



Immuron CEO, Steven Lydeamore participation in Maxim Virtual Healthcare Conference - addendum

Melbourne, Australia, October 16, 2024: Immuron Limited (ASX: IMC; NASDAQ: IMRN) is pleased to advise our Chief Executive Officer, Steven Lydeamore will be participating in a fireside chat at the Maxim Virtual Healthcare Conference on Wednesday 16th October 2024 (4.30pm U.S. Eastern time).

A copy of the presentation covering information being discussed is included below.

This addendum replaces the corresponding announcement released earlier today, which inadvertently omitted a number of slides from the presentation.

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](#)).

References

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Hutton, M.L., Cunningham, B.A., Mackin, K.E. et al. Bovine antibodies targeting primary and recurrent *Clostridium difficile* disease are a potent antibiotic alternative. *Sci Rep* 7, 3665 (2017). <https://doi.org/10.1038/s41598-017-03982-5>

Leung AK, Robson WL, Davies HD. Travelers' diarrhea. *Adv Ther.* Jul-Aug; 23(4): 519-27; 2006

Otto W, Najnigier B, Stelmasiak T and Robins-Browne RM. Randomized control trials using a tablet formulation of hyperimmune bovine colostrum to prevent diarrhea caused by enterotoxigenic *Escherichia coli* in volunteers *Scandinavian Journal of Gastroenterology* 46: 862– 868; 2011.

Riddle MS, Sanders JW, Putnam SD, and Tribble DR. Incidence, etiology, and impact of diarrhea among long-term travelers' (US military and similar populations): A systematic review. *American Journal of Tropical Medicine and Hygiene.* 74(5): 891-900; 2006.

Sears KT, Tennant SM, Reymann MK, Simon R, Konstantopolos N, Blackwelder WC, Barry EM and Pasetti MF. Bioactive Immune Components of Anti-Diarrheagenic Enterotoxigenic *Escherichia coli* Hyperimmune Bovine Colostrum products. *Clinical and Vaccine Immunology.* 24 (8) 1-14; 2017.

Steffen R. Epidemiology of travelers' diarrhea. *J Travel Med.* 24(suppl_1): S2-S5; 2017.

For more information visit: <https://www.immuron.com.au/> and <https://www.travelan.com>
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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.



NASDAQ: IMRN
ASX: IMC

Maxim Virtual Healthcare Conference

Steven Lydeamore
Chief Executive Officer

16 October 2024



SAFE HARBOR STATEMENT

Certain statements made in this presentation are forward-looking statements and are based on Immuron's current expectations, estimates and projections. Words such as "anticipates," "expects," "intends," "plans," "believes," "seeks," "estimates," "guidance" and similar expressions are intended to identify forward-looking statements.

Although Immuron believes the forward-looking statements are based on reasonable assumptions, they are subject to certain risks and uncertainties, some of which are beyond Immuron's control, including those risks or uncertainties inherent in the process of both developing and commercializing technology. As a result, actual results could materially differ from those expressed or forecasted in the forward-looking statements.

The forward-looking statements made in this presentation relate only to events as of the date on which the statements are made. Immuron will not undertake any obligation to release publicly any revisions or updates to these forward-looking statements to reflect events, circumstances or unanticipated events occurring after the date of this presentation except as required by law or by any appropriate regulatory authority.

YTD FY2025 results in this presentation are subject to audit review.



Executive summary

Immuron Ltd (NASDAQ:IMRN) (ASX:IMC) is a globally integrated biopharmaceutical company focused on developing, and commercialising, oral immunotherapeutics for the treatment of gut mediated diseases



Company Overview

Two commercially available oral immunotherapeutic products – Travelan® and Protectyn®
3 clinical programs: Travelan®(IMC: Phase 2 CHIM trial), Travelan®(USU: Phase 4 field study), IMM-529 (IMC: preparing IND, Phase 2 trial)



Business Update

Travelan® (IMM-124E) Phase 2 CHIM trial topline results;
Pharmaron presentation at International [Conference](#)
Travelan® (IMM-124E) Travelan® Uniformed Services University IMM-124E Phase 4 trial recruited ~85% of 866
CampETEC Phase 2 clinical trial topline results announced;

NMRC presentation at International [Conference](#)
U.S. Department of Defense Research [Award](#) for NMRC and WRAIR to develop an enhanced formulation of Travelan®
IMM-529 Immuron completes pre-IND [meeting](#) with FDA on the development of IMM-529



