

US Department of Defense Research Collaboration Moves Forward

Key Highlights:

- **Three US Defense Health funded research projects on Travelan® successfully completed**
- **Studies commissioned by the US Department of Defense to evaluate Travelan®'s ability to neutralise pathogenic bacteria of interest, including**
 - *Campylobacter*
 - ETEC
 - *Shigella*
- **Programs now advance to evaluate the therapeutic efficacy of Travelan® in pre-clinical Shigellosis Challenge studies**
- **Research agreement with CSIRO to develop Shigella specific anti-microbial therapeutics for preclinical evaluation**
- **A preventative treatment that protects against enteric diseases, specifically Shigella, is a high priority objective for the US Army**

Melbourne, Australia, July 16, 2018: Immuron Limited (ASX: IMC; NASDAQ: IMRN), an Australian microbiome biopharmaceutical company focused on developing and commercializing oral immunotherapeutics for the 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 US DoD commissioned several studies to characterise the antibodies within Travelan, the company's commercially available flagship over-the-counter gastrointestinal and digestive health supplement. The aim is to progress trials to determine Travelan's effectiveness in neutralising pathogenic gastrointestinal bacterial infections as a preventative treatment for US military personnel stationed in locations where such infections may be debilitating.

"Travelan has been designed to target selected surface antigens from the most common strains of Enterotoxigenic *E. coli* (ETEC), bacteria which play a dominant and causative role in Travellers' diarrhea," said Dr. Jerry Kanellos, CEO of Immuron.

"The work completed at the US Armed Forces Research Institute of Medical Sciences, US Naval Medical Research Center and the Walter Reed Army Institute of Research has highlighted that in laboratory testing Travelan was effective across all strains and species of enteropathogenic bacteria tested. The specificity of antibodies incorporated into Travelan cross-react with multiple *Campylobacter*, ETEC and *Shigella* strains. The product is truly cross-reactive indicating a substantially broader spectrum of

antimicrobial action than previously reported. This new research offers a pathway to further testing which could lead to a major new preventative modality for the US DoD,” concluded Dr. Kanellos.

The global burden of diarrhoeal 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 *Shigella*, is a high priority objective for the US Army. *Shigella* is 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.

The following studies undertaken by US DoD research units confirm the efficacy of Travelan:

US Naval Medical Research Center (NMRC) Study demonstrated Travelan[®] bound to and neutralized key components used by the ETEC bacteria to attach to host cells and cause disease. This study was performed by the NMRC’s Department of Enteric Infections and reported that Travelan was specifically shown to:

- React with the major colonization factor antigens
- Bind to key fimbrial proteins which are used by the bacteria to attach to host cells and cause disease
- Inhibit the bacteria binding and causing cell hemagglutination
- React with the heat labile enterotoxin produced by ETEC bacteria

Walter Reed Army Institute of Research (WRAIR) Study demonstrated Travelan[®] bound to similar targets present on ETEC and *Shigella* bacteria. The Department of Enteric Infections, Bacterial Diseases Branch at the WRAIR assessed Travelan[®] immune-reactivity with ETEC and *Shigella* antigens, which demonstrated they were reacting to common bacterial antigens.

The above studies add to the previous research reported in January 2018 summarised below:

Armed Forces Research Institute of Medical Sciences (AFRIMS) Study demonstrated Travelan[®] effectively reacted to 180 clinical isolates tested from personnel infected with *Campylobacter*, Enterotoxigenic *Escherichia coli* (ETEC) and *Shigella*. This first study involving Travelan[®] was performed at the Department of Enteric Diseases of AFRIMS.

The research and development program will now progress to evaluate the therapeutic potential of Travelan[®] in **Shigellosis Challenge studies**. AFRIMS will fund and evaluate the therapeutic potential of Travelan[®] in Non-Human primate (NHP) clinical studies which replicates the full clinical spectrum of the disease as seen in humans. The plan studies will be performed at the Department of Enteric Diseases

of AFRIMS, an overseas laboratory of the WRAIR, located in Bangkok, Thailand and will be initiated at the end of July 2018.

The company is also pleased to report that it has once again engaged the services and facilities of the Commonwealth Scientific & Industrial Research Organisation (CSIRO) to produce three Shigella therapeutic products for preclinical assessment by the WRAIR. Approval was obtained from Biosecurity Australia early this year to import the Shigella specific vaccines developed and produced by the WRAIR which will be used to manufacture the products. The vaccination program will be initiated in August this year and the finished products should be available by the end of the calendar year. Under the current terms of the Cooperative Research Agreement the WRAIR will fund the evaluation of the anti-Shigella therapeutics and assess their protective capacity in established small animal models.

Furthermore, the Campylobacter research team at the NMRC and Immuron have recently submitted a grant funding proposal for the development of a therapeutic product against campylobacter and other enteric pathogens. If approved the US DoD will fund the clinical development of the product.

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ABOUT IMMURON:

Immuron Limited (ASX: IMC, NASDAQ: IMRN), is an Australian microbiome biopharmaceutical company focused on developing and commercializing orally delivered targeted polyclonal antibodies for the treatment of inflammatory mediated and infectious diseases. Immuron has a unique and safe technology platform that enables a shorter development therapeutic cycle. The Company currently markets and sells Travelan® for the prevention of Travelers' Diarrhoea and its lead clinical candidate, IMM-124E, is in Phase II clinical trials for **Non-Alcoholic Steatohepatitis (NASH)**, **Severe Alcoholic Hepatitis (SAH)** and Pediatric **Nonalcoholic Fatty Liver Disease (NAFLD)**. Immuron's second clinical stage asset, IMM-529, is targeting **Clostridium difficile Infections (CDI)**. These products together with the Company's other preclinical immunotherapy pipeline products targeting immune-related diseases currently under development, will meet a large unmet need 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 travellers' diarrhoea. Travelan® is a highly purified tabletised preparation of hyper immune bovine antibodies and other factors, which when taken with meals bind to diarrhoea-causing bacteria and prevent colonization and the pathology associated with travellers' diarrhoea. In Australia Travelan® is approved by the Therapeutic Goods Administration (TGA) as a listed medicine on the Australian Register of Therapeutic Goods (AUST L106709) and is indicated to reduce the risk of travellers' diarrhoea and associated symptoms of minor gastrointestinal disorders. In the USA Travelan® is sold as a dietary supplement in accordance with section 403 (r)(6) of the Federal Drug Administration (FDA).

About Travellers' diarrhea

Travellers' diarrhoea is a gastro-intestinal 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 travellers' diarrhoea 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.