



# FORGING COMMERCIAL & CLINICAL PATHWAYS

TARGETING INFECTIOUS DISEASES WITH ORAL  
IMMUNOTHERAPIES – NOVEMBER 2019

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**ASX: IMC**



# SAFE HARBOR STATEMENT

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# 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<sup>®</sup> Generating Revenue**
- IMM-124E & IMM-529, in **Clinical Development** for Treatment of Gastrointestinal Disorders and *C. difficile* Infections
- Plan for Accelerated **Regulatory Path** to Approval for IMM-124E (Travelan<sup>®</sup>) as Drug to Prevent Travelers' Diarrhea in USA

# DEVELOPMENT PIPELINE: THREE-PRONGED PLAN



	DEVELOPMENT STAGE					HIGHLIGHTS
	PRE-CLINICAL	PHASE 1	PHASE 2	PHASE 3	MARKET	
<b>ANTI-INFLAMMATORY PROGRAMS</b>						
Travelan®	TGA ARTG Aust L106709 (2004)					Commercial product - Australia
	Health Canada NPN 80046016 (2015)					Commercial product - Canada
	Dietary supplement (2015)					Commercial product - USA
<b>1</b>	IMM-124E (Travelan®)	▶				PLAN TO DEVELOP AS DRUG TO PREVENT TRAVELERS' DIARRHEA IN USA
<b>2</b>	IMM-529	▶				TO PREVENT RECURRENCE IN C. DIFFICILE PATIENTS
<b>3</b>	Department of Defense Program	▶				US ARMY – SHIGELLA US NAVY - CAMPLYLOBACTER

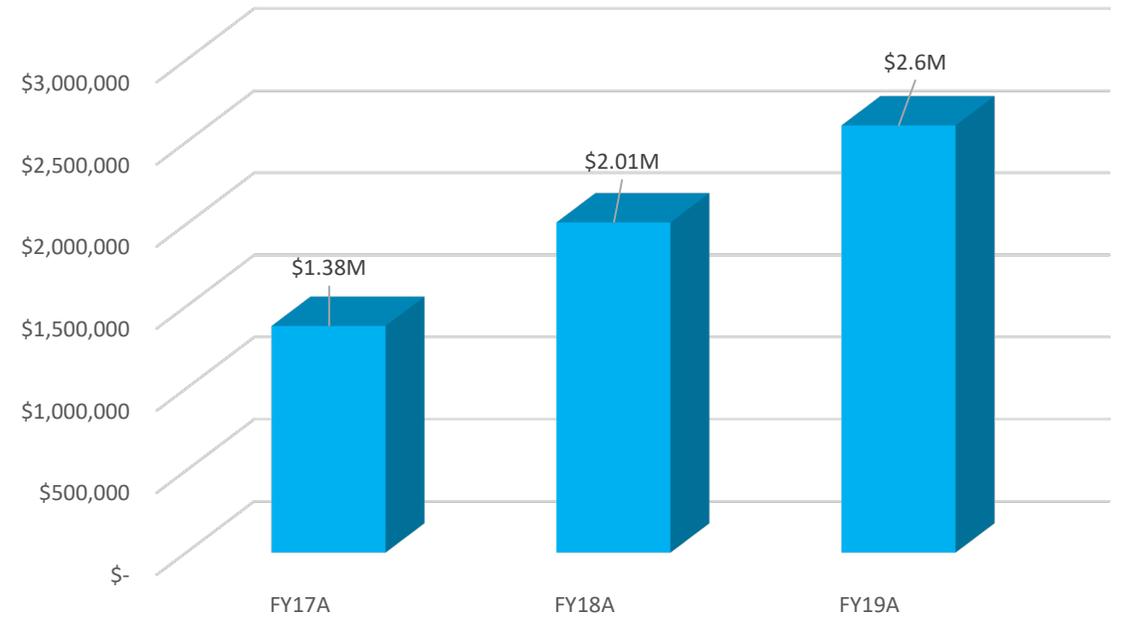
# TRAVELAN® COMMERCIAL PROFILE: INCREASING SALES ADDRESSING LARGE MARKETS



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

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 North American revenue surges by 52% in FY19

## *Key Highlights:*

- Immuron FY19 revenue surged by 52% in North America, reaching \$1.16M.
- In the USA, FY19 Travelan® sales exceeded the \$1M AUD milestone for the first time and grew by +32% to \$1.02M AUD.
- In May 2019, USA Travelan® sales achieved a record-breaking \$182K AUD.
- The first Canadian sales of Travelan® were reported in Q4 of FY19.
- Global Immuron sales for FY19 grew at +29% YoY, representing a record-breaking year for the company with revenue before rebates reaching \$2.6M AUD.

