

New U.S. Department of Defense Research Collaboration with Immuron to Develop and Clinically evaluate a New Therapeutic against Campylobacter

Key Highlights:

- AU \$5.5 (USD \$3.7) million funding approved by the U.S. Department of Defense to develop and clinically evaluate a new oral therapeutic targeting Campylobacter and ETEC
- Naval Medical Research Center will fund the manufacture and therapeutic evaluation of the new therapeutic to protect against acute infectious diarrhea
- Two human clinical trials to be conducted with new therapeutic under terms of grant

Melbourne, Australia, October 02, 2019: 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, is pleased to announce the funding of a new research agreement with the Naval Medical Research Center (NMRC), Silver Spring, MD, USA.

The focus of this new agreement will be to develop a combined *Campylobacter* and enterotoxigenic *E. coli* (ETEC)-specific anti-microbial preventative for clinical evaluation. Under this agreement, Immuron and NMRC will be collaborating on the manufacture and evaluation of the new product designed to protect against travelers' diarrhea caused by Campylobacter and ETEC pathogens. The 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 moderate to severe campylobacteriosis, and the second trial focusing on ETEC infections.

"The good news is that we just had the confirmation that the funds were transferred, and we are ready and eager to start the project," said **Dr. Frédéric Poly, Head of the Campylobacter research division, Enteric Diseases Department at NMRC.** "Deployed military personnel are a unique population of travelers that have a long history of being affected by acute infectious diarrhea. *Campylobacter jejuni* and ETEC are leading causes of travelers' diarrhea and represent a major burden for deployed US troops. And despite robust research efforts to develop vaccines against major enteric pathogens, there are currently no licensed vaccines available. To address this unmet need, we will be utilizing our own vaccine expertise along with Immuron's proprietary technology platform to develop an oral preventative product which directly targets pathogenic bacteria at the site of infection within the gastrointestinal tract. We have previously shown that the ETEC vaccine is immunogenic in small animal models and demonstrated that *Campylobacter jejuni* vaccines were 100% protective against campylobacteriosis in the non-human primate model. We have also independently developed a prophylactic anti-diarrheal oral bovine colostrum-derived immunoglobulin product and demonstrated protective efficacy against an ETEC strain in a controlled human infection model (CHIM)."

Dr. Frédéric Poly of the NMRC goes on to say: “The ultimate goal of this research effort is to lay the scientific foundation for development of a multi-pathogen product that confers protection against both *C. jejuni* and ETEC, the predominant causes of infectious diarrhea in deployed warfighters. Ultimately, the data resulting from these studies will provide military policymakers with information needed to make decisions on product acquisition and, if successful, Immuron should be enabled to manufacture the product at scale to meet the needs of military personnel and the traveling community on an ongoing basis.”

“This is wonderful news,” said **Dr. Gary S. Jacob, CEO of Immuron**. “The new project expands our anti-infectious diseases clinical development program to include this Campylobacter project with the U.S. Department of Defense, covering an additional key pathogen, Campylobacter, responsible for travelers’ diarrhea. Along with our current program with the Walter Reed Army Institute of Research which is focused on Shigella, this project highlights the continued commitment Immuron is making to use our hyperimmune bovine polyclonal colostrum technology to benefit the U.S. Military as well as the civilian population. This program also further enhances our efforts to raise the profile of our flagship product Travelan® and our in-house clinical program to develop IMM-124E as an FDA approved drug to prevent Travelers’ Diarrhea.”

Infectious diarrhea is the most common illness reported by travelers visiting developing countries and among US troops deployed overseas. Diarrhea morbidity decreases daily performance, affects judgment, decreases morale and declines operational readiness. The first line of treatment for infectious diarrhea is prescription of antibiotics. Unfortunately, in the last decade, several enteric pathogens have an increasing resistance to commonly prescribed antibiotics. In addition, travelers’ 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.

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 being developed as a drug to prevent 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

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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>

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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 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.

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.

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