Results & Outlook

Sales 1 July 24 to 30 September 24 of A\$1.5 million up 13% on prior quarter (unaudited)
North American Travelan® sales A\$0.5 million up 48% on prior quarter (unaudited)
Evaluating options to enter international markets
Evaluating options to add to marketed products portfolio

Financial Snapshot

Shares on Issue	229,145,429
Total Options	13,931,756
Last Traded Price	IMC: A\$0.082
52 week High/Low	IMC: A\$0.17/0.065 IMRN: \$5.96/1.481
Market Cap	IMC: A\$18.8m
Cash & Cash Equivalents (as at 30 June 2024)	A\$11.7m

Major Shareholders

Holder	Units	% of CSO
BNY Mellon Asset Management	77,385,904	33.8 %
Authenticus Australia Pty. Ltd.	5,500,000	2.4 %
Grandlodge	3,846,712	1.7 %
Management & Board	3,101,153	1.4 %

as of 14 October 2024

Travelan® continued strong sales growth



Global

+ Q1 FY2025 AUD\$1.5 million up 13% on prior quarter



Australia

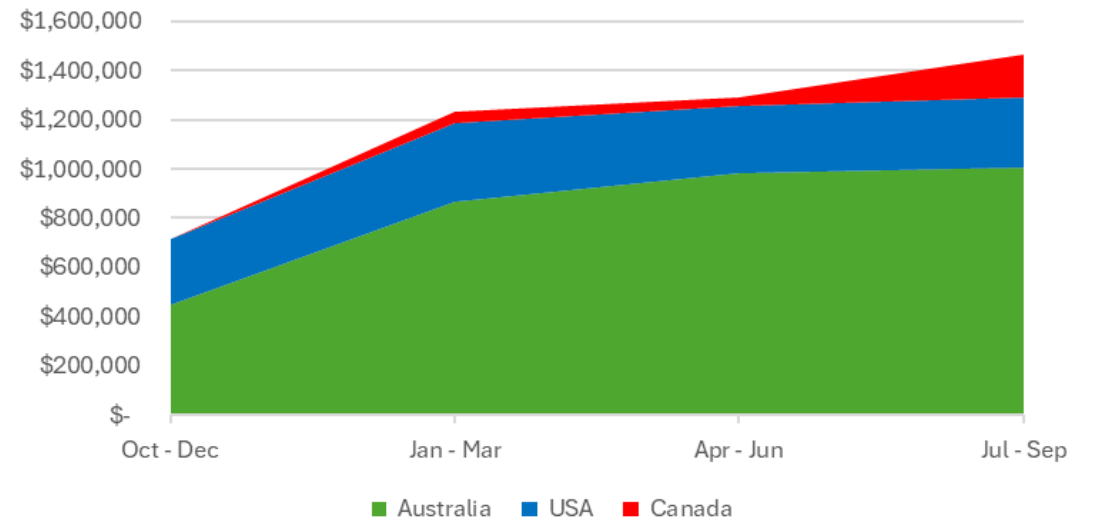
- + Q1 2025 AUD\$1.0 million up 3% on prior quarter
- + Secured core ranging in another nine pharmacy banner groups



North America

- + Q1 2025 AUD\$0.5 million up 48% on prior quarter
- + Strongest monthly sales on amazon.com
- + Secured distribution in ten pharmacy/grocery retailers in Canada

Travelan Quarterly Net Sales (\$ AUD)



Status of product portfolio and key milestones

Travelan®

MTEC 21-10-013 grant Phase 2
randomized clinical challenge study to examine a dosing regimen for Travelan® more suited to the military IMM-124E (Travelan®) IND 29087
FDA approval Dec 22

Top-line data 7 March 2024
Clinical Study Report – **October 2024**

Clostridioides difficile

IMM-529

Prevention of recurrent CDI infections
Vaccine (spores, vegetative cells, and Toxin B)
600mg solid dose active formulation developed

Pre-IND submission to FDA – 1 July 2024
IND, clinical protocol and trial preparation in progress

Immuron's Clinical Programs

Compound or brand name	Indication	Phase I	Phase II	Phase III	Market
IMM-124E Travelan®	Travelers' Diarrhea ETEC challenge				
IMM-529	<i>Clostridioides difficile</i> Infection & Recurrence				

Collaborative studies

Travelan® P2TD

Field study Uniformed Services University

Phase 2 randomized clinical trial with Travelan® /Placebo to evaluate prophylactic effectiveness during deployment or travel to a high TD risk region

Status ~85% of participants have been recruited (866 target)

