



FORGING COMMERCIAL & CLINICAL PATHWAYS

TARGETING INFECTIOUS DISEASES WITH ORAL
IMMUNOTHERAPIES – SEPTEMBER, 2020

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CEO

NASDAQ: IMRN
ASX: IMC



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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.



COMPANY HIGHLIGHTS

We are a commercial and clinical-stage biopharmaceutical company focusing on infectious diseases with oral immunoglobulin-based therapies

- Validated Technology Platform – with One Registered Asset, **Travelan® Generating Revenue**
- IMM-124E & IMM-529, in **Clinical Development** for Treatment of Gastrointestinal Disorders and *C. difficile* Infections
- US DoD Research Collaboration – New Therapeutic in Clinical Development **for Treatment of moderate to severe Campylobacteriosis and Infectious diarrhea** caused by **ETEC** pathogens

DEVELOPMENT PIPELINE: FOUR-PRONGED PLAN



	DEVELOPMENT STAGE					HIGHLIGHTS
	PRE-CLINICAL	PHASE 1	PHASE 2	PHASE 3	MARKET	
ANTI-INFLAMMATORY PROGRAMS						
Travelan®	<div style="display: flex; justify-content: space-between;"> <div style="width: 60%;"> <p style="text-align: center;">TGA ARTG Aust L106709 (2004)</p> <p style="text-align: center;">Health Canada NPN 80046016 (2015)</p> <p style="text-align: center;">Dietary supplement (2015)</p> </div> <div style="width: 35%; text-align: right;"> <p>Commercial product - Australia</p> <p>Commercial product - Canada</p> <p>Commercial product - USA</p> </div> </div>					
1	IMM-124E (Travelan®)				<ul style="list-style-type: none"> Plan to develop as drug to prevent Travelers' Diarrhea in USA. US DoD field study to evaluate the efficacy of OTC products (Travelan) for Travelers' Diarrhea prevention (USU IDCRP, UK Ministry of Defense & NYC Travel Clinic). Evaluation to identify substance in IMM-124E that inhibits SARS-CoV-2, the virus that causes COVID-19. 	
2	IMM-529				<ul style="list-style-type: none"> To prevent recurrence in C. Difficile patients. 	
3	Naval Research Medical Centre				<ul style="list-style-type: none"> New drug development to prevent Campylobacteriosis and infectious diarrhea caused by ETEC. 	
4	Walter Reid Army Institute of Research				<ul style="list-style-type: none"> Testing on three new products for potential use as a Shigella specific therapeutic. 	

PLATFORM OVERVIEW: ORAL IMMUNOGLOBULINS



Development
of Highly
Specific
Vaccines



Isolation of
hyperimmune
antibody-rich
bovine
colostrum



Oral
Antimicrobial
therapeutics
without
drawbacks of
antibiotics



Toxin
Neutralization
+
Clearance of
targeted gut
pathogens

MECHANISM OF ACTION - TARGETING ENTERIC PATHOGENS



Pre-Clinical Studies

- Delivers high levels of orally active antibodies to specific enteric pathogenic bacteria which colonize the gastrointestinal tract and cause infection and disease.
- Biological therapeutics which directly target the major pathogenic virulent components;
 - Molecules which facilitate bacterial adhesion to host cell intestinal epithelium
 - Surface layer proteins which contribute to bacterial colonization and motility
 - Endotoxins and enterotoxins that cause disease

Without Travelan®: Bacteria attach to gut wall and infect



With Travelan®: Bacteria neutralized by Travelan® antibodies



US DOD R&D COLLABORATION AGREEMENTS



Research Collaborations:

- 1) Characterisation of Travelan®**
- 2) Shigella-Specific Target – US Army**
- 3) Campylobacter-specific Target – US Navy**

- Armed Forces Research Institute of Medical Sciences (AFRIMS) – June 2016
- Naval Medical Research Center (NMRC) – August 2016
- Walter Reed Army Institute of Research (WRAIR) – June 2016
- Travelan® binds 180 pathogenic strains of bacteria from infected personnel deployed in Bhutan, Cambodia, Nepal and Thailand (ETEC, Shigella, Campylobacter).
- Travelan® binds to 71 pathogenic strains of Vibrio cholera from infected personnel in Bangladesh, Cambodia, and Thailand.





New U.S. Department of Defense Research Collaboration with Immuron to Develop and Clinically evaluate a New Therapeutic against Campylobacter

Key Highlights:

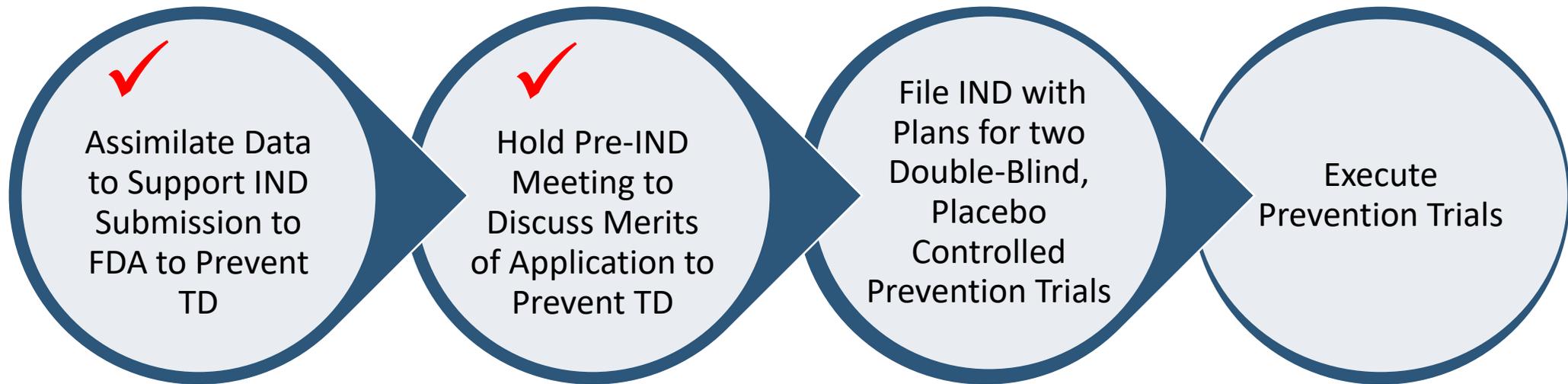
- **AU \$5.5 (USD \$3.7) million funding approved by the U.S. Department of Defense to develop and clinically evaluate a new oral therapeutic targeting Campylobacter and ETEC**
- **Naval Medical Research Center will fund the manufacture and therapeutic evaluation of the new therapeutic to protect against acute infectious diarrhea**
- **Two human clinical trials to be conducted with new therapeutic under terms of grant**

Melbourne, Australia, October 02, 2019: Immuron Limited (ASX: IMC; NASDAQ: IMRN), an Australian biopharmaceutical company focused on developing and commercializing oral immunotherapeutics for the prevention and treatment of gut mediated pathogens, is pleased to announce the funding of a new research agreement with the Naval Medical Research Center (NMRC), Silver Spring, MD, USA.



NMRC DRUG DEVELOPMENT PLAN

Two Human Clinical Trials Planned: New Drug to Prevent Moderate To Severe
Camylobacteriosis and Infectious Diarrhea Caused by ETEC





WHAT IS TRAVELERS' DIARRHEA?

