



Immuron CEO, Steven Lydeamore webinar on MarketOpen Direct Connect

Melbourne, Australia, August 8, 2024: Immuron Limited (ASX: IMC; NASDAQ: IMRN) is pleased to advise our Chief Executive Officer, Steven Lydeamore will be hosting a webinar on MarketOpen Direct Connect on Thursday 8th August 2024, 11:00am AEST (9:00am AWST).

This webinar can be viewed live via zoom & you register for FREE via the link below.

https://us06web.zoom.us/webinar/register/WN_QV-yMVvGRQuYq698XMTQxA

A recorded copy of the webinar will be made available following the event.

A copy of the presentation being made is included below.

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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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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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

Direct Connect Webinar

MarketOpen



Steven Lydeamore
Chief Executive Officer

8 AUGUST 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 FY2024 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®

4 clinical programs: Travelan®(IMC: Phase 2 CHIM trial), Travelan®(USU: Phase 4 field study), CampETEC (NMRC: Phase 2 CHIM trial), IMM-529 (IMC: Protocol development phase, Phase 2 trial)

Business Update



Flagship product Travelan® growing strongly as overseas travel rebounds

Travelan® (IMM-124E) Phase 2 CHIM trial topline results

Travelan® (IMM-124E) Travelan® Uniformed Services University (USU) P2TD IMM-124E field clinical trial

recruited ~77% of target 866

CampETEC Phase 2 clinical trial completed inpatient phase

IMM-529 pre-IND filed with FDA

Results & Outlook



Sales 1 Jul 23 to 30 June 24 of A\$4.9 million up 174% on pcp (unaudited)

Evaluating options to enter international markets

Evaluating options to add to marketed products portfolio

Financial Snapshot

Shares on Issue	227,998,346
Total Options	15,078,839
Last Traded Price	IMC: A\$0.098
52 week High/Low	IMC: A\$0.17/0.065 IMRN: \$5.96/1.48
Market Cap	IMC: A\$22.3m
Cash & Cash Equivalents (as at 31 Dec 23)	A\$15.2m

Major Shareholders

Holder	Units	% of CSO
BNY Mellon Asset Management	78,066,184	34.2 %
Authentics Australia Pty. Ltd.	5,500,000	2.4 %
Grandlodge	3,846,712	1.7 %
Management & Board	1,954,070	0.9 %

as of 6 August 2024

Immuron

Addressable market & industry overview



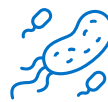
Billion Dollar Market

Traveller's diarrhoea treatment market is large and growing at a CAGR of ~7%



Industry tailwinds

Travel picking up significantly following COVID lockdowns



Frequent Symptom

30% - 70% of travelers experience traveller's diarrhoea**



Chief Commercial Officer has 20+ year's experience with local and global (Asia, UK) commercial leadership roles with GSK and P&G



USA Market

FY24: launch on amazon.com and Walmart.com
Planning for increased market penetration in FY25



Evaluating options

for entry into international markets
to add marketed products to portfolio in FY25

\$83m

Based on US annual travel numbers and a penetration rate of 15%, the market potential is estimated at \$83m*

\$50m

Based on EU travel numbers and a penetration rate of 15%, the market potential is estimated at \$50m*