Anticipated topline results – **April 2025**

CampETEC

NMRC Campylobacter and enterotoxigenic E. coli product

Manufactured by Immuron for NMRC

Top-line data reported **4 October 2024**

Our Partners' Clinical Programs

Compound or brand name	Partner	Phase I	Phase II	Phase III	Market
Travelan®					

IMMURON'S CLINICAL PROGRAMS – OPPORTUNITY ASSESSMENT

Updated Revenue Estimate for IMM-529



Luminate* Opportunity Assessment for IMM-124E

- › Immuron's development of **IMM-124E** (hyperimmune bovine colostrum) as a prescription medication has the potential to address this unmet need
- › Primary care physicians (PCP)s impressed with clinical efficacy endpoint targets demonstrating > 80% protection against the development of diarrhea.
- › If IMM-529 can achieve a significant reduction in recurrences among patients with CDI, it can reach peak revenues of ~**US\$400** million in USA
- › Based on new information about the overall CDI market and IMM-529's potential to be used earlier in the treatment algorithm (based on approvals for treatment and prevention of recurrence)
- › Derived wholly from secondary research, price target increased to Vowst level, as a second mover IMM-529 is projected to reach a 30% share of the advanced treatment market

Luminate Opportunity Assessment for IMM-529

- › Infectious disease experts reacted favorably to the **IMM-529** MOA, and its unique ability to target three elements of the rCDI infection – the spores, vegetative cells, and Toxin B
- › Non-microbiome approaches (such as IMM-529) are still appealing to experts, who noted that clinical trial efficacy (reduction in relapse rate) and cost/access will be the key drivers of clinical use in recurrent patients, not mechanism of action
- › Based on the estimated market size, anticipated payer restrictions, pricing, and competition, base case yearly revenue in USA for IMM-529 is conservatively projected at **US\$93M** for the target patient population (limited to 2nd recurrence and later based on trial design and payer coverage)
- › Positioning IMM-529 earlier than second recurrence and/or efficacy targets could lead to higher uptake.

Compound or brand name

Indication

Phase I

Phase II

Phase III

Market

IMM-124E - Travelan®

Traveler's Diarrhea ETEC challenge

IMM-529

Clostridioides difficile Infection (CDI) & Recurrence

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Luminate, a leading lifescience consulting company: <https://luminate.com/company/our-story/>