- Caused by consuming food or water infected with pathogens. Three or more unformed stools in 24 hours.
- Bacterial pathogens are the predominant risk¹.
- Enterotoxigenic *E. coli* (ETEC) are the predominant pathogens^{2,3}:
 - 42% in Latin America
 - 28% in Southeast Asia
- Up to 70% of travelers suffer from travelers' diarrhea⁴.



1 – Steffen, R. 2017 Epidemiology of travelers' diarrhea. Journal of Travel Medicine 24(1)

2 – Leder, K. 2015 Advising Travellers about Management of Travelers' Diarrhea. Australian Family Physician, vol 44 No. 1-2 Jan. Feb 2015

3 – Castelli et. al., Epidemiology of Travelers' Diarrhea, J. Travel Medicine 2001; 8 (Suppl2) S26-S30

4 – CDC Yellow Book 2018, Chapter 2 Travelers' Diarrhea.

ANTIBIOTIC RESISTANCE: OPPORTUNITY FOR TRAVELAN®



International Society of Travel Medicine
Promoting healthy travel worldwide
Established 1991

International Society of Travel Medicine, 2017 guidelines for treating Travelers' Diarrhea included¹:

- Antibiotics should **NOT** be used routinely, except patients at high risk of complications
- Rifaximin recommended when antibiotic prophylaxis is indicated
- Fluoroquinolones not recommended for prophylaxis²
- Insufficient evidence to recommend prebiotics or probiotics

The opportunity: Travelan®, the alternative to antibiotic treatment of TD

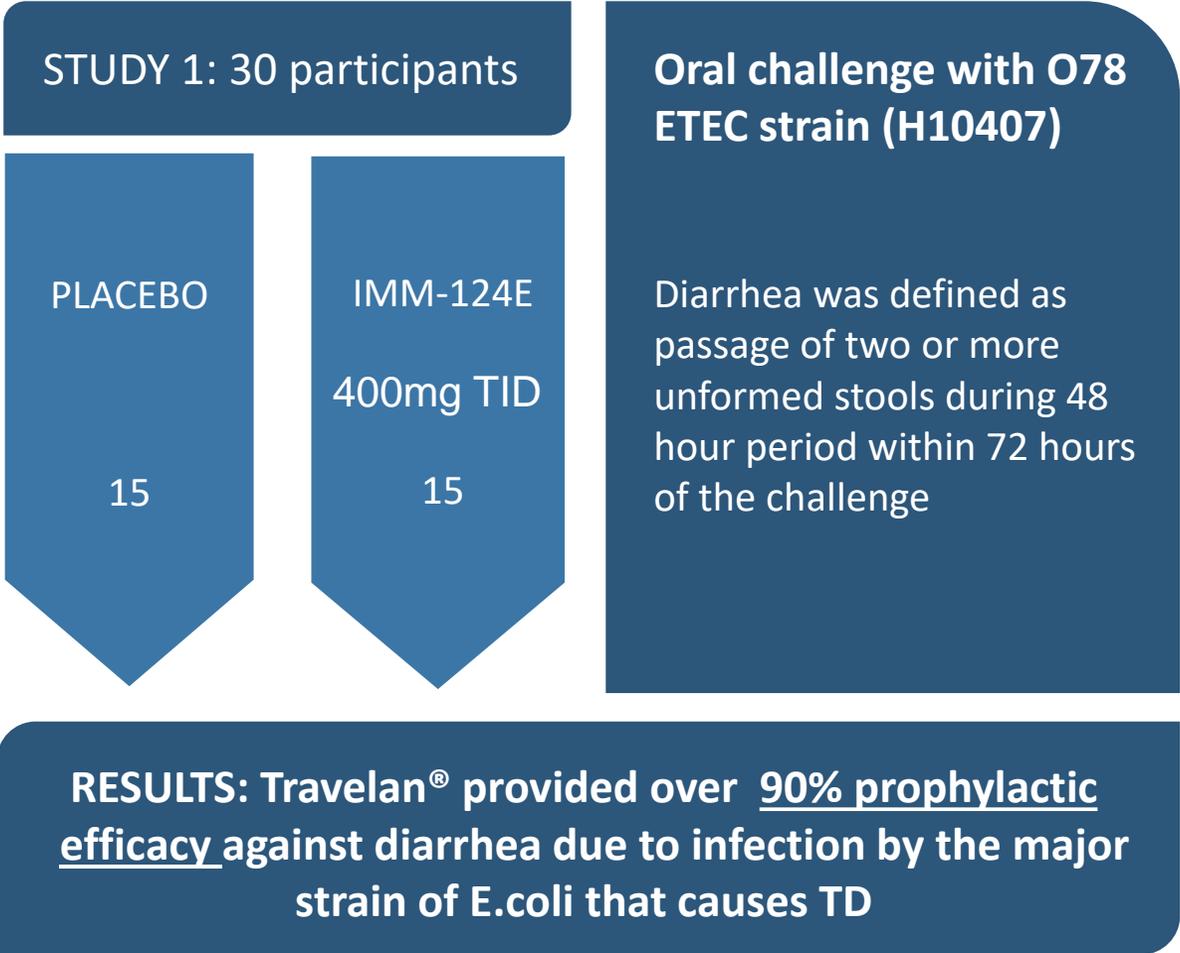
1 Riddle et al. 2017. Guidelines for the prevention and treatment of travellers' diarrhea: a graded expert panel report. Journal of Travel Medicine 24(1).

2 Tribble, D. 2017 Resistant pathogens as causes of traveller's diarrhea globally and impact(s) on treatment failure and recommendations. Journal of Travel Medicine 24(1)

TRAVELAN® AS A DRUG TO PREVENT TRAVELERS' DIARRRHEA



- Travelan® evaluated in two randomised, double-blind, placebo-Controlled Human Infection Model challenge clinical trials
- 90 healthy volunteers in Study 1 & 2
- Published in Scandinavian Journal of Gastroenterology





SUMMARY OF RESULTS FROM STUDY 1

	Treatment Group		<i>p</i>
	Placebo	Colostrum	
Number of volunteers	15	15	
Number of volunteers with diarrhea	11 (73%)	1 (7%)	0.0005
Number of diarrheal stools/volunteer (mean + SEM)	4.4 ± 0.9	0.4 ± 0.4	0.0004
Mean number of diarrheal stools per volunteer with diarrhea (mean and range)	6 (2 – 8)	6 (6)	NS
Abdominal pain	5 (33%)	0 (0%)	0.04
ETEC H10407 isolated from feces after challenge	15 (100%)	12 (80%)	NS

*Fisher's exact test or Student's t-test (two-tailed) as appropriate.