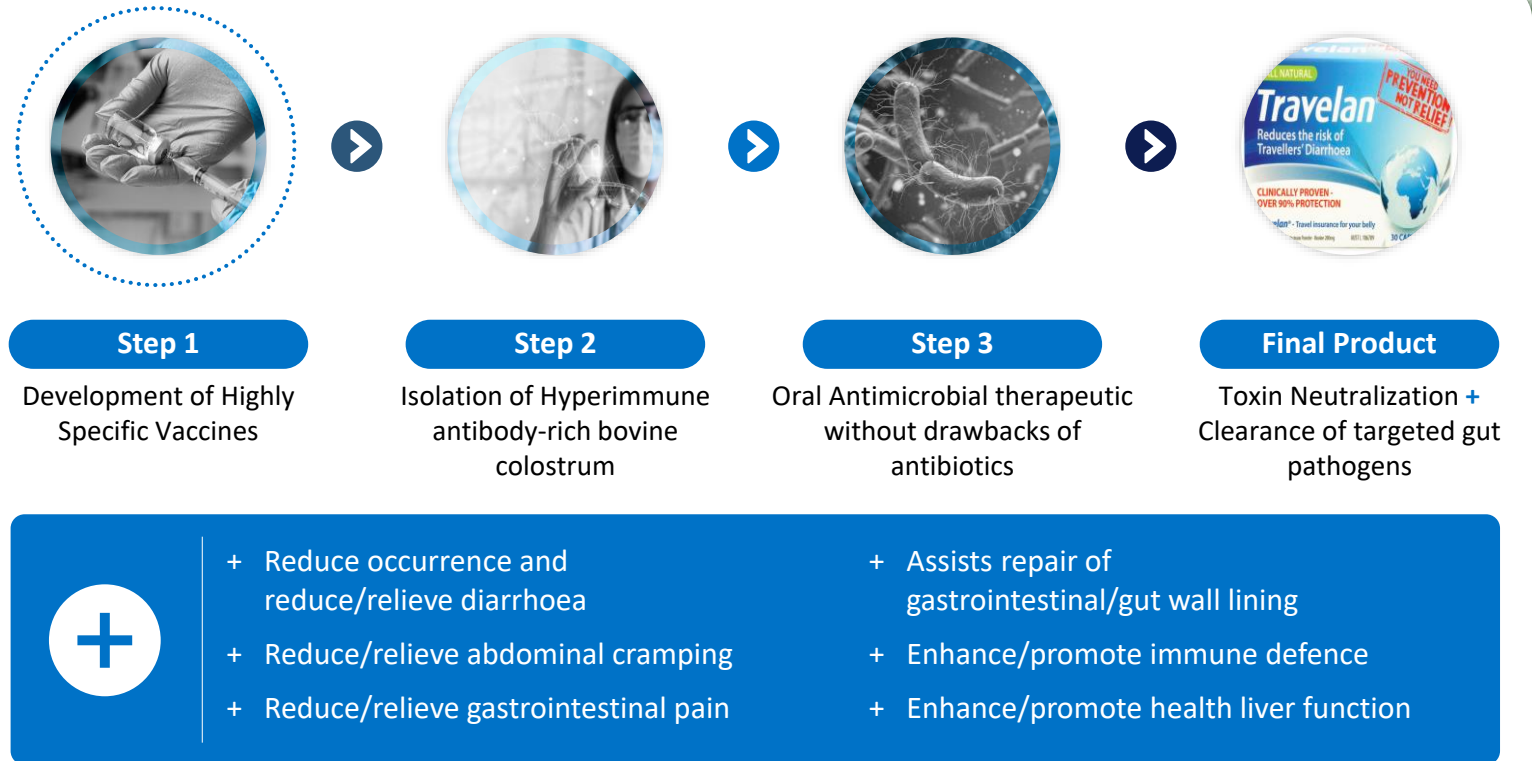
\$1.7b

Clostridioides difficile infections (CDIs) to grow to almost \$1.7 billion by 2026, according to GlobalData

Technology platform

Immuron's proprietary technology platform combines the natural human nutrition & health benefits of bovine colostrum with a novel class of specifically targeted oral polyclonal antibodies that offer delivery within the gastrointestinal ("GI") tract and can be used to target viruses or bacteria and neutralize the toxins they produce at mucosal surfaces.

Bovine colostrum is the first milk of cows after calving. It is rich in immunoglobulins, lactoferrin, lysozyme, lactoperoxidase, growth factors and bioactive peptides. Colostrum has higher levels of protein, fat, vitamins, and minerals when compared to milk. This enables full development of the newborn calf in addition to immunity against several pathogens.*



Australian Permitted indications; these statements have not been evaluated by the Food and Drug Administration (FDA)