WORLD FIRST TRIPLE MECHANISM OF ACTION FOR CDI



IMM-529: pre-IND filed with FDA July 2024; successful pre-IND meeting

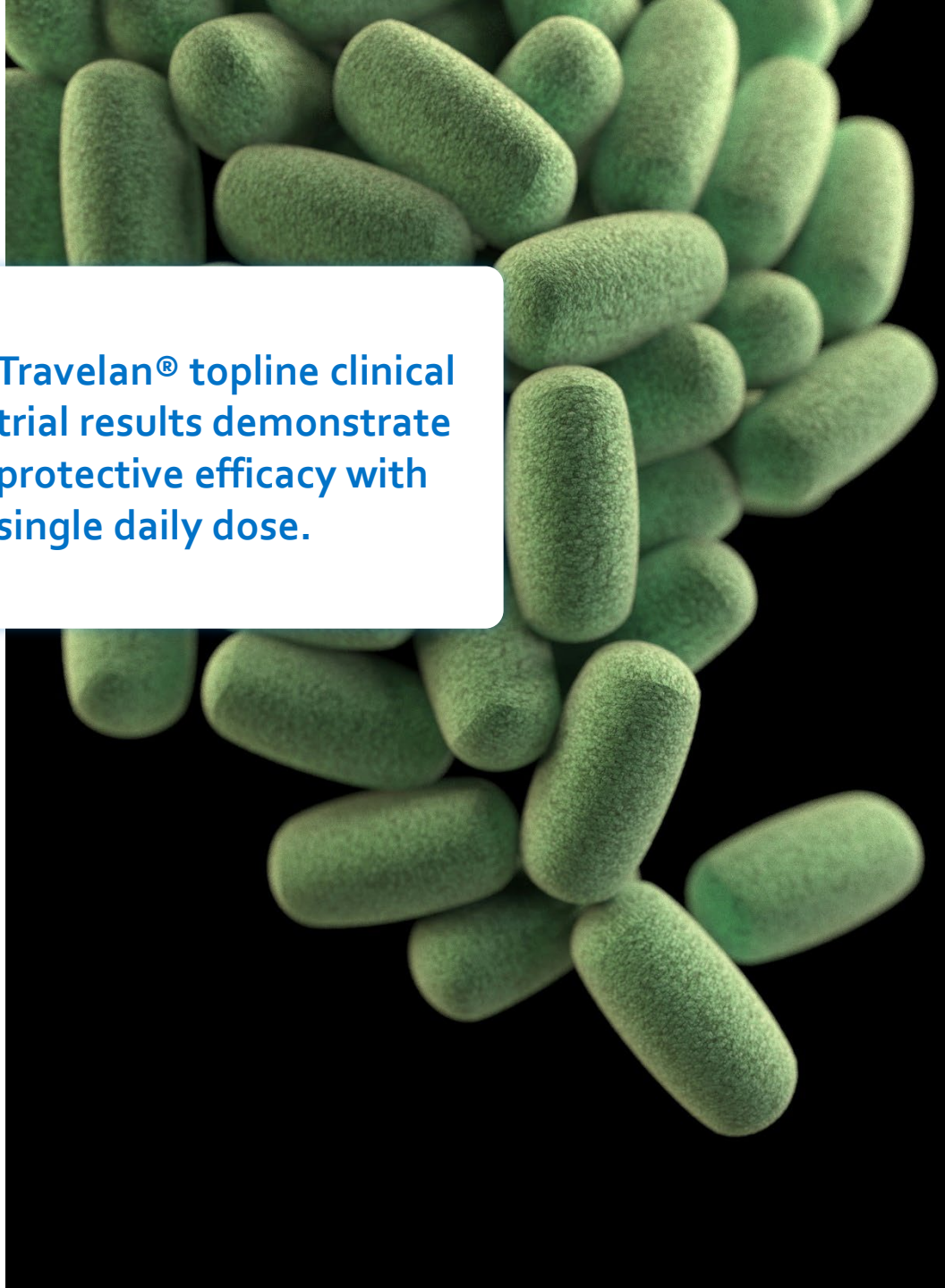
Indication / Target Population	IMM-529 will be indicated for the treatment of recurrent <i>C. difficile</i> infection
Product Description / Mechanism of Action	• Novel antibody-containing therapeutic which neutralizes <i>C. difficile</i> but does not impact the microbiome • Targets not only toxin B but also spores and vegetative cells responsible for recurrence • Potential for use in combination with standard of care (e.g. vancomycin, fidaxomicin) • Targets many isolates
Dosage and ROA	• Oral administration, 3 x daily • Trial to test safety 7-day treatment course on top of standard of care (vancomycin, fidaxomicin)
Efficacy	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).
Safety / Tolerability	• To be evaluated in Phase 2 study • Equivalent or better than current standard of care