Melbourne, Australia, July 16, 2019: 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 sales results for the year ended 30 June 2019 ('FY19') for its commercially available products, including Travelan®, the over-the-counter gastrointestinal and digestive health supplement.



# Immuron North American Q1 Sales Up 111% YoY

## *Key Highlights:*

- **First Quarter of FY2020 (Q1) North American sales grew by 111% YoY to \$269K AUD**
- **Q1 US Travelan® sales increased by +81% YoY to \$232K AUD**
- **Global Immuron sales continued an upward trend in Q1 with a +54% YoY sales increase, reaching \$741K AUD**
- **In Australia, Q1 Travelan® sales increased by +34% YoY to \$458K AUD**

Melbourne, Australia, October 14, 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 sales results for its commercially available, over-the-counter gastrointestinal and digestive health supplement Travelan®, for the quarter ended September 30, 2019, of fiscal year 2020 (Q1).

# FY20 MARKETING OVERVIEW: USA

## TRAVEL CLINICS

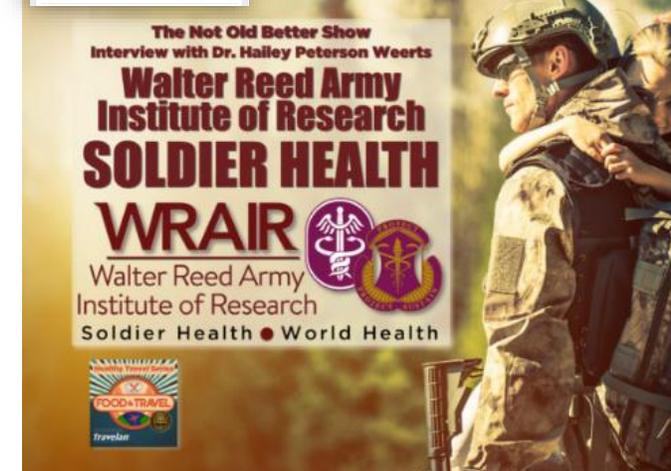
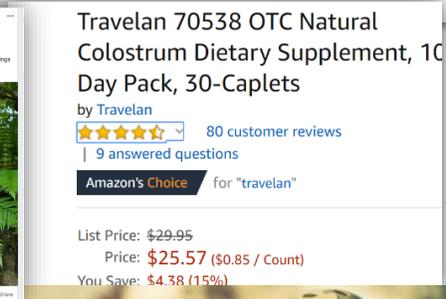
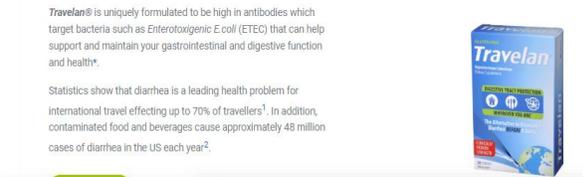
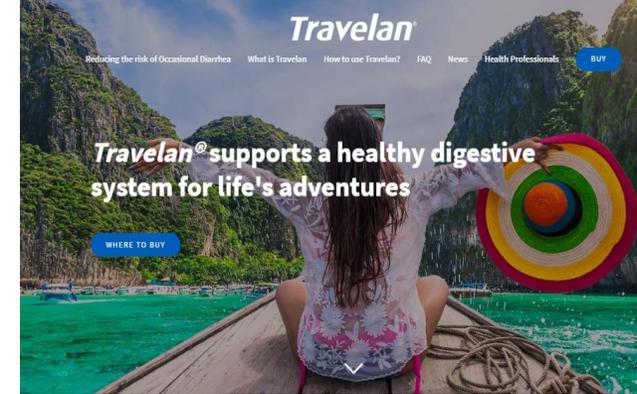
## CONSUMER MARKETING

### FY19 REVIEW

- Increased sales in 190 Passport Health Clinics across the USA.
- Training & incentive program for travel clinic nurses.
- USA website launched June 2019.
- Travel blogger & influencer collaborations to target travellers (28 globally).
- 2 podcast campaigns to stimulate Amazon sales (80% uplift in YoY Medique sales).