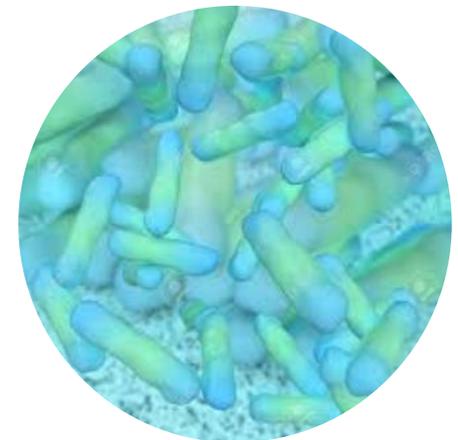
NS, not significant

TRAVELAN®: ORAL CHALLENGE STUDY PREVENTION OF SHIGELLOSIS (BACILLARY DYSENTERY) IN PRIMATES*



- 12 juvenile rhesus monkeys randomly assigned to Travelan® (n=8) or placebo (high protein milk powder) (n=4) treatment groups
- Travelan® or placebo (500mg) was administered 2x daily for 6-days, starting on day 0
- Each monkey challenged with 2.8×10^9 *Shigella flexneri* 2a intragastrically on day 3
- Travelan® /placebo treatment stopped on day-6. Monkeys monitored through to day 14
- Faecal samples taken 2 x daily and cultured to establish presence/absence of *Shigella flexneri*
- Animals continually monitored for clinical signs

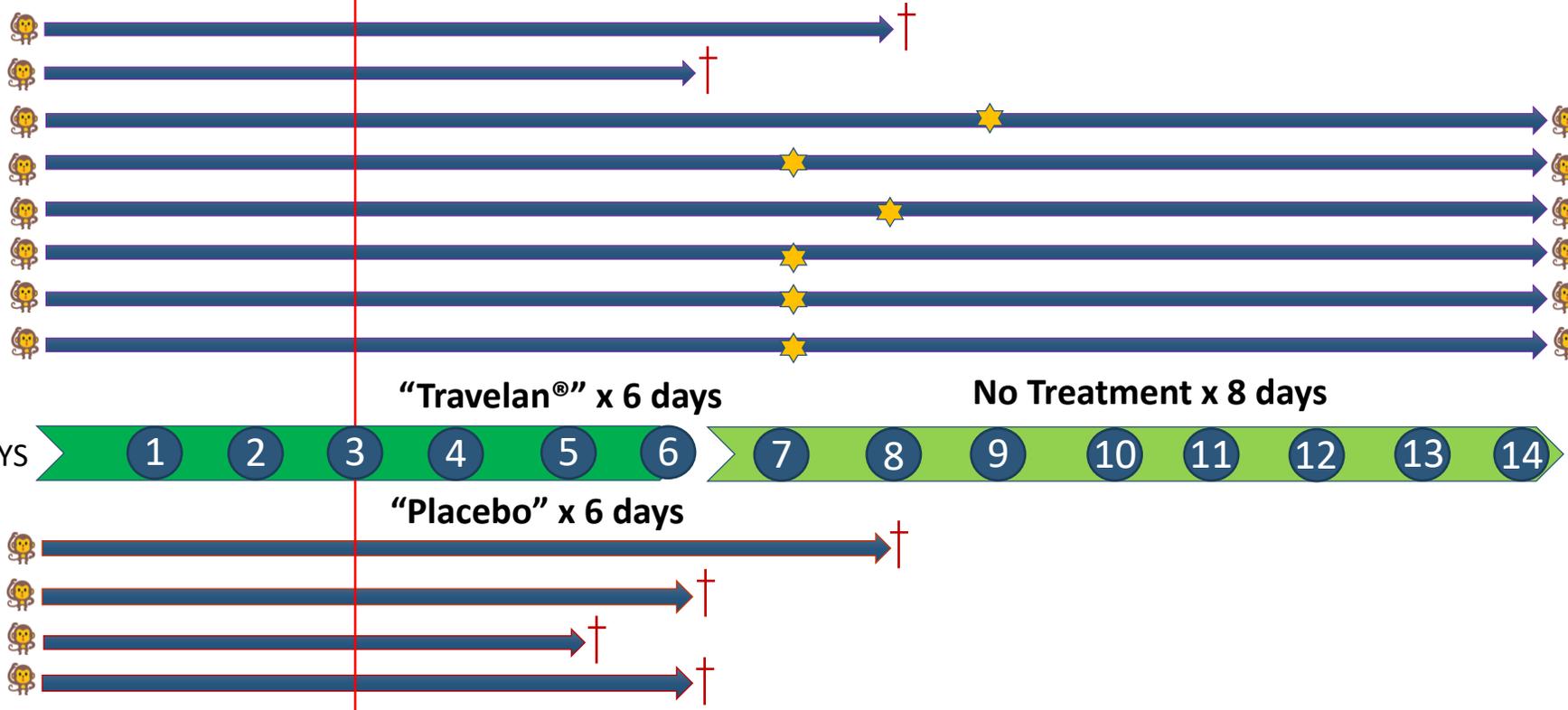
***Collaborative animal model study with AFRIMS & WRAIR**



RESULTS OF TRAVELAN® SHIGELLA CHALLENGE STUDY*



3 x 10⁹
S. flexneri



Travelan® group

S. flexneri was undetectable in consecutive fecal samples by day 7 in 4 of 6 (67%) survivors and by day 9 in the remaining 2 (33%) survivors

Placebo control group

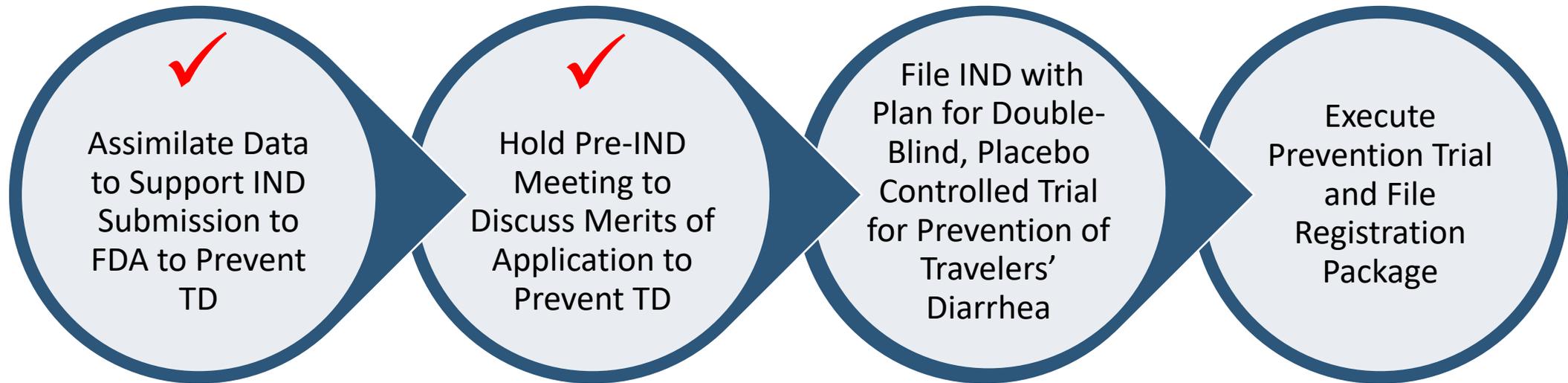
★ = last day of *S. flexneri* consecutive +ve stool culture

*Collaboration with AFRIMS & WRAIR



IMM-124E DRUG DEVELOPMENT PLAN

Revamp Travelan® for FDA approval as drug to prevent Travelers' Diarrhea (TD) in travelers to endemic areas:



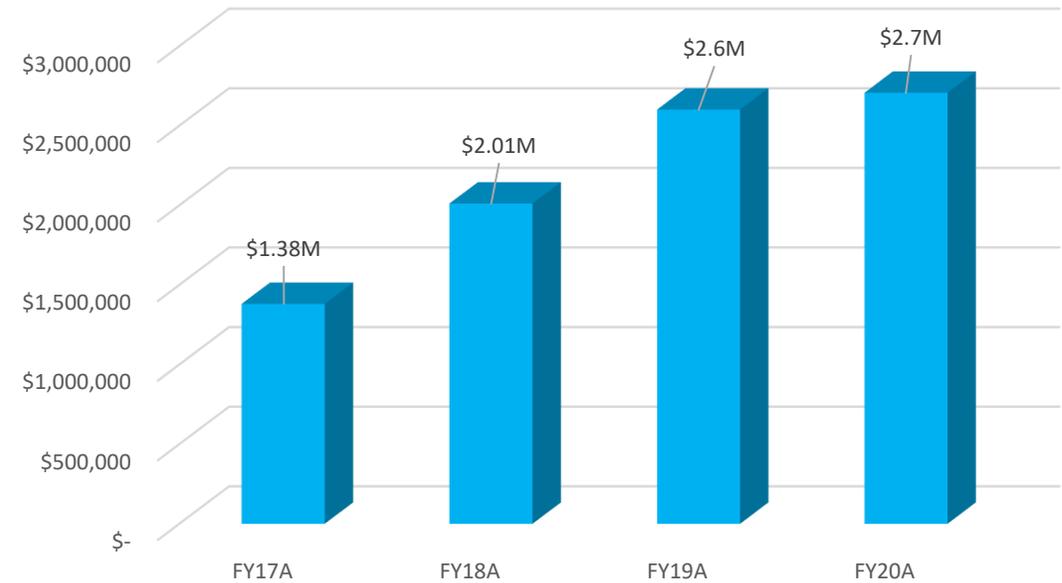
TRAVELAN® COMMERCIAL PROFILE: INCREASING SALES ADDRESSING LARGE MARKETS



**2019 Global market - US \$630M
Expected to reach US \$890M by
2024 at 7% CAGR ¹**

1. <https://www.marketwatch.com/press-release/at-71-cagr-travelers-diarrhea-therapeutics-market-size-to-reach-usd-890-million-by-2024-2019-05-08>

Global Immuron Sales - AUD



AUD



Immuron Global Sales Up 60%

Key Highlights:

- Immuron achieved 60% YoY growth in worldwide product sales in Q3 FY20.
- YTD March 31, FY20 worldwide sales reached AU \$2.67M, increasing 57% YoY.
- In Australia, Q3 FY20 gross sales grew by 35% YoY to \$475K.
- In the USA, Q3 FY20 gross sales increased by 50% YoY to AU \$412K.
- In Canada, Q3 FY20 sales reached \$96K.

Melbourne, Australia, April 20, 2020: Immuron Limited (ASX: IMC; NASDAQ: IMRN), an Australian biopharmaceutical company focused on developing and commercializing oral immunotherapeutics for the treatment of gut mediated diseases, today announced the sales results of its commercially available and over-the-counter gastrointestinal and digestive health immune supplement Travelan® for the third quarter of the fiscal year 2020 ending on March 31, 2020.

MARKET OVERVIEW

FY20 MARKET OVERVIEW

- **Target Market:** business and leisure travellers in the USA, Canada and Australia, travelling to high-risk locations for Travellers' Diarrhoea.

USA

- Presence in 215 Passport Health Clinics across the USA.
- Direct sales via Amazon platform.

AUSTRALIA

- Available in 2,275 retail pharmacies across Australia.

CANADA

- Relunched to market in May 2019.
- Available in 2,5000 retail pharmacies in Canada.

FY20 Marketing Program

- USA consumer PR campaign targeting travel media.
- Global influencer/travel blogger campaigns.
- Canadian social media advertising.
- Retail pharmacy advertising and promotions in Australia and Canada.

How to Maintain Tummy Health on Your Next Trip



HOW TO MAINTAIN



Hi I'm Kiki, a California native, who left my career in corporate finance to become a world traveler. Since then, I've traveled to over 70 countries and have knocked some big adventures off my bucket list.

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FIRST NAME

EMAIL ADDRESS

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mariaconcha • Follow
Desgab: Ireland

AND traveling treasur's illness caused by contaminated food and water. It's my secret weapon and has saved me in places like Morocco and Thailand especially. I refuse to travel without it.

Click the link in my bio to learn more about [@TeamTravelan](#) and I often freely give it to my friends to see what you want abroad and not get sick. Use code: 10MCAACCR014 for 10% off Travelan 70536 when purchasing on Amazon US only!

P.S. Yes this post is sponsored, but I've been using and promoting Travelan on my blog long before this partnership. I only promote things I really love and I stand by this product.

Liked by explorewithrain and 1,359 others

HOV2020

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Post

US SALES FORECAST FOR TRAVELAN®: IF APPROVED AS DRUG TO PREVENT TD



MARKET POTENTIAL FOR TRAVELAN® SALES:

USD >\$100 MILLION

Market potential figure derived from:

2014 figures of US citizens traveling to high risk destinations for TD (44.3 million)¹ and obtaining pretravel advice (22.2 million)². Sources of pre-travel advice include primary care provider, travel medicine specialist, company doctors, pharmacist, and travel agencies². Our forecast utilizes a very conservative estimate for % of US citizens purchasing Travelan® after seeking pre-travel advice.



1. U.S. Department of Commerce, International Trade Administration, National Travel and Tourism Office. U.S. Citizen Traffic to Overseas Regions, Canada & Mexico 2014. Monthly Statistics, U.S.Outbound Travel by World Regions. 2014. Available at: <http://travel.trade.gov/view/m-2014-O-001/index.html>. Accessed June 26, 2015.
2. Mathyas Wang , MD , Thomas D. Szucs , MD, MBA, MPH, LLM , and Robert Steffen , MD. Economic Aspects of Travelers ' Diarrhea. Journal of Travel Medicine, Volume 15, Issue 2, 2008, 110–118