Positive results support Travelan® progress to phase 3

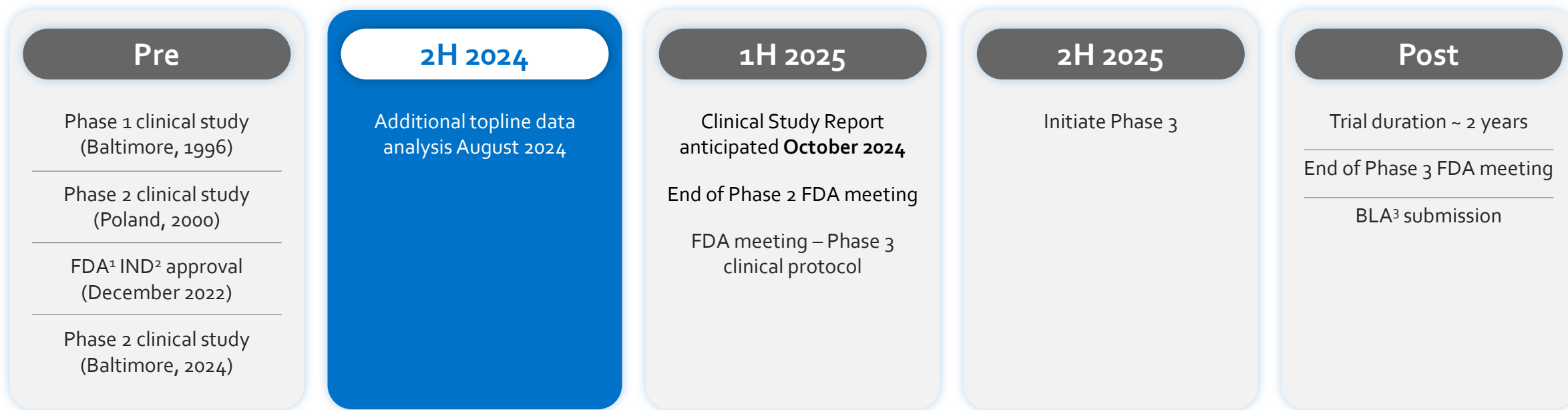
IMM-124E Phase 2

- + Healthy volunteers were recruited and randomized to receive a single daily oral dose of 1200 mg of Travelan® or placebo. Dosing commenced 2 days prior to challenge with ETEC strain H10407 and continued for 7 days.
- + 60 subjects completed the inpatient challenge component of this current clinical study.
- + **36.4% protective efficacy** against Enterotoxigenic Escherichia coli (ETEC) induced moderate to severe diarrhea was observed in the Travelan® group compared to the Placebo group (primary endpoint) even though the attack rate for this study was 37%, much lower than the planned 70%.
- + The attack rates on previous Phase 2 (Otto et al. 2011) were 73% and 86% with protective efficacy of 90.9% and 76.7%.
- + **43.8% reduction in diarrhea of any severity** in the Travelan® group compared to the Placebo group during the 5-day period post challenge which is **approaching statistical significance; $p=0.066$**
- + **The number of cumulative adverse events per participant in the Travelan® group (58) was statistically significantly lower than the Placebo group (109); $p<0.05$.**
- + Phase 2 clinical study data supports the excellent safety and tolerability profile of Travelan®.



Travelan® topline clinical trial results demonstrate protective efficacy with single daily dose.

IMM-124E Phase 3 strategy



- + The pivotal registration studies is anticipated to involve two randomized, double-blind, parallel-group, placebo-controlled Phase 3 clinical studies (drug substance IMM-124E) to assess the efficacy and safety of Travelan® for prevention of traveler's diarrhea (TD)
- + Anticipated enrolment of approximately 1200 healthy adult subjects (600 subjects in two studies) traveling to regions with high TD risk.

- + Subjects anticipated to be randomized 1:1 to receive Travelan® or placebo.
- + Dosing anticipated to begin 3 days prior to arrival in country and for at least 14 days in country.
- + The primary endpoint requested will be traveler's diarrhea.

Scientific references

Travelan® (IMM-124E)	
Travelan® has been shown to reduce both the incidence and severity of ETEC-induced diarrhea in up to 90% of volunteers	Scandinavian Journal of Gastroenterology, 46:7-8, 862-868, DOI: 10.3109/00365521.2011.574726
Clinical Evaluation of Travelan® an Oral Prophylactic for Prevention of Travelers' Diarrhea in Active Duty Military Service Assigned Abroad.	Military Health System Research Symposium 14-17 Aug 2023 Abstract 1
Travelan as a broad Spectrum anti-bacterial	Immuron Limited, 29 April, 2011
Travelan® demonstrates broad reactivity to Vibrio cholera strains from Southeast Asia indicating broad potential for prevention of traveler's diarrhea	US Department of Defense, Armed Forces Research Institute of Medical Sciences (AFRIM), 4 September, 2019
Travelan® prevented clinical shigellosis (bacillary dysentery) in 75% of Travelan® treated animals compared to placebo and demonstrated a significant clinical benefit	US Department of Defense, Armed Forces Research Institute of Medical Sciences (AFRIM), 5 September, 2018
Travelan® able to bind and was reactive to 60 clinical isolates of each bacteria, Campylobacter, ETEC, and Shigella	US Department of Defense, Armed Forces Research Institute of Medical Sciences (AFRIM), 30 January, 2017
Bioactivity and efficacy of a hyperimmune bovine colostrum product- Travelan, against shigellosis in a non-Human primate model (Macaca mulatta)	Islam D, Ruamsap N, Imerbsin R, Khanijou P, Gonwong S, Wegner MD, et al. (2023) Bioactivity and efficacy of a hyperimmune bovine colostrum product- Travelan, against shigellosis in a non-Human primate model (Macaca mulatta). PLoS ONE 18(12): e0294021.
Bioactive Immune Components of Travelan®	Clin Vaccine Immunol 24:e00186-16. https://doi.org/10.1128/CVI.00186-16
Hyperimmune bovine colostrum containing lipopolysaccharide antibodies (IMM-124E) has a non-detrimental effect on gut microbial communities in unchallenged mice	Infect Immun. 2023 Nov; 91(11): e00097-23.
Administration of the Hyper-immune Bovine Colostrum Extract IMM-124E Ameliorates Experimental Murine Colitis	Journal of Crohn's and Colitis, Volume 13, Issue 6, June 2019, Pages 785–797, https://doi.org/10.1093/ecco-icc/jiy213
IMM-529	
Bovine antibodies targeting primary and recurrent Clostridium difficile disease are a potent antibiotic alternative	Sci Rep 7, 3665 (2017). https://doi.org/10.1038/s41598-017-03982-5



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