### FY20 APPROACH

- Expansion into additional 35+ Passport Health travel clinics.
- Continued training programme for travel nurses.
- Podcast interview with Passport Health Travel Nurse for consumer targeted advertising.
- Integrated consumer awareness campaign planned for Feb 2019 (influencer, travel advertorial & earned media components).
- Amazon cross-promotions with travel influencers - starting Nov 19.
- Amazon paid promotions.
- 4 podcast interviews to stimulate Amazon sales.





# BACKGROUND OF TRAVELAN®: PLAN TO EXPAND USE

## COMMERCIAL PRODUCT

Marketed in Australia, USA and Canada



## DRUG CANDIDATE IMM-124E

Status with FDA:  
IND 14,933\*



\*IMM-124E for treatment of NASH

Plan to develop IMM-124E as an approved drug to prevent 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 included<sup>1</sup>:

- Antibiotics should **NOT** be used routinely, except patients at high risk of complications
- Rifaximin recommended when antibiotic prophylaxis is indicated
- Fluoroquinolones not recommended for prophylaxis<sup>2</sup>
- Insufficient evidence to recommend prebiotics or probiotics

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

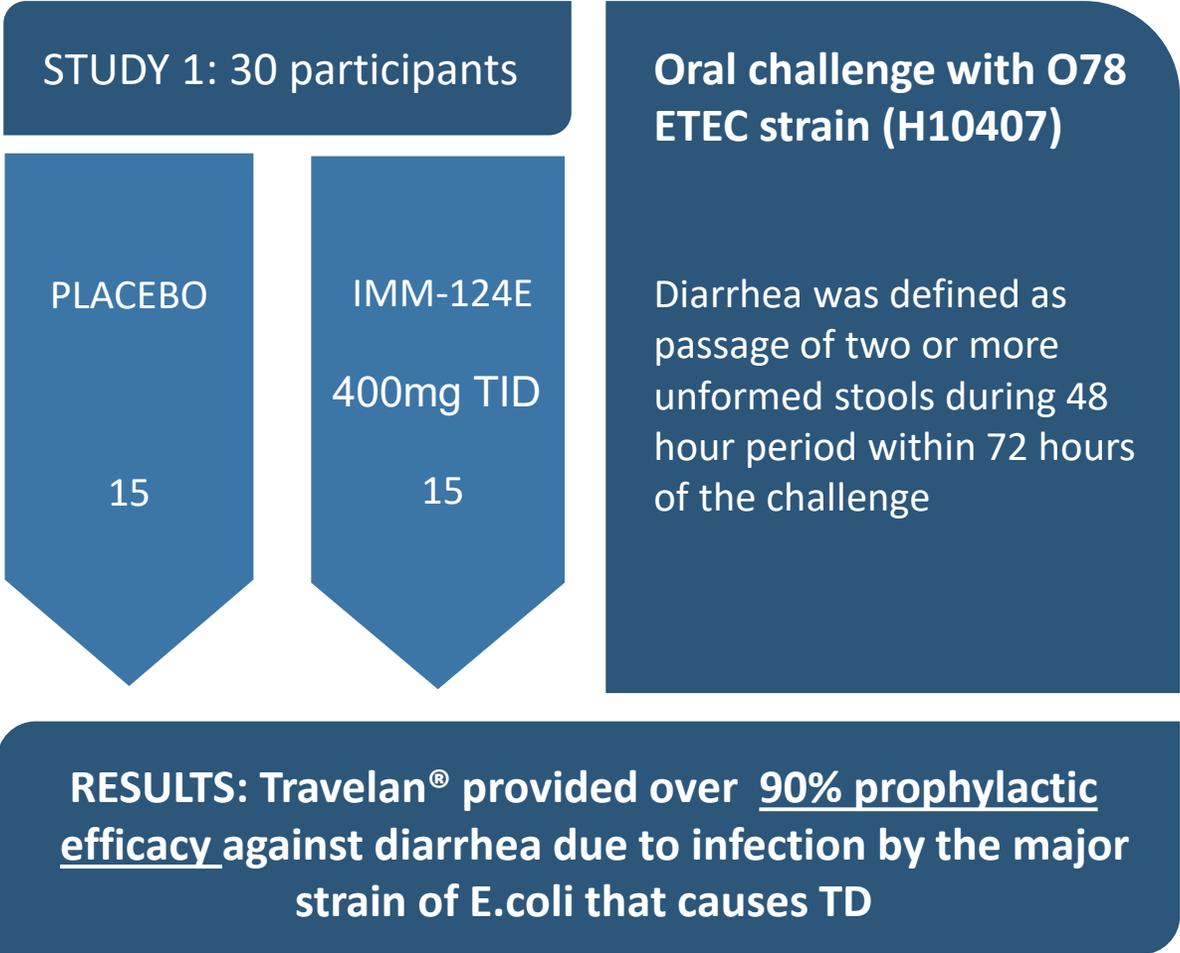
1 Riddle et al. 2017. Guidelines for the prevention and treatment of travellers' diarrhea: a graded expert panel report. Journal of Travel Medicine 24(1).

