Immuron Announces Clinical Trial Update

- **IMM-529 IND: currently under review, FDA request for Information – minor updates to clinical protocol completed and submitted**
- **Travelan® P2TD (n=851) Uniformed Services University study topline data delayed to the end of November due to U.S government shutdown**

Melbourne, Australia, October 31, 2025: Immuron Limited (ASX: IMC; NASDAQ: IMRN), an Australian based and globally integrated biopharmaceutical company provides a clinical trial update on Travelan® and IMM-529.

IMM-529 IND (*Clostridioides difficile* infection)
Immuron announced on October 8, 2025 submission of an Investigational New Drug (IND) application to the United States Food and Drug Administration (FDA) for the clinical development of IMM-529 to prevent or treat *Clostridioides difficile* Infection.

Immuron has received formal acknowledgment of its Investigational New Drug (IND) application from the Center for Biologics Evaluation and Research (CBER), including assignment of a biologic product name and IND number. On October 25th, the U.S Food and Drug Administration (FDA) informed the company that the IND is currently under active review and issued a request for additional clinical information. In response, Immuron submitted a comprehensive reply addressing the FDA's queries and made minor updates to the clinical trial protocol to incorporate the agency's recommendations ahead of the IND 30-day decision date.

Travelan® Uniformed Services University P2TD study (Incidence of gut health deficiencies)
Immuron was expecting the Uniformed Services University to provide topline results from this study by the end of October 2025. Due to delays associated with government shutdown, results are now not expected until the end of November 2025.

Travelan® end of Phase 2 meeting with the FDA
The results of the P2TD clinical study, conducted by the Uniformed Services University, will play a pivotal role in shaping Immuron's dosing strategy for its upcoming End-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA). Should the study demonstrate favorable outcomes, Immuron intends to propose a twice-daily dosing regimen. However, if the data do not show superiority over previous findings associated with a three-times-daily regimen, the company will consider maintaining the existing three-times-daily dosing recommendation.

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 Travelan®

or Placebo (600mg) taken as 1 **sachet twice daily** with meals. The dosage form and administration is different than our commercial product, Travelan®, 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*
IMM-124E Non-Challenge Field Study (double-blind placebo controlled)		
4	868 subjects received 600mg Travelan/Placebo **2x daily** Diarrhea attack rate = 24%	Results TBC

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®.

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®.

IMM-529

Immuron is developing IMM-529 as an adjunctive therapy in combination with standard of care antibiotics for the prevention and/or treatment of recurrent Clostridioides difficile infection (CDI). IMM-529 antibodies targeting Clostridioides difficile (C. diff) may help to clear CDI infection and promote a quicker re-establishment of normal gut flora, providing an attractive oral preventative for recurrent CDI.

Immuron is collaborating with Dr. Dena Lyras and her team at Monash University, Australia to develop vaccines to produce bovine colostrum-derived antibodies. Dairy cows were immunised to generate hyperimmune bovine colostrum (HBC) that

contains antibodies targeting three essential C. diff virulence components. IMM-529 targets Toxin B (TcB), the spores and the surface layer proteins of the vegetative cells.

This unique 3-target approach has yielded promising results in pre-clinical infection and relapse models, including (1) Prevention of primary disease (80% P =0.0052); (2) Protection of disease recurrence (67%, P <0.01) and (3) Treatment of primary disease (78.6%, P<0.0001; TcB HBC). Importantly IMM-529 antibodies cross-react with whole cell lysates of many different human strains of C. diff including hypervirulent strains.

To our knowledge, IMM-529 is, to date, the only investigational drug that has shown therapeutic potential in all three phases of the disease (Hutton et al., 2017).

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