



## Immuron CEO, Steven Lydeamore to present at Sharewise

Melbourne, Australia, July 9, 2024: Immuron Limited (ASX: IMC; NASDAQ: IMRN), an Australian based and globally integrated biopharmaceutical company is pleased to advise our Chief Executive Officer, Steven Lydeamore will be presenting at Sharewise on Tuesday 9 July 2024, 11:00am AEST.

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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### COMPANY CONTACT:

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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 tableted 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**

Connor P, Porter CK, Swierczewski B and Riddle MS. Diarrhea during military deployment: current concepts and future directions. *Curr Opin Infect Dis.* 25(5): 546-54; 2012.

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

# Sharewise Webinar

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**Steven Lydeamore**  
Chief Executive Officer

9 JULY 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 recruited ~75% of target 866

Travelan® (IMM-124E) Phase 2 CHIM trial topline results CampETEC Phase 2 clinical trial completed inpatient phase

Travelan® (IMM-124E) Travelan® Uniformed Services University (USU) P2TD IMM-124E field clinical trial IMM-529 pre-IND filed with FDA

## Results & Outlook



Sales 1 Jul 23 to 31 Mar 24 of A\$3.6 million up 154% 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	15,194,959
Last Traded Price	IMC: A\$0.088
52 week High/Low	IMC: A\$0.17/0.065 IMRN: \$5.96/1.48
Market Cap	IMC: A\$20.06m
Cash & Cash Equivalents (as at 31 Dec 23)	A\$15.2m

## Major Shareholders

Holder	Units	% of CSO
BNY Mellon Asset Management	79,141,044	34.7 %
Authentic Australia Pty. Ltd.	5,500,000	2.4 %
Grandlodge	3,846,712	1.7 %
Management & Board	1,954,070	0.9 %

as of 5 July 2024

# 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.\*



## Step 1

Development of Highly Specific Vaccines



## Step 2

Isolation of Hyperimmune antibody-rich bovine colostrum



## Step 3

Oral Antimicrobial therapeutic without drawbacks of antibiotics



## Final Product

Toxin Neutralization + Clearance of targeted gut pathogens



- + Reduce occurrence and reduce/relieve diarrhoea
- + Reduce/relieve abdominal cramping
- + Reduce/relieve gastrointestinal pain

- + Assists repair of gastrointestinal/gut wall lining
- + Enhance/promote immune defence
- + Enhance/promote health liver function

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

# Travelan® | Mechanism of action

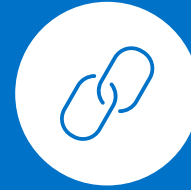
## Pre-Clinical Studies



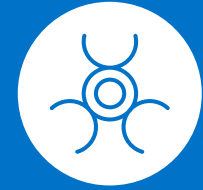
Broad spectrum antimicrobial



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

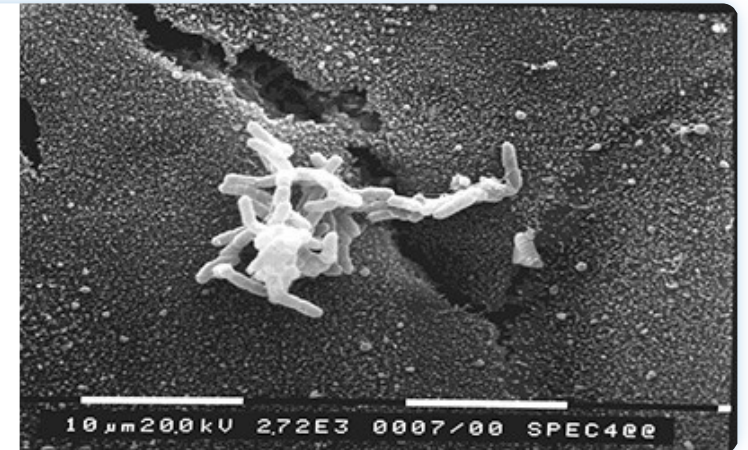
### Without Travelan®

Bacteria attach to gut wall and infect



### With Travelan®

Bacteria neutralized by Travelan® antibodies





# 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  
 Additional topline data – end July 2024  
 Clinical Study Report – August 2024

## Clostridioides difficile

**IMM-529**  
 Prevention of recurrent CDI infections Vaccine (spores, vegetative cells, and Toxin B)  
 600mg solid dose active formulation developed

Clinical protocol and trial preparation in progress  
 pre-IND submission to FDA – 1 July 2024

## Immuron's Clinical Programs

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

## 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 ~75% of participants have been recruited (866 target)  
 Anticipated topline results – 1Q 2025

### CampETEC

#### NMRC Campylobacter and enterotoxigenic E. coli product

Manufactured by Immuron  
 Immuron sponsored GLP Toxicology study completed – Dec 2022  
 Phase 2 CHIM completion of inpatient phase – December 2023  
 6 month follow up completed – June 2024  
 Anticipated topline results – August 2024

## Our Partners' Clinical Programs

Compound or brand name	Partner	Phase I	Phase II	Phase III	Market
Travelan®		Uniformed Services University →			
CampETEC		Naval Medical Research Command →			

