Uniformed Services University to Release Topline Data

Highlights:

- ***Primary Endpoint did not reach statistical significance***
- ***Investigational product was manufactured by a third party and was not administered in accordance with Travelan® directions for use***
- ***Immuron will propose the established and clinically validated three times daily dosing schedule at an End-of-Phase 2 meeting with the FDA***
- ***Immuron will continue to collaborate with the Naval Medical Research Command and the Walter Reed Army Institute of Research in the development of novel vaccines targeting Campylobacter and Shigella***
- ***Immuron has also advanced discussions with AFRIMS to conduct testing of Travelan® against EAEC and EPEC strains of E.coli***

Melbourne, Australia, December 10, 2025: Immuron Limited (ASX: IMC; NASDAQ: IMRN), an Australian based and globally integrated biopharmaceutical company announces that the Uniformed Services University has released topline results from its clinical trial evaluating the effectiveness of a third party manufactured product containing enterotoxigenic *E. coli* (ETEC) hyperimmune bovine colostrum (IMM-124E) in maintaining gut health during deployment and travel.

On October 31, 2025, Immuron announced that the Uniformed Services University (USU) completed the P2TD study (NCT04605783). This study was not conducted under an Investigational New Drug (IND) Application approved by the FDA. The investigational drug product, contract manufactured for USU by a third party, was formulated as 600 mg of powder in sachets and administered twice daily in a randomized, placebo controlled trial.

It is important to note that this product was not administered in accordance with Travelan® directions for use. Travelan® is administered before meals, three times a day.

Details of this USU Study can be found on clincaltrials.gov; ClinicalTrials.gov ID: NCT04605783.

As Immuron did not manufacture the investigational product and given the differences in administration, Immuron does not consider the results of this trial to reflect the performance of Travelan® when taken in compliance with directions for use.

Immuron previously indicated that the results of this study would inform its dosing recommendation to the FDA at the upcoming End-of-Phase 2 meeting. If the study demonstrated satisfactory outcomes, the company would have considered proposing a twice-daily dosing regimen. However, the data failed to show superiority over prior clinical trial results supporting superiority of the current three-times-daily regimen for Travelan® caplets. Immuron will propose the established and clinically validated dosage form and three-times-daily dosing schedule.

Immuron has identified several factors that may have influenced the primary endpoint outcome, including:

- **Timing of dosing**: not all participants initiated dosing less than two days prior to arrival
- **Compliance with study procedures**: not all participants complied with the study dosing and administration protocols
- **Dosing adherence**: a number of participants missed more than three consecutive doses or four or more non-consecutive doses.
- **Administration method**: a number of participants dosed with meals and not before

These insights, together with a comprehensive review of the clinical study report, will guide the design of future clinical programs. Importantly, the findings from the USU study provide an input to refining trial design prior to Immuron's planned End-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA).

Background on Travelan® Clinical Trials

Immuron has conducted multiple Travelan® clinical trials which are summarized in the Table below. It is important to note that dosing in the Uniformed Services University P2TD study (NCT04605783) is 600mg taken as 1 **sachet twice daily**. The dosage form and administration differ from our commercial product, Travelan® for which directions for use are to take one to two **caplets before each meal** (i.e., **three times daily**). Immuron recently completed a Travelan® Phase 2 clinical trial (NCT05933525) during which 6 **caplets** (1200mg) were taken **once daily**.

Travelan® ETEC Challenge Studies (double-blind placebo controlled)		
1	30 subjects received 400mg Travelan/placebo **3x daily** Diarrhea attack rate = 73%	Travelan provided: • 90.5% protection against diarrhea* • 91% reduction in number of loose/diarrheal stools* • 100% reduction in abdominal pain* • Faster clearance of ETEC challenge strain
2	60 subjects received 200 - 400mg Travelan/placebo **3x daily** Diarrhea attack rate = 86%	Travelan provided: • 58 -83% protection against diarrhea* • 54-87% reduction in number of loose/diarrheal stools* • 60-100% reduction in abdominal pain*
3	60 subjects received 1200mg Travelan/Placebo **1x daily** Diarrhea attack rate = 37% Cohort 1 (n=26) attack rate[1] = 54%	Travelan provided: • 37% -57%[1] protection against diarrhea • 29% reduction in number of loose/diarrheal stools • 57% reduction in abdominal pain, fever, nausea, anorexia • Faster clearance of ETEC challenge strain*

Clinical trial 1 and 2 published in Otto et al., 2011. Clinical trial 3 recently completed once daily dosing Clinical trial 4 USU study. *Statistically significant; [1] range covers all diarrhea to severe diarrhea cases; [2] For the USU study the formulation is a powdered-form of Travelan also known as IMM-124E, which is the active component of Travelan®.