COMPETITOR MARKET ANALYSIS – ANTI-DIARRHEAL DRUGS



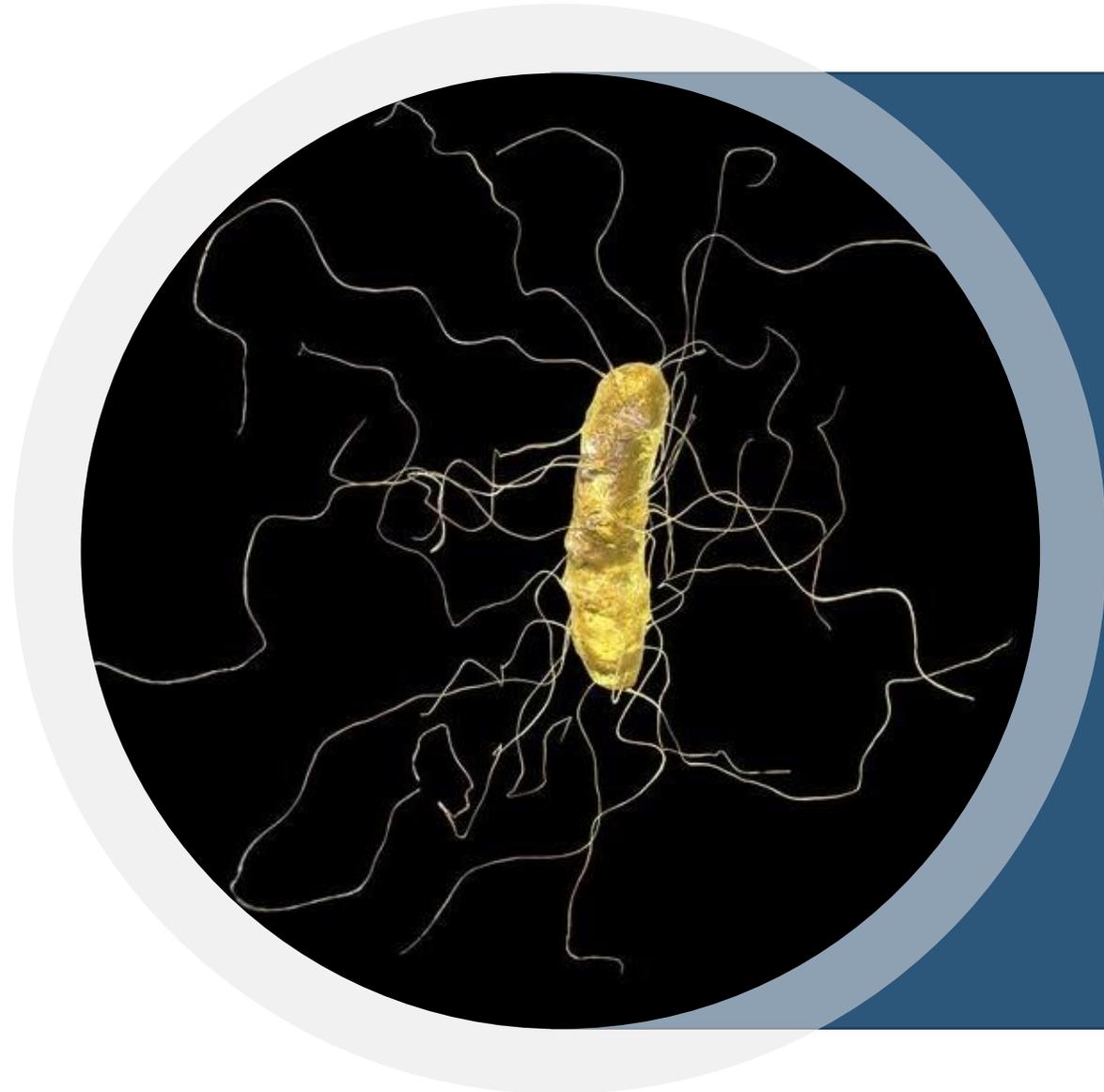
Drug	Indication	Dosing	Ave cost – 2 week trip	Revenue USD Millions (Year)
FDA APPROVED DRUG TREATMENTS FOR DIARRHEA				
PEPTO BISMOL (BSS) 	Relief for heartburn, nausea, indigestion, upset stomach and diarrhea.	2 tabs QID	\$20.97 ¹	82.6 (2013) ²
IMMODIUM 	Decrease the frequency of diarrhea in TD, gastroenteritis, inflammatory bowel disease, and short bowel syndrome.	2 tabs (2 mg)	\$17.33 ¹ (48 caplets)	82.5 (2013) ²
CIPROFLOXACIN (FLUOROQUINOLINE) 	Bacterial infections.	500 mg	\$44.52 ³	40.8 (2015) ³
RIFAXIMIN 	Treatment of Travellers' Diarrhea.	3 caps (200 mg) TID	\$657 ⁴	
PRESENTLY, THERE IS NO FDA APPROVED DRUG TO PREVENT TRAVELERS' DIARRHEA				
TRAVELAN®	Dietary Supplement.	3 caps (200 mg) TID	\$30 – 30 caplets	0.77 (2018) ⁵

1. Amazon.com
2. Top 10 OTC brands for digestives by revenue in the USA in 2013
3. Almalki et. al., Utilization, spending & price trends for quinolones in the US, Pharmacocon Open 2017 Jun: 1(2): 123-131
4. Drugs.com Xifaxan (rifaximin) price guide. Cost of Xifaxan oral tablet 200 mg ~\$657 for 30 tablets
5. US Sales for Travelan – FY2018



**NEUTRALIZING
CLOSTRIDIUM DIFFICILE,
WHILE SPARING THE
MICROBIOME**

IMM-529





CLOSTRIDIUM DIFFICILE MARKET OPPORTUNITY

Clostridium difficile (*C. difficile*) is a bacterium that causes diarrhea and more serious intestinal conditions such as colitis

- Therapeutic market expected to grow from USD \$630 million in 2016 to over \$1.7 billion by 2026 – CAGR 15%¹
- Leading cause of gastroenteritis-associated mortality in U.S.²
- Approx. 44,500 patients³ died in 2014 from *C. difficile* infections (U.S.)
- Potential orphan disease (7 years market exclusivity and premium pricing)

1. <https://www.globaldata.com/global-clostridium-difficile-infection-market-approach-2016-2026>
2. Jagai, et.al., BMC Gastroenterology, 2014:14:211 Trends in gastroenteritis-associated mortality in the USA.
3. K. Desai, BMC Infect. Dis., 2016,16:303



THE UNMET NEED

- Current standard of care for *C. difficile* includes vancomycin, metronidazole & fidaxomicin
- Therapies plagued by significant CDI recurrences (*1st relapse: 25%; 2nd: 40%; 3rd: 60%) underscoring need for new treatments
- Growing resistance to vancomycin treatment
- Some treatments are administered intravenously rather than via the gut where *C. difficile* resides



*Isobel Ramsay, Nicholas Brown and David Enoch. Recent Progress for the Effective Prevention and Treatment of Recurrent Clostridium difficile Infection. Infectious Diseases: Research and Treatment Volume 11: 1–4 (2018). DOI: 10.1177/1178633718758023

IMM-529 OPPORTUNITY



- IMM-529 highly differentiated – neutralizes *C. difficile* but does not impact microbiome
- Targets not only toxin B but also spores and vegetative cells responsible for recurrence
- Potential use in combination with standard of care
- Targets many isolates