Travelan® | Mechanism of action

Pre-Clinical Studies



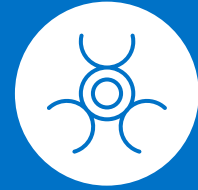
Broad spectrum antimicrobial



Protects against bacterial adhesion to host cell intestinal epithelia



Binds to surface layer proteins preventing bacterial colonization and motility



Toxin neutralization and clearance of targeted gut pathogens

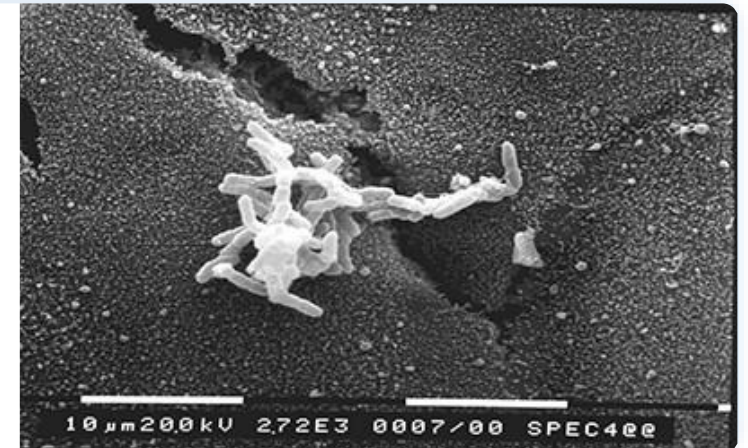
Without Travelan®

Bacteria attach to gut wall and infect



With Travelan®

Bacteria neutralized by Travelan® antibodies





IMM-124E (Travelan®) Phase 2 Study

Additional data analysis

Protective Efficacy

- Further analysis of the Phase 2 Study found that some subjects did not experience any diarrhoea until after antibiotics were administered
- Diarrhoea could be related to antibiotic administration
- Protective Efficacy was calculated for the 5-day period post challenge
- There were 4 subjects in the Travelan® group that did not experience any diarrhoea until antibiotics were administered
- **There was a 43.8% reduction in diarrhoea in the Travelan® group which is approaching statistical significance ($p=0.066$)**

SUBJECTS WITH DIARRHEA OF ANY SEVERITY



Intent-to-treat Analysis Set	Travelan® (N=30)	Placebo (N=30)
Number of subjects with ETEC-induced diarrhoea of any severity [1]	13 (43.3%)	16 (53.3%)
P-value		0.438
95% 2-sided Confidence Interval		(-15.2%, 35.2%)
PE for a 5-Day Period Post Challenge	Travelan® (N=30)	Placebo (N=30)
Number of subjects with ETEC-induced diarrhoea of any severity [2]	9 (30.0%)	16 (53.3%)
P-value		0.066
95% 2-sided Confidence Interval		(-0.9%, 47.6%)
Reduction in number of subjects with diarrhoea of any severity in Travelan® group In a 5-day period post challenge		43.8%

[1] Number of subjects with any grade 3-5 stools post challenge

[2] Includes time period subjects received daily dosing of Travelan/placebo, inclusive of subjects who received early antibiotics. After day 5 dosing of Travelan®/placebo stopped, and all subjects received antibiotics (Days 6-9)

Comments:

- Data not included in interim analysis
- 18 subjects met the primary endpoint a further 11 subjects had milder diarrhoea
- 4 subjects in the Travelan® group did not experience any diarrhoea until the Travelan® dosing was complete and antibiotics were administered

IMM-124E (Travelan®): Kaplan-Meier Plot



Conclusion:

In the clinical trial, the Kaplan-Meier plot shows that the Travelan® therapeutic treatment group has a higher survival probability over time compared to the placebo group, it suggests that the therapeutic treatment is effective in delaying the onset of diarrhoea.

Objective: To compare the time to diarrhoea onset between patients receiving a therapeutic treatment and those receiving a placebo.

Data Collection:

- Patients are monitored over a specified period.
- The time to the **onset of diarrhoea** is recorded for each patient.
- Patients are divided into two groups: those receiving the therapeutic treatment and those receiving the placebo.

Kaplan-Meier Estimation:

- **Survival Function:** Plots the probability of not having diarrhoea as a function of time for both groups.
- **Censoring:** Accounts for patients who do not develop diarrhoea during the study period or drop out of the study.

Plot Interpretation:

- **X-Axis:** Time to onset of diarrhoea (e.g., days).
- **Y-Axis:** Probability of remaining diarrhoea-free (survival probability).
- **Curves:** Two separate curves represent the therapeutic group and the placebo group.
- **Stepwise Decline:** Each step represents an event (onset of diarrhoea) or a censored observation.
- **Comparison:** The therapeutic curve is compared to the placebo curve to assess the effectiveness of the treatment.

Statistical Tests:

- **Log-Rank Test:** Commonly used to compare the survival distributions of the two groups.
- **Hazard Ratios:** Can be calculated to quantify the difference in risk between the groups.