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

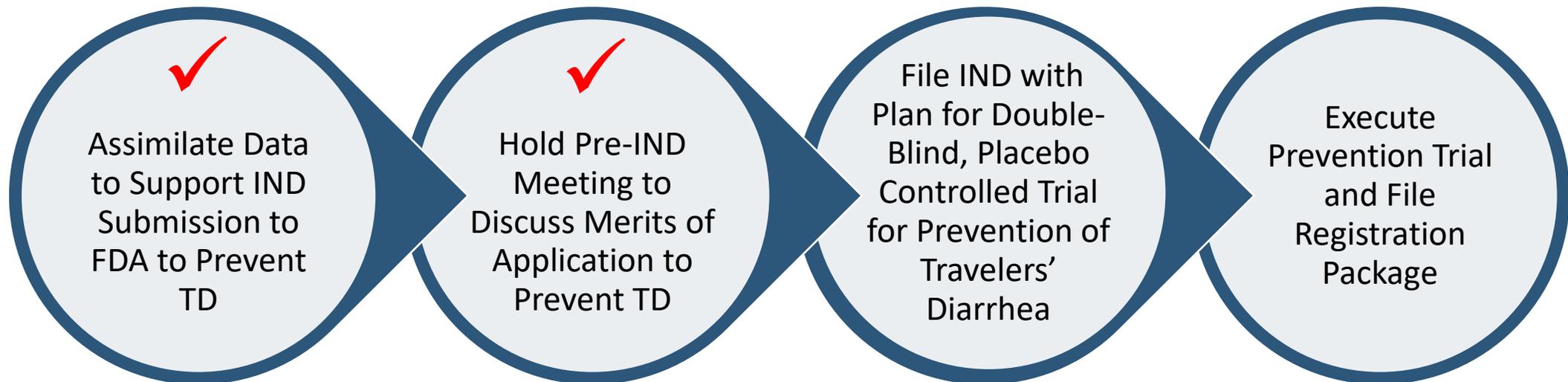
\*Fisher's exact test or Student's t-test (two-tailed) as appropriate.

NS, not significant



# IMM-124E DRUG DEVELOPMENT PLAN

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



# 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)<sup>1</sup> and obtaining pretravel advice (22.2 million)<sup>2</sup>. Sources of pre-travel advice include primary care provider, travel medicine specialist, company doctors, pharmacist, and travel agencies<sup>2</sup>. 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