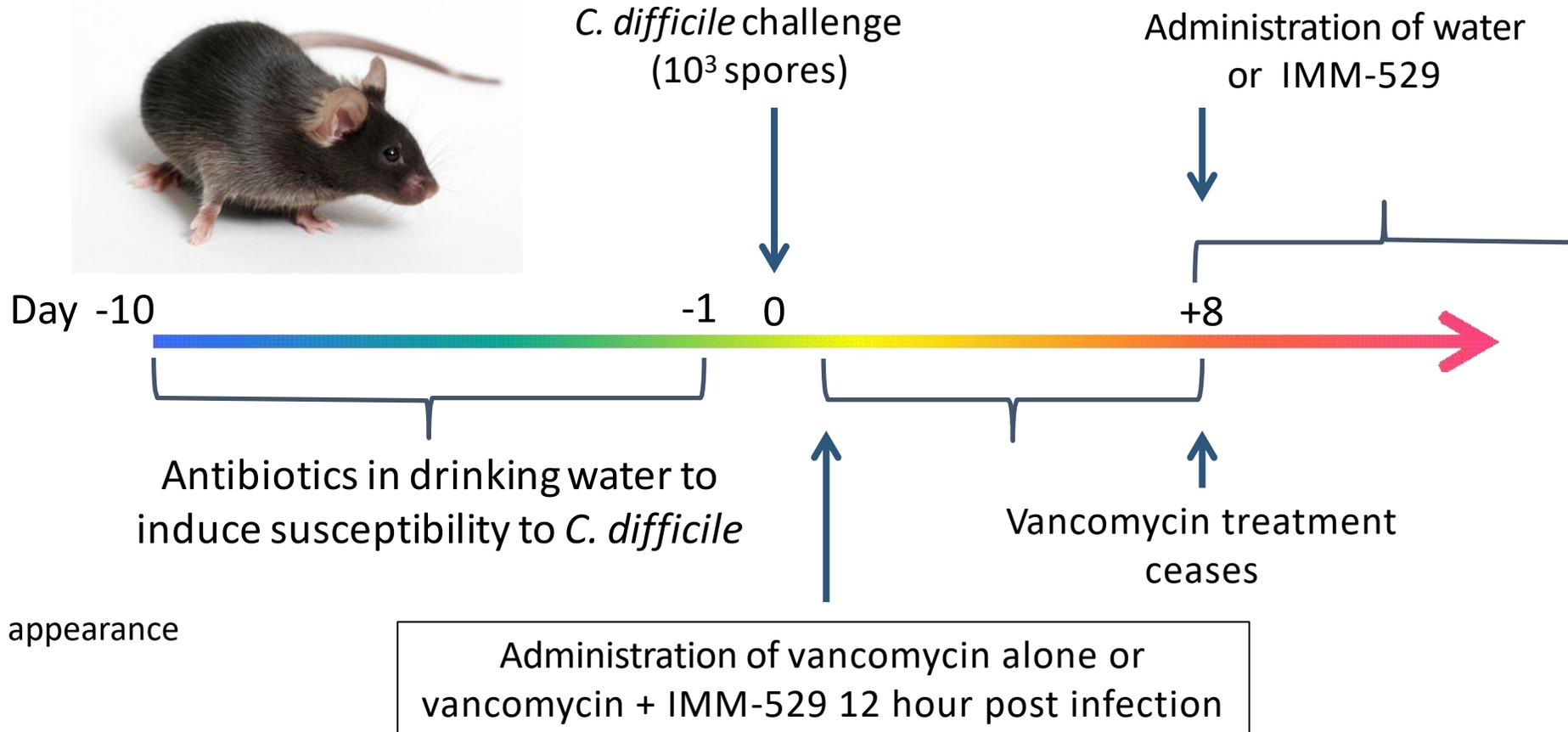


Toxin B

THE *C. DIFFICILE* PREVENTION OF RECURRENT CDI MOUSE MODEL*



C57BL/6 mice 6–7 weeks



Monitor:

- Weight loss
- Physiological appearance
- Activity
- Diarrhoea

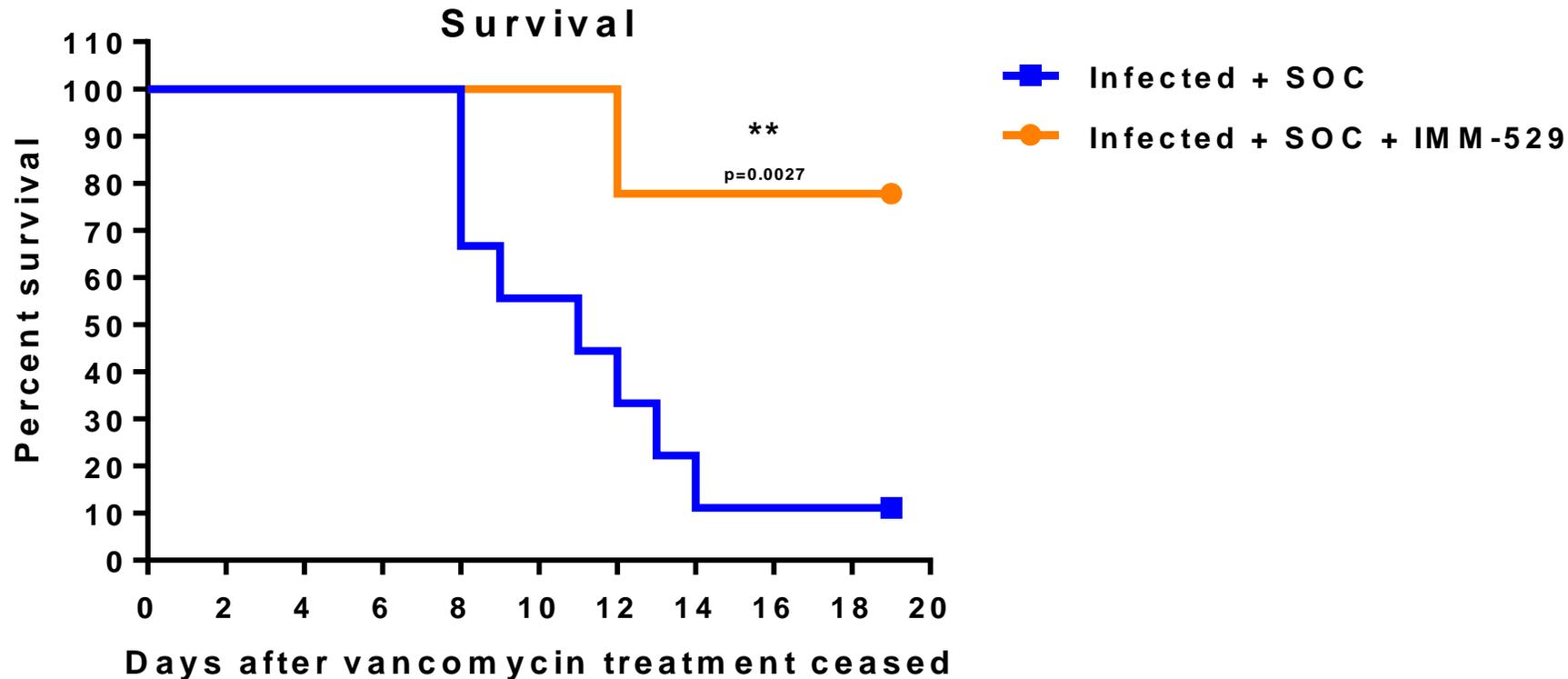
*Collaboration with Prof. Dena Lyras, Monash University, Australia