As announced on August 16, 2024, the Naval Medical Research Command and the Walter Reed Army Institute of Research, in collaboration with Immuron, are progressing the development of novel vaccines targeting *Campylobacter* and *Shigella*. Under a recently executed collaborative research agreement with the Henry M. Jackson Foundation, vaccine preparations against these pathogens will be developed and formulated at the military research institutes and subsequently provided to Immuron. Utilizing its proprietary technology platform, Immuron will produce two hyper-immune bovine colostrum products for pre-clinical evaluation, with the objective of advancing a combined colostrum-based therapeutic specifically designed for military relevance.

Immuron has also advanced discussions with the Department of Enteric Diseases at the Armed Forces Research Institute of Medical Sciences (AFRIMS) to conduct testing of Travelan® against Enteroaggregative Escherichia coli (EAEC) and Enteropathogenic Escherichia coli (EPEC) strains. This would inform Immuron as to whether another vaccine should be added to the manufacturing process for IMM-124E to increase the overall protective efficacy of a military-relevant Travelan®.

Immuron continues to market Travelan® assertively in its progression towards EBITDA (ex R&D) breakeven as outlined at the Annual General Meeting (AGM) of November 11, 2025. At the AGM, Immuron advised that it had cost effectively raised capital necessary to proceed with a Phase 2 clinical trial for IMM-529 in Clostridioides difficile infection, following approval of the IMM-529 IND by the FDA. Immuron announced on December 4, 2025, that it had issued 45.472 million shares at A$0.07910 which raised A$3.5 million. This has exhausted the At-The-Market Facility. These funds will be deployed towards meeting these objectives.

1. Earnings before Interest, Tax, Depreciation and Amortisation (EBITDA); ex-R&D: add back Research & Development, less R&D Tax Incentive and R&D grants

This release has been authorised by the directors of Immuron Limited.

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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 infectious diseases.

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.

Travelers' diarrhea (TD)

TD is generally defined as the passage of ≥ 3 unformed stools per 24 hours plus at least one additional symptom (such as nausea, vomiting, abdominal cramps, fever, blood/mucus in the stools, or fecal urgency) that develop while abroad or within 10 days of returning from any resource-limited destinations (Leung et al., 2006). Diarrhea continues to be the most frequent health problem among travelers to destinations in lower- and middle-income regions (Steffen, 2017). Deployed US military personnel, essentially representing a long-term traveller population, are particularly affected given their population dynamics and the context in which they seek care and treatment (Connor et al., 2012). Diarrhea is the leading infectious disease threat to the overall health and preparedness of deployed US armed forces, with diarrheagenic E. coli, Campylobacter spp., and Shigella spp. among the most commonly reported etiologies (Riddle et al., 2006).

Immuron Platform Technology

Immuron's proprietary technology is based on polyclonal immunoglobulins (IgG) derived from engineered hyper-immune bovine colostrum. Immuron has the capability of producing highly specific immunoglobulins to any enteric pathogen and our products are orally active. Bovine IgG can withstand the acidic environment of the stomach and is resistant to proteolysis by the digestive enzymes found in the Gastrointestinal (GI) tract. Bovine IgG also possesses this unique ability to remain active in the human GI tract delivering its full benefits directly to the bacteria found there. The underlying nature of Immuron's platform technology enables the development of medicines across a large range of infectious diseases. The platform can be used to block viruses or bacteria at mucosal surfaces such as the Gastrointestinal tract and neutralize the toxins they produce.

IMM-124E (Travelan®)

IMM-124E was developed using Immuron's platform technology. IMM-124E is produced from the colostrum of birthing cattle that have been immunised during pregnancy with a vaccine containing the outer antigens of multiple human derived ETEC. A total of 13 ETEC strains are used in the vaccine to produce high levels of antibodies against selected surface antigens from the most common strains of ETEC.

The resultant hyperimmune colostrum IMM-124E from ETEC vaccinated cows contains significant levels of polyclonal antibodies specific for ETEC antigens LPS, CFA-I and Flagellin (Sears et al., 2017).

The antibodies produced in IMM-124E have been found to have a stronger binding and neutralizing activity (than the antibodies of unvaccinated cattle) against a wide range of LPS antigens including both the variable O-polysaccharide region and the preserved oligosaccharide core 'R' region of LPS from the 13 serotypes used in the ETEC vaccine.

IMM-124E is manufactured into a tablet form referred to as Travelan®.

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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.