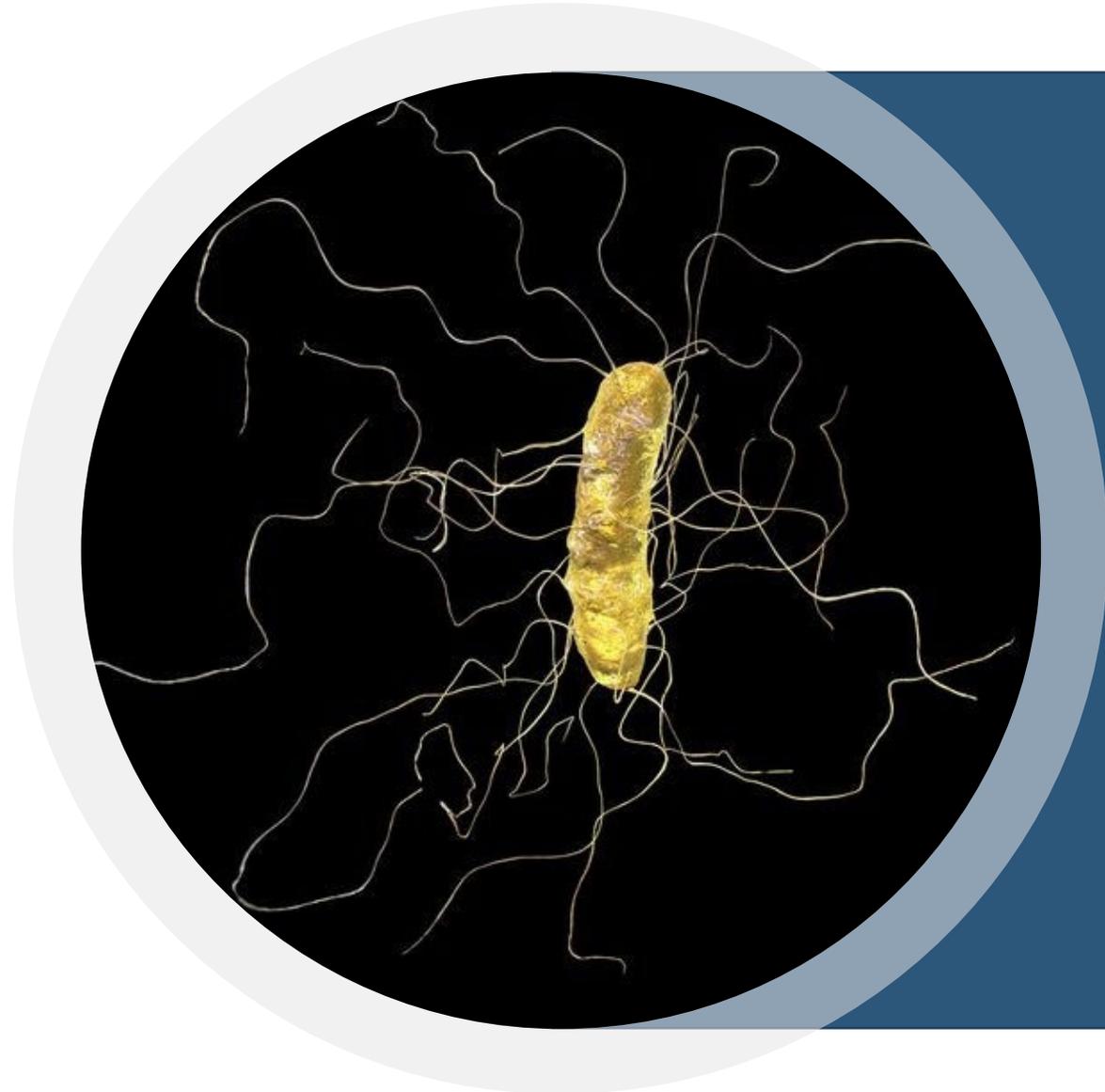
Drug	Indication	Dosing	Ave cost – 2 week trip	Revenue USD Millions (Year)
<b>FDA APPROVED DRUG TREATMENTS FOR DIARRHEA</b>				
PEPTO BISMOL (BSS) 	Relief for heartburn, nausea, indigestion, upset stomach and diarrhea.	2 tabs QID	\$20.97 <sup>1</sup>	82.6 (2013) <sup>2</sup>
IMMODIUM 	Decrease the frequency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

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%<sup>1</sup>
- Leading cause of gastroenteritis-associated mortality in U.S.<sup>2</sup>
- Approx. 44,500 patients<sup>3</sup> 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