IMM-529 ANIMAL MODEL 'RECURRENCE' STUDY



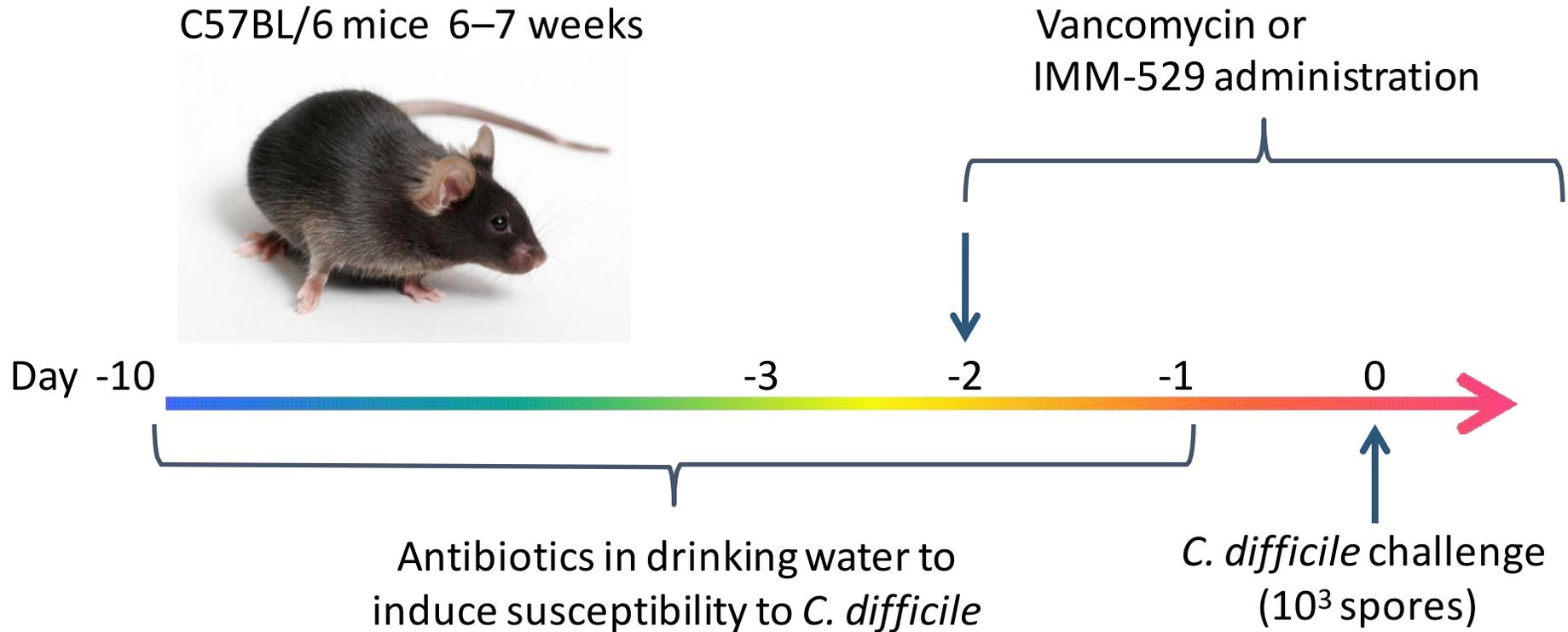
Relapse Study

All studies statistically significant



Demonstrated ~80% survival rate (7/9) vs. ~10% survival rate in control group (1/9)

THE *C. DIFFICILE* PREVENTION MOUSE MODEL



Monitor:

- Weight loss
- Physiological appearance
- Activity
- Diarrhoea

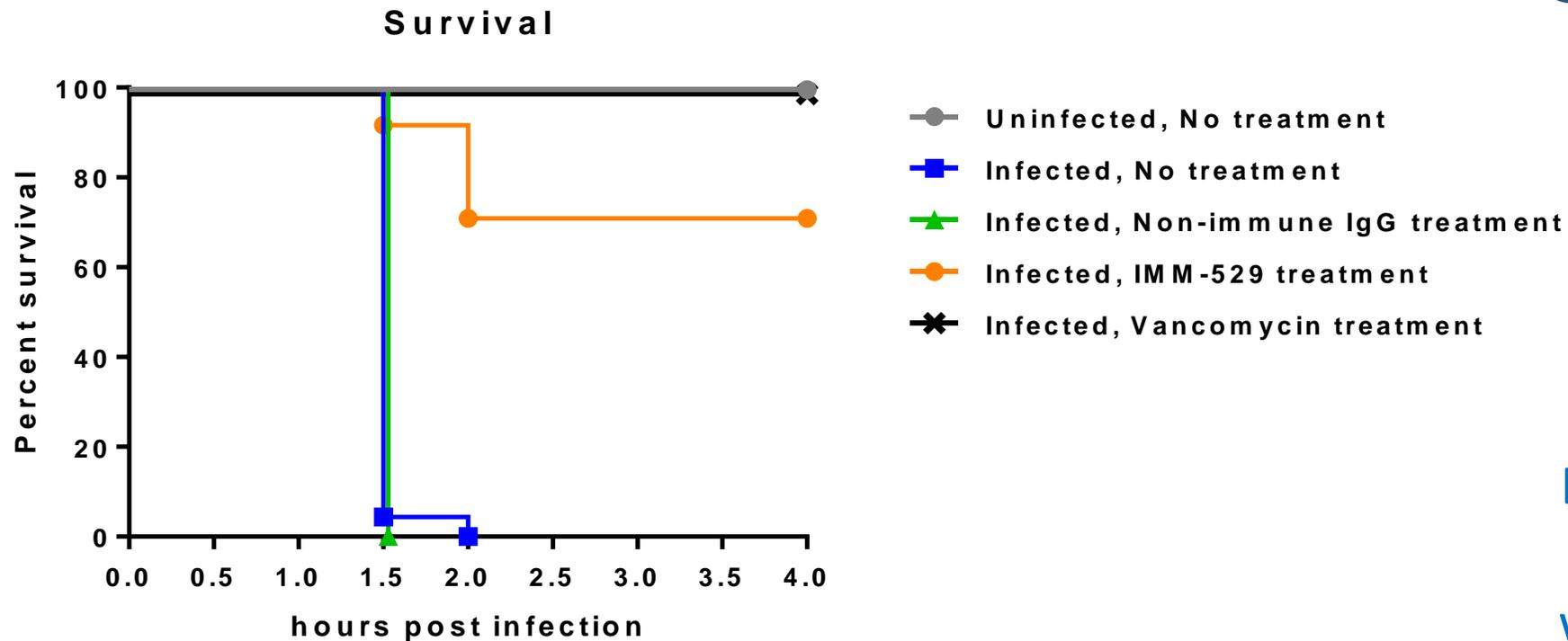
*Collaboration with Prof. Dena Lyras, Monash University, Australia

