

## Immuron Announces Travelan® Clinical Trial Update

### Highlights:

- Travelan® (IMM-124E) Phase 2 Clinical Study Report submitted to the FDA
- Travelan® (IMM-124E) Phase 2 Clinical Study Statistically Significant Immunology Results
- Travelan® (IMM-124E) Phase 2 Clinical Study Statistically Significant Microbiome Responses
- Travelan® P2TD (n=866) Uniformed Services University field study randomized 776 subjects

Melbourne, Australia, January 14, 2025: Immuron Limited (ASX: IMC; NASDAQ: IMRN), an Australian based and globally integrated biopharmaceutical company is pleased to announce that it has submitted the Clinical Study Report to the U.S. Food and Drug Administration (FDA) for the recently completed Phase 2 study and will soon request and end of Phase 2 meeting which is a pre-cursor to proceeding to Phase 3.

### Travelan® (IMM-124E) Phase 2 Clinical Study

NCT05933525: A Randomized, Double-blind, Placebo-controlled Trial Assessing the Efficacy of IMM-124E (Travelan®) in a Controlled Human Infection Model for Enterotoxigenic Escherichia Coli (ETEC)

### Immunology

Statistically significant lower levels of IgA and IgG were observed for the subjects who received Travelan® compared to those who received the placebo, which may also reflect levels of exposure to ETEC antigen. Travelan® antibodies target and bind to ETEC antigen in the gastrointestinal tract, block LPS epitopes and therefore reduce antigen exposure, resulting in lower overall IgA and IgG antibody titers.

Clinical data also demonstrated there was a statistically significant reduction in the number of colony forming units (CFUs) in the stools of subjects who received Travelan® ( $p=0.0121$ ), measured 48 hours post challenge, indicating faster clearance of the challenge strain from the GI tract.

### Microbiome

Participants in the Travelan® group have a more stable gastrointestinal microbiota over the treatment time period when compared with the Placebo group. Alpha diversity, a measurement of the richness (how many different species) and evenness (abundance or number of different species) revealed that the Travelan group had improved richness and Shannon diversity results compared to the Placebo group. The data indicated a difference in the richness in the diversity of certain species rather than just the abundance or number of bacterial species between the two groups.

Statistically significant differences were identified between the two treatment groups in the Beta diversity tests (number of species and abundance). The relative abundance results revealed that the

Travelan group had increased levels of beneficial bacteria such as *Akkermansia* and *Faecalibacterium*. The differential abundance results confirmed increases in *Agathobaculum*, *Slackia* the *Eubacterium eligens* group, and the *Eubacterium siraeum* group; and decreases in *Rumminococcus* and *Bacteroides*. The abundance data indicates a possible link between the species of bacteria associated with reduced inflammation.

This study data implies that Travelan® appears to aid in the reduction and clearance over time of pathological ETEC bacteria, by shortening the recovery period after ETEC challenge. The mechanism indicates there is an increase in the propagation of bacteria associated with decreases in inflammation and repairing the intestinal lining. Further investigation into this association is required to fully understand the benefits of Travelan® on the gut microbiome.

#### **Uniformed Services University field study**

[NCT04605783](#): A Randomized, Double-Blind, Placebo-Controlled Trial to Evaluate a Dietary Supplement to Maintain Gut Health During Deployment and Travel

776 subjects have been randomized. We anticipate the last enrollments to occur in March 2025 and follow-up to be completed around June 2025.

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  $\geq 3$  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](#)).

### References

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