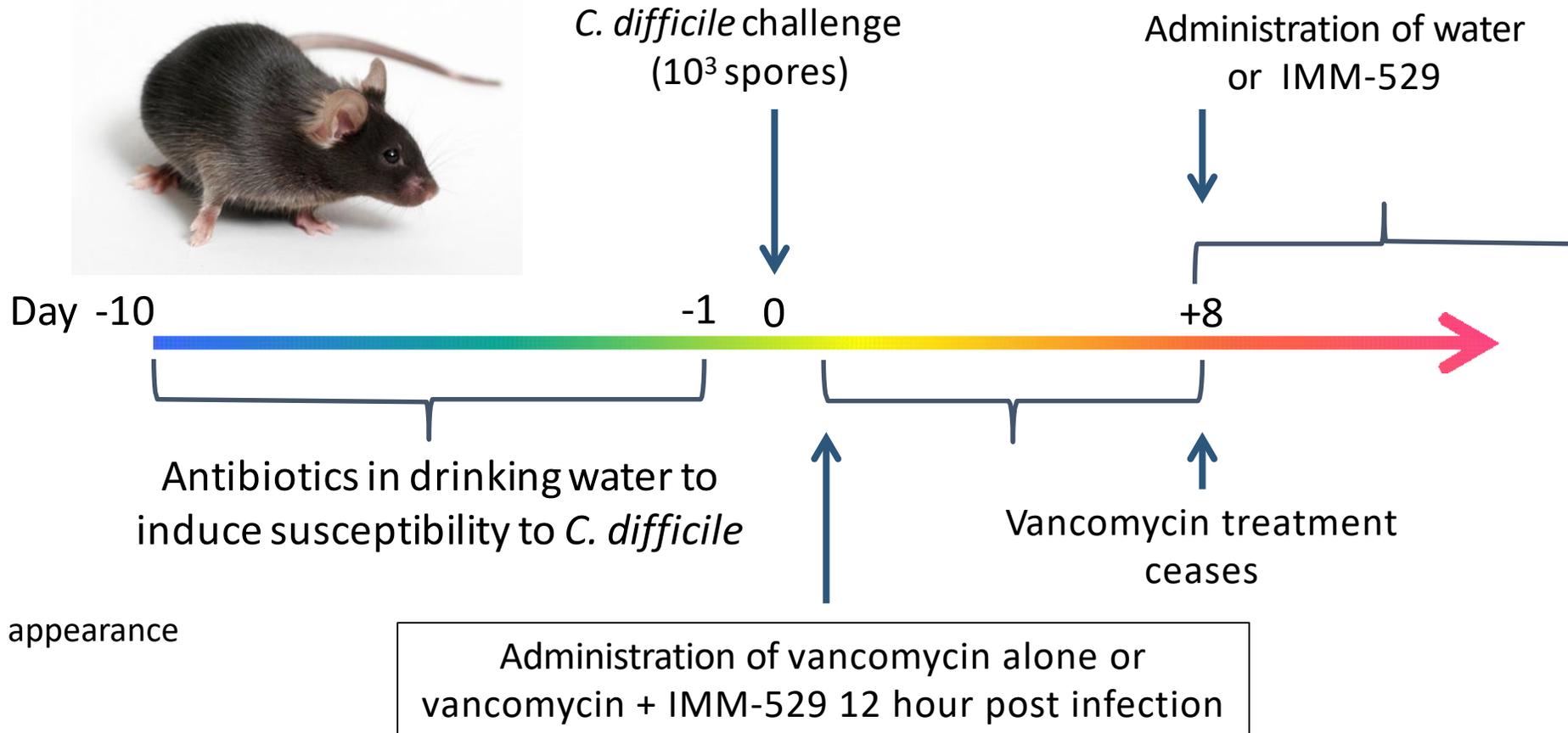
\*Isobel Ramsay, Nicholas Brown and David Enoch. Recent Progress for the Effective Prevention and Treatment of Recurrent Clostridium difficile Infection. Infectious Diseases: Research and Treatment Volume 11: 1–4 (2018).