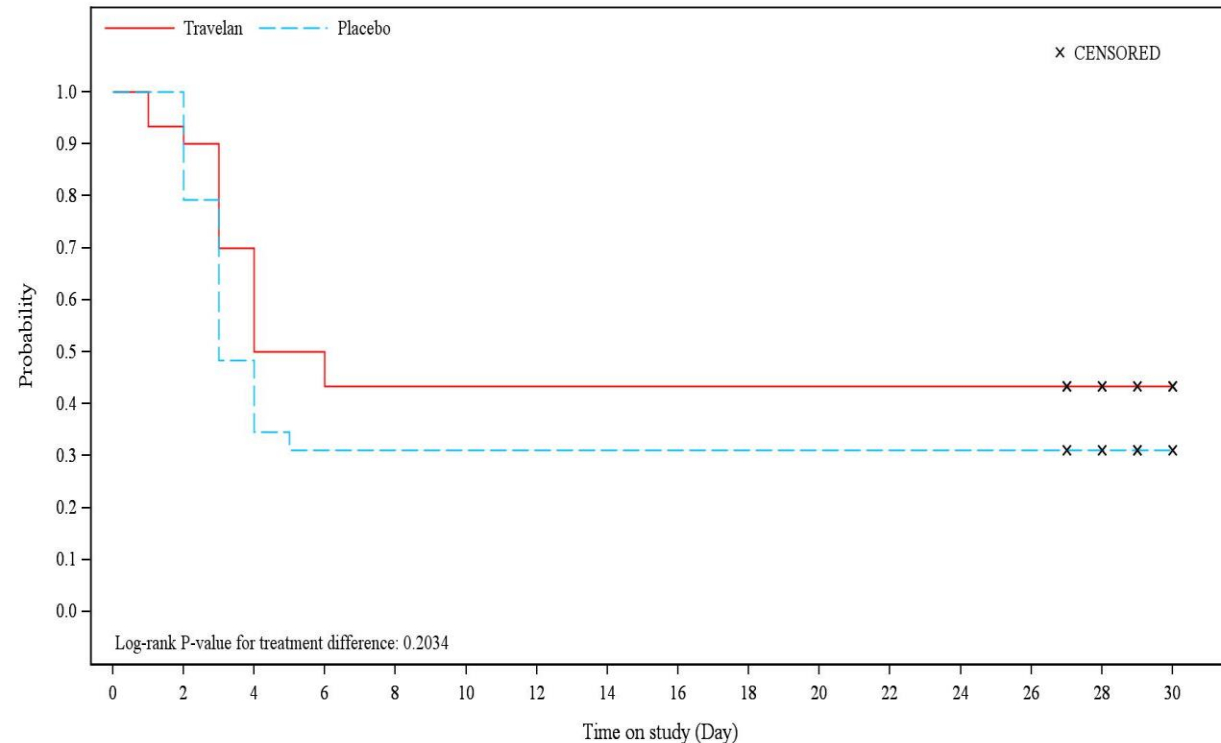
Interpretation of Results:

- **Therapeutic Effectiveness:** If the curve for the therapeutic group remains higher (indicating a higher probability of being diarrhoea-free for a longer time) compared to the placebo group, the therapeutic treatment can be considered effective.
- **Statistical Significance:** A significant p-value from the log-rank test suggests a statistically significant difference between the two groups.
- **Clinical Implications:** Helps in deciding whether the therapeutic treatment should be recommended over the placebo.



TIME TO DIARRHOEA ONSET

Time to Diarrhea onset



Antibiotic treatment after day 6

- The Kaplan-Meier estimator is useful for determining **the time of the onset of diarrhoea** between patients receiving Travelan® or placebo treatment
- **Y-Axis:** Probability of remaining diarrhoea-free
- **X-Axis:** Time to onset of diarrhoea
- The **Red Travelan®** curve remains higher than the **Blue Placebo** curve indicating the Therapeutic Effectiveness of treatment with Travelan®
- Travelan® patients have a higher probability of being diarrhoea free compared to Placebo
- Censoring = Patients who did not develop diarrhoea or who dropped out of the study
- Each step is a diarrhoea event (diarrhoea of any severity)
- 50% chance of diarrhoea up to day 6 in the Travelan® group
- 66.7% chance in the Placebo group



IMM-124E (Travelan®)

Phase 2 Study – additional data analysis

Adverse Events

- Includes all safety data set (63 subjects) and additional 3 subjects who were not challenged
- Considers all Adverse Events and number of events over the whole study period pre and post challenge
- **Number of events is reduced in the Travelan® treated group for all organ classes**