# Addressable market & industry overview



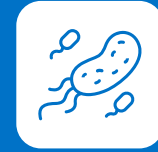
## Billion Dollar Market

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

# Travelan<sup>®</sup> sales continue strong growth



## Global

- + FYTD Mar 2024 AUD\$3.6 million up 154% on (prior comparative period) pcp
- + Mar 2024 Quarter AUD\$1.3 million up 51% on pcp and 75% on last quarter



## Australia

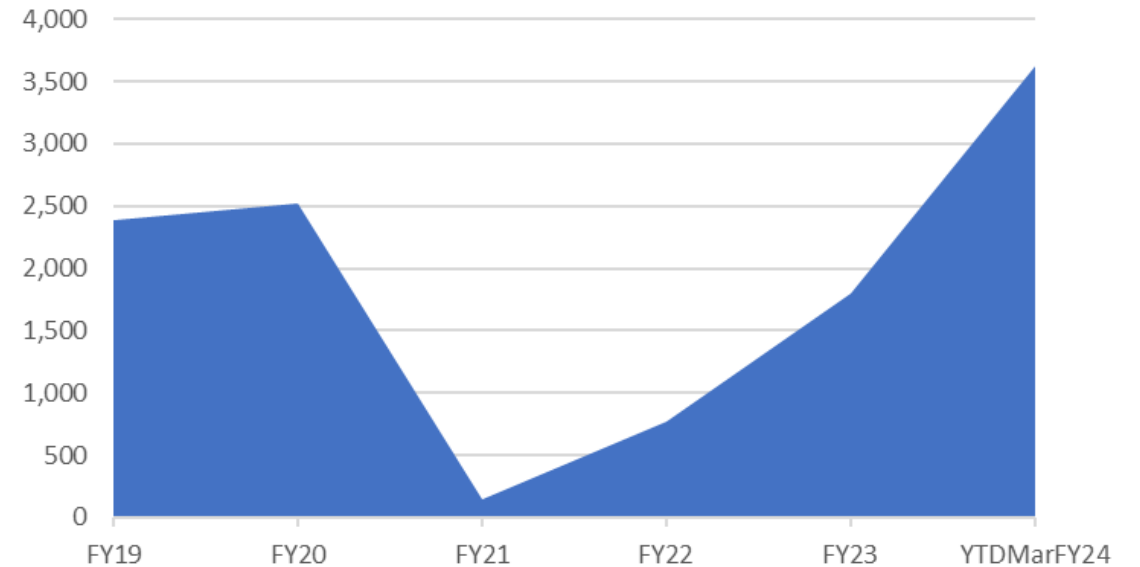
- + FYTD Mar 2024 AUD\$2.8 million up 234% on pcp
- + Mar 2024 Quarter AUD\$0.9 million up 66% on pcp and 99% on last quarter



## USA

- + FYTD Mar 2024 AUD\$0.8 million up 35% on pcp
- + Mar 2024 Quarter AUD\$0.3 million up 7% on pcp and 18% on last quarter
- + Sales commenced on Walmart.com

Net Sales A\$'000



# 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.

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

**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 expected 70%

The attack rates on previous Phase 2 ([Otto et al. 2011](#)) studies were 73% and 86% with protective efficacy of 90.9% and 76.7%

**66.7%** protective efficacy against ETEC induced severe diarrhea was observed in the Travelan® group compared to the placebo group (secondary endpoint)

**83.3%** statistically significant reduction in the number of subjects in the Travelan® group requiring early antibiotic treatment post challenge compared to the placebo (secondary endpoint)

**100%** of the subjects requiring IV fluids post challenge were in the placebo (secondary endpoint)

**55.6%** reduction in the number of subjects experiencing adverse events associated with the ETEC challenge observed in the Travelan® group compared to the placebo group (secondary endpoint)

Phase 2 clinical study data supports the excellent safety and tolerability profile of Travelan®

# WORLD FIRST TRIPLE MECHANISM OF ACTION FOR CDI



## IMM-529: pre-IND filed with FDA July 2024

Indication / Target Population	IMM-529 will be indicated for the treatment of recurrent <i>C. difficile</i> infection
Product Description / Mechanism of Action	<ul style="list-style-type: none"><li>• Novel antibody-containing therapeutic which neutralizes <i>C. difficile</i> but does not impact the microbiome</li><li>• Targets not only toxin B but also spores and vegetative cells responsible for recurrence</li><li>• Potential for use in combination with standard of care (e.g. vancomycin, metronidazole, fidaxomicin)</li><li>• Targets many isolates</li></ul>
Dosage and ROA	<ul style="list-style-type: none"><li>• Oral administration, 3 x daily</li><li>• Trial to test safety 7-day treatment course on top of standard of care (vancomycin, metronidazole, fidaxomicin)</li></ul>
Efficacy	<ol style="list-style-type: none"><li>1. Prevention of primary disease (80% P =0.0052)</li><li>2. Protection of disease recurrence (67%, P &lt;0.01) and</li><li>3. Treatment of primary disease (78.6%, P&lt;0.0001; TcB HBC).</li></ol>
Safety / Tolerability	<ul style="list-style-type: none"><li>• To be evaluated in Phase I/IIA study</li><li>• Equivalent or better than current standard of care</li></ul>



# 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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