DOI: 10.1177/1178633718758023

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



C57BL/6 mice 6–7 weeks



Monitor:

- Weight loss
- Physiological appearance
- Activity
- Diarrhoea

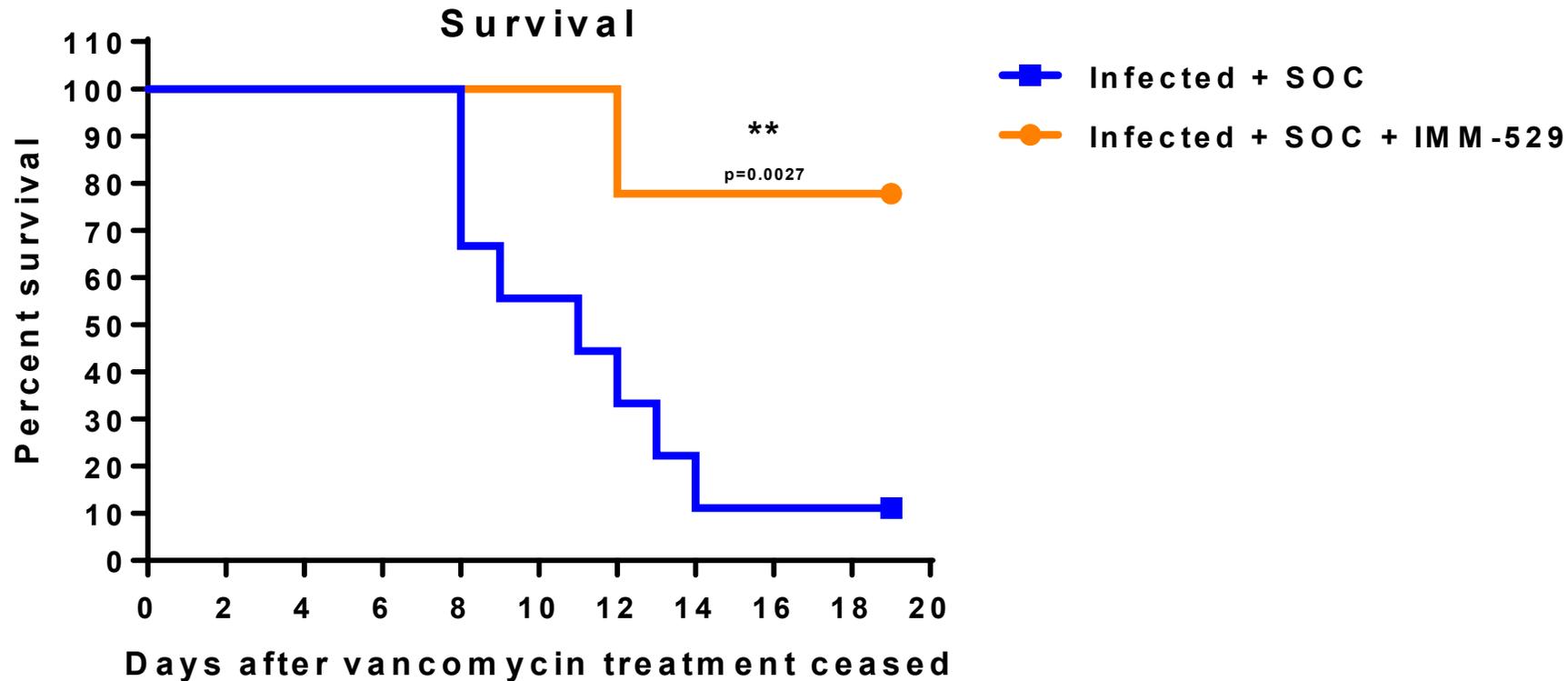
\*Collaboration with Prof. Dena Lyras, Monash University, Australia

