US Department of Defense Reports Travelan Protects Against Shigella in Primates

Key Highlights:

- **Travelan® pre-clinical shigellosis challenge studies in non-human primates (NHP) successfully completed**
- **Travelan® prevented clinical shigellosis (bacillary dysentery) in 75% of Travelan® treated NHPs compared to placebo.**
- **A preventative treatment that protects against enteric diseases, specifically *Shigella*, is a high priority objective for the US Army**

Melbourne, Australia, September 05, 2018: Immuron Limited (ASX: IMC; NASDQ: IMRN), an Australian microbiome 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 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 was to conduct trials to determine the product's effectiveness in neutralising pathogenic gastrointestinal bacterial infections as a preventative treatment for US military personnel and civilians stationed or traveling in locations where such infections may be debilitating.

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, conducted the study that evaluated the therapeutic potential of **Travelan®** in a non-human primate (NHP) preclinical challenge model that closely mimics the disease seen in humans. The study was performed in collaboration with the Department of Enteric Diseases and the Department of Veterinary Medicine, AFRIMS, and the Department of Enteric Infections, Bacterial Diseases Branch, WRAIR.

The placebo-controlled study was carried out in 12 NHPs segregated into 2 groups: a **Travelan®** treatment cohort of 8 and a placebo cohort of 4, which were treated with either **Travelan®** or placebo respectively 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 flexneri* strain 2a organisms. All (4 of 4 - 100%) placebo-treated animals displayed acute dysentery symptoms within 24 – 36 hours of *Shigella flexneri* 2a challenge. A single (1 of 8 – **12.5%**) of the **Travelan®**-treated cohort displayed dysentery symptoms at this time point. The remaining individuals (7 of 8 – **87.5%**) in the **Travelan®** treatment cohort remained symptom-free to 4-days post *Shigella flexneri* 2a challenge. Once the treatment period was concluded a second individual in the Travelan treatment group developed symptoms (2 of 8 - **25%**).

The remainder (6 of 8 - **75%**) of the **Travelan®** treated cohort remained symptom-free to the conclusion of the study 11-days post *Shigella flexneri* 2a challenge.

"**Travelan®** was 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 Traveler's diarrhea. Previous studies found several of these antigens are shared with bacillary dysentery-causing organisms such as *Shigella* species," said Dr. Jerry Kanellos, CEO of Immuron. "The work completed at AFRIMS highlighted for the first time that in a preclinical NHP challenge model of shigellosis (also known as bacillary dysentery), **Travelan®** protected **75%** of **the animals** from clinical bacillary dysentery. All the placebo-treated animals displayed classic dysentery symptoms after challenge with a virulent strain of *Shigella* sp. It is also very interesting to note the second case of dysentery in the Travelan cohort developed once the treatment terminated."

"The results from this study are very exciting and provide a positive signal for future investigations" said Dr. Robert Kaminski, Chief, Subunit Enteric Vaccines and Immunology, Department of Enteric Infections, Bacterial Diseases Branch, WRAIR. "We received funding to evaluate the Immuron Travelan product for cross-reactivity with *Campylobacter,* other ETEC strains, and *Shigella* using *in vitro* and *in vivo* methodologies. Our *in vitro* data set clearly indicated that antibodies in the product cross react with all bacterial pathogens tested. More recently, the NHP study completed at AFRIMS demonstrated that Travelan protects against shigellosis/dysentery in the model. All the animals treated with placebo and then challenged with *Shigella flexneri* 2a, 2457T became infected and had severe dysentery. Only 25% of the animals (2 of 8) treated with Travelan and then challenged with *S. flexneri* 2a, 2457T had any constitutional/clinical symptoms. The results from this study, in combination with the results from the *in vitro* assays, suggest that the Travelan product offers protection/cross reactivity from *Shigella*."

"The results go some way in confirming that **Travelan®** is effective across all strains and species of enteropathogenic bacteria tested. They significantly strengthen and extend previous results that demonstrated the specificity of antibodies incorporated into **Travelan®** cross-react with multiple enteric pathogens, including *Campylobacter*, ETEC, *Klebsiella*, *Salmonella* and *Shigella* strains. The current study demonstrates that the **Travelan®** product is functionally cross-reactive and prophylactically effective and confirms that **Travelan®** has a substantially broader spectrum of antimicrobial action than previously reported. These results offer 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.

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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 diarhoea-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, 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 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.