IMM-529 ANIMAL MODEL STUDY



Prevention Study

All studies statistically significant

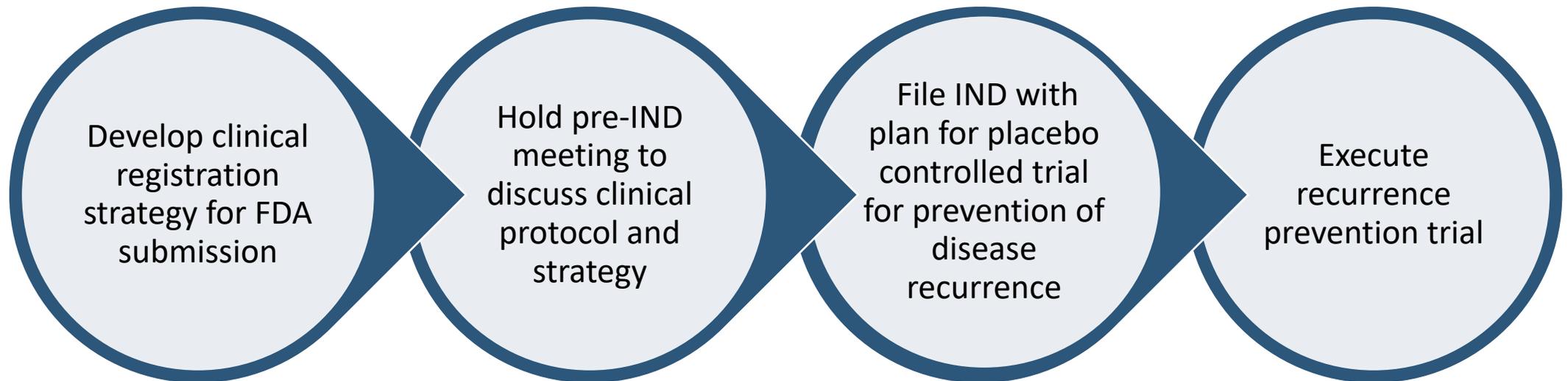


Demonstrated
80% efficacy
without use of
antibiotics



IMM-529 DRUG DEVELOPMENT PLAN

Develop clinical protocol for FDA approval as drug to prevent recurrent *Clostridium difficile* Infection:





COMPETITOR MARKET ANALYSIS – CDI

Company	Drug	Type	Status
Reduce recurrence of CDI			
 MERCK	Zinplava (bezlotoxumab)	IV Monoclonal Antibody	FDA approved 2016
 SERES THERAPEUTICS™	SER-109	Oral microbiome therapeutic	Phase 3
 FINCH	CP101	Oral microbiome therapeutic	Phase 2
Treatment of Primary CDI			
 summit	Ridinilazole	Oral antibiotic	Phase 3
 ACTELION A JANSSEN PHARMACEUTICAL COMPANY OF <i>Johnson & Johnson</i>	Cadazolid	Oral antibiotic	Failed Phase 3
 SERES THERAPEUTICS™	SER-262	Oral microbiome therapeutic	Phase 1b



Immuron Reports Neutralizing activity Against SARS-CoV-2

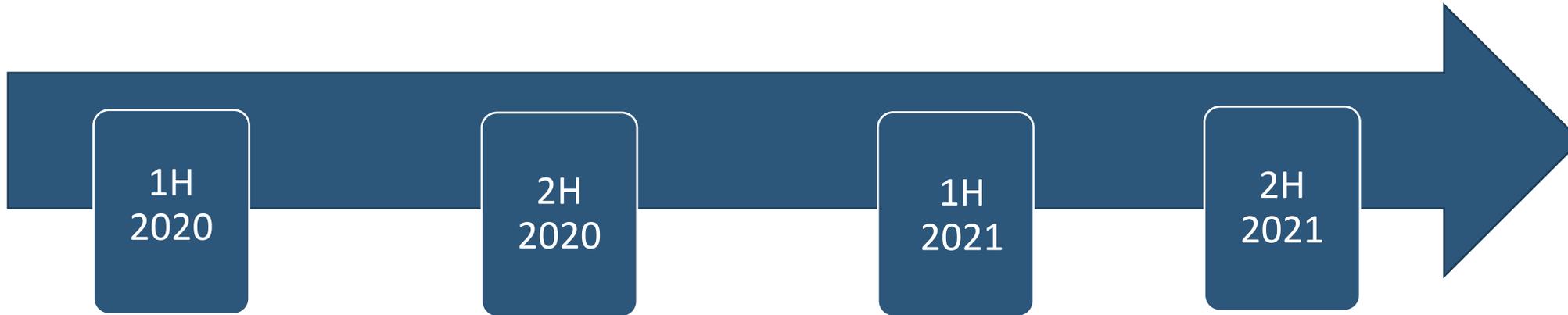
Key Points

- **Immuron's Hyper-immune Bovine Colostrum used to manufacture Travelan[®] and Protectyn[®] demonstrates antiviral activity against the COVID-19 virus in laboratory studies**
- **Immuron's technology platform offers a potential new oral therapeutic approach to target SARS-CoV-2 in the GI Tract**

Melbourne, Australia, July 21, 2020: Immuron Limited (ASX: IMC; NASDAQ: IMRN), an Australian biopharmaceutical company focused on developing and commercialising oral immunotherapeutics for the prevention and treatment of gut mediated pathogens, today is pleased to announce that the hyper-immune bovine colostrum used to manufacture the company's flag ship commercially available and over-the-counter gastrointestinal and digestive health immune supplements Travelan[®] and Protectyn[®] has demonstrated neutralizing activity against the severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2), the virus that causes COVID-19.



KEY MILESTONES EXPECTED TO DRIVE VALUE



- Pre-IND Meeting to Discuss IMM-124E Phase 3 Clinical Development
- Pre-IND Meeting to Discuss Phase 2 NMRC Clinical Development



- cGMP Manufacture
 - Drug Substance
 - Drug Product
- NMRC IND Submission

- Initiate Phase 2 Clinical Trials
- Camylobacteriosis prevention study
- ETEC Infectious diarrhea prevention study
- Pre-IND Meeting on IMM-529 *C. difficile* program

- Phase 2 Clinical Data Available
- Plan to initiate U.S. Phase 2 trial on IMM-529 to treat recurrent CDI

Results from US Army Shigella animal studies expected in 2021

MANAGEMENT



Dr Jerry Kanellos – Chief Executive Officer

- Over twenty years' experience in pharmaceutical and biotechnology industries.
- Former Chief Operating Officer of TransBio Ltd. Responsible for strategic identification, development and maintenance of global commercial partnerships, along with development, management and IP portfolio, R&D and technology transfer.
- Leadership roles in business development, project management, IP portfolio management, R&D, senior management.
- Consultant to academic institutes, private and publicly listed companies and government departments specializing in development and commercialization strategies.
- PhD in medicine from the University of Melbourne.

BOARD OF DIRECTORS – CHAIRMAN & EXECUTIVE VICE CHAIRMAN



Dr Roger Aston

CHAIRMAN - B. Sc. (Hons), PhD.

Dr Aston has more than 20 years experience in the pharmaceutical and biotech industries. He was Chief Executive Officer of Mayne Pharma Group Limited, after leading HalcyGen's acquisition of Mayne Limited in 2009. He has extensive experience with FDA and EU product registration, clinical trials, global licensing, private placement fundraising and prospectus preparation. Dr Aston has held numerous other board positions in the sector including with Clinuvel Limited, HalyGen Limited and Ascent Pharma Health Limited, recently acquired by Watson.



Peter Anastasiou

EXECUTIVE VICE CHAIRMAN - BBSc

Mr. Anastasiou has extensive business experience in a wide range of organisations. He has been a successful entrepreneur from an early age with his first biotech venture, Neuro Developments Australia, seeded at age 24. Mr. Anastasiou was the founder of Investment Group Grandlodge, and ACS International both of which have generated significant wealth through Investment and Management

NON-EXECUTIVE DIRECTORS

- **Stephen Anastasiou**
- **Daniel Pollock**
- **Professor Ravi Savarirayan**