SUMMARY OF ADVERSE EVENTS



Subjects with at least 1 AE per System organ class <small>Includes all safety data set (63 subjects)</small>	Travelan (N=32)		Placebo (N=31)		Reduction in number of Events %
	Subjects n	Events (m)	Subjects n	Events (m)	
Total	24 (75%)	58	28 (90.3%)	109	46.8%
Gastrointestinal disorders (diarrhea, abdominal pain & distension nausea, vomiting, constipation)	23	43	28	66	34.9%
Nervous system disorders (headache, dizziness, hyper anaesthesia)	7	7	10	13	46.2%
Musculoskeletal and connective tissue (back pain, myalgia, arthralgia)	1	1	7	7	85.7%
General disorders (chills, pyrexia, muscle weakness)	3	3	2	4	25%
Nutrition disorders (decreased appetite)	1	1	4	4	75%
Skin and tissue (rash, itch, redness)	1	1	2	3	66.7%
Cardiac disorders (tachycardia)	0	0	3	3	100%
Infections (viral, upper respiratory)	1	1	2	2	50%



IMM-124E (Travelan®) Phase 2 Study – additional data analysis Summary of Enrolled Participants and Demographics



ALL ENROLLED SUBJECTS

	Travelan® (N=32)	Placebo (N=31)	Total (N=63)
Randomization	32	31	63
Included in			
Safety Analysis Set	32	31	63
Intent-to-Treat Analysis Set	30	30	60
Completed Study	27	27	54
Discontinued Study	5	4	9
Subject Withdrew Consent	3	3	6
Investigator Discretion	2	0	2
Lost to Follow Up	0	1	1

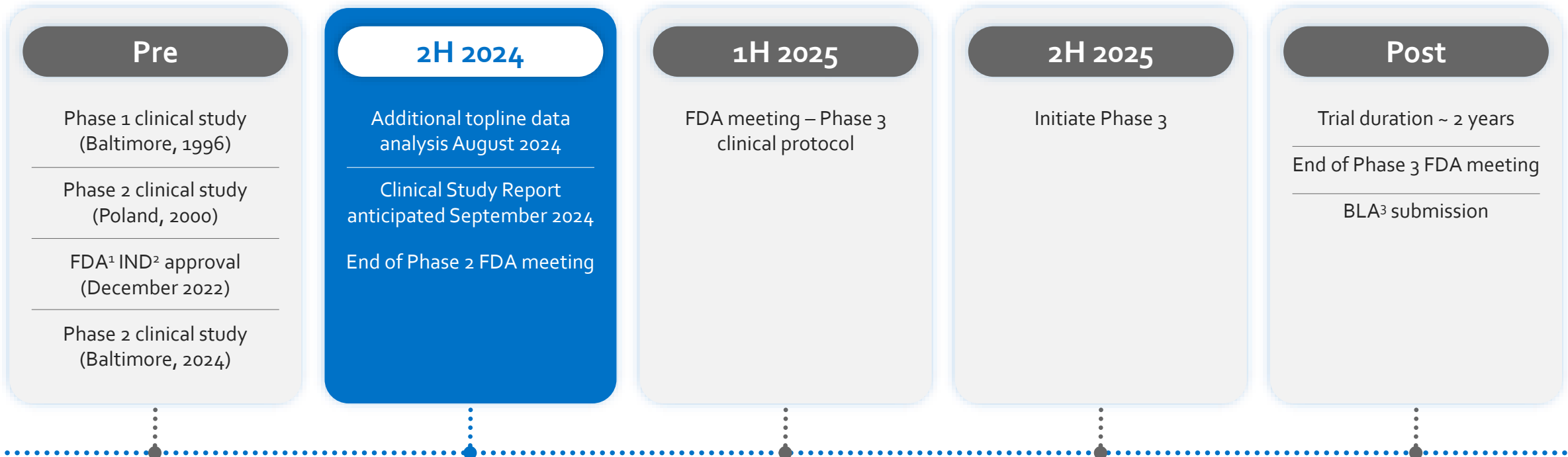
Note: Intent-to-treat analysis set defined as randomized subjects who received study medication and were challenged.

DEMOGRAPHICS



	Travelan® (N=32)	Placebo (N=31)	Total (N=63)
Mean Age at Consent	33.1	35.1	34.1
Sex at Birth			
Male	18	16	34
Female	14	15	29
Ethnicity			
Hispanic/Latino	5	10	15
Not Hispanic/Latino	27	21	48
Race			
White	8 (25%)	5 (16.1%)	13 (20.6%)
Black or African American	23 (71.9%)	22 (71%)	45 (71.4%)
Asian	1 (3.1%)	0	1 (1.6%)
Mixed/Other	0	4 (12.9%)	4 (6.3%)

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.



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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