuron.** "The work completed by our research collaborators at the WRAIR has clearly demonstrated the effectiveness of Travelan® and the Immuron technology platform in neutralizing pathogenic gastrointestinal bacterial infections and offers significant potential as a preventative treatment for US military personnel and civilians stationed or traveling in locations where such infections may be debilitating."

The company is also pleased to report that it has completed the manufacture of three new *Shigella* specific therapeutic products which have been manufactured with proprietary vaccines developed by the WRAIR. Preliminary laboratory evaluation has indicated that all three products have generated a strong antibody response to the *Shigella* antigens used in the manufacturing campaign. The three products will be evaluated in preclinical models of shigellosis developed by the WRAIR.

"The WRAIR has been developing vaccines against *Shigella* for over a decade and the combination of our *Shigella* vaccine research and development efforts with Immuron's oral immunotherapy platform make perfect sense. The WRAIR will fund the evaluation of the anti-*Shigella* specific activity of the new products including assessing their protective capacity in established small animal models which will be completed and reported throughout the remainder of this year," **said Dr. Robert Kaminski**.

The global burden of diarrheal diseases outweighs any of the more complex diseases seen in gastroenterology clinics. Every year, there are an estimated 1.5 billion episodes of diarrhea worldwide. These episodes result in the deaths of approximately 2.2 million people, mostly children in developing countries (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2699001/). A preventative treatment that protects against enteric diseases, specifically shigellosis, is a high priority objective for the US Army. *Shigella* spp are estimated to cause 80 –165 million cases of disease worldwide, resulting in 600,000 deaths annually and is particularly prevalent in both sub-Saharan Africa and South Asia.

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 Travelan® generating revenue. Immuron's lead clinical candidate, IMM-124E, is presently in Phase II trials in Severe Alcoholic Hepatitis (SAH) and Paediatric Non-alcoholic Fatty Liver Disease (NAFLD). The company now has plans to develop a U.S. registration dossier for IMM-124E for Travelers' Diarrhea. Immuron's second clinical-stage asset, IMM-529, targets *Clostridium difficile* Infections (CDI), and is presently in a clinical trial in CDI patients. These products together with the Company's other preclinical immunotherapy pipeline products currently under development targeting immune-related and infectious diseases are anticipated to meet pressing needs in the global immunotherapy market.

For more information visit: http://www.immuron.com

About Travelan®

Travelan® is an orally administered passive immunotherapy that prophylactically reduces the likelihood of contracting travelers' diarrhea. 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 Travellers' 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 Travellers' Diarrhea. In the U.S., Travelan® is sold as a dietary supplement for digestive tract protection.

About Travellers' diarrhea

Travelers' diarrhea is a gastrointestinal infection with symptoms that include loose, watery (and occasionally bloody) stools, abdominal cramping, bloating, and fever, Entropathogenic 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.

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.