# IMM-529 ANIMAL MODEL 'RECURRENCE' STUDY



## Relapse Study

All studies statistically significant

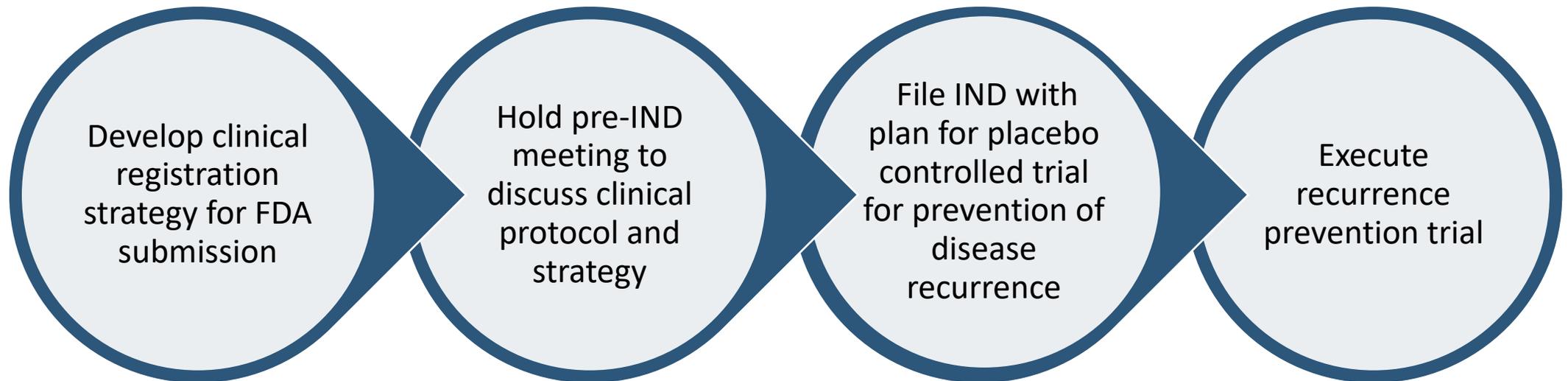


Demonstrated ~80% survival rate (7/9) vs. ~10% survival rate in control group (1/9)



# IMM-529 DRUG DEVELOPMENT PLAN

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



# DEVELOPMENT PIPELINE: THREE-PRONGED PLAN



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<b>1</b>	IMM-124E (Travelan®)					PLAN TO DEVELOP AS DRUG TO PREVENT TRAVELERS' DIARRHEA IN USA
<b>2</b>	IMM-529					TO PREVENT RECURRENCE IN C. DIFFICILE PATIENTS
<b>3</b>	Department of Defense Program					US ARMY – SHIGELLA US NAVY - CAMPLYLOBACTER

# US DOD R&D COLLABORATION AGREEMENTS



## Collaboration on Development: 1) Shigella-Specific Target – US Army 2) 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





## US Department of Defense Reports Final Results from Travelan® Shigellosis Challenge Study

### ***Key Highlights:***

- **Travelan® shigellosis challenge studies in non-human primates successfully completed**
- **Travelan® prevented clinical shigellosis (bacillary dysentery) in 75% of Travelan® treated animals compared to placebo and demonstrated a significant clinical benefit**
- **Prophylactic administration of Travelan® may provide an effective prevention alternative to antibiotics for gastrointestinal infections in humans**
- **Three new *Shigella* specific anti-microbial therapeutics under preclinical evaluation**
- **A preventative treatment that protects against enteric diseases, specifically *Shigella*, is a high priority objective for the US Army**

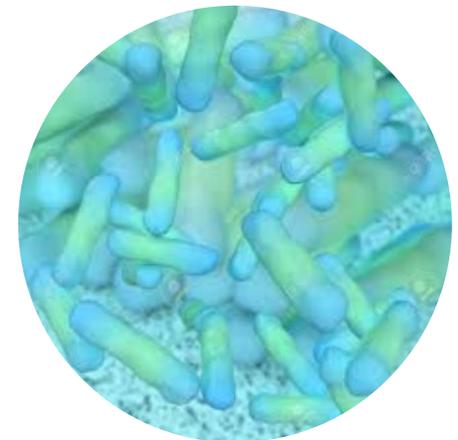
Melbourne, Australia, June 12, 2019: Immuron Limited (ASX: IMC; NASDAQ: IMRN), an Australian biopharmaceutical company focused on developing and commercializing oral immunotherapeutics for the prevention and treatment of many gut mediated pathogens, today is pleased to provide shareholders with an update on the company's cooperative research and development agreements with the US Department of Defense (US DoD).

# 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  $2.8 \times 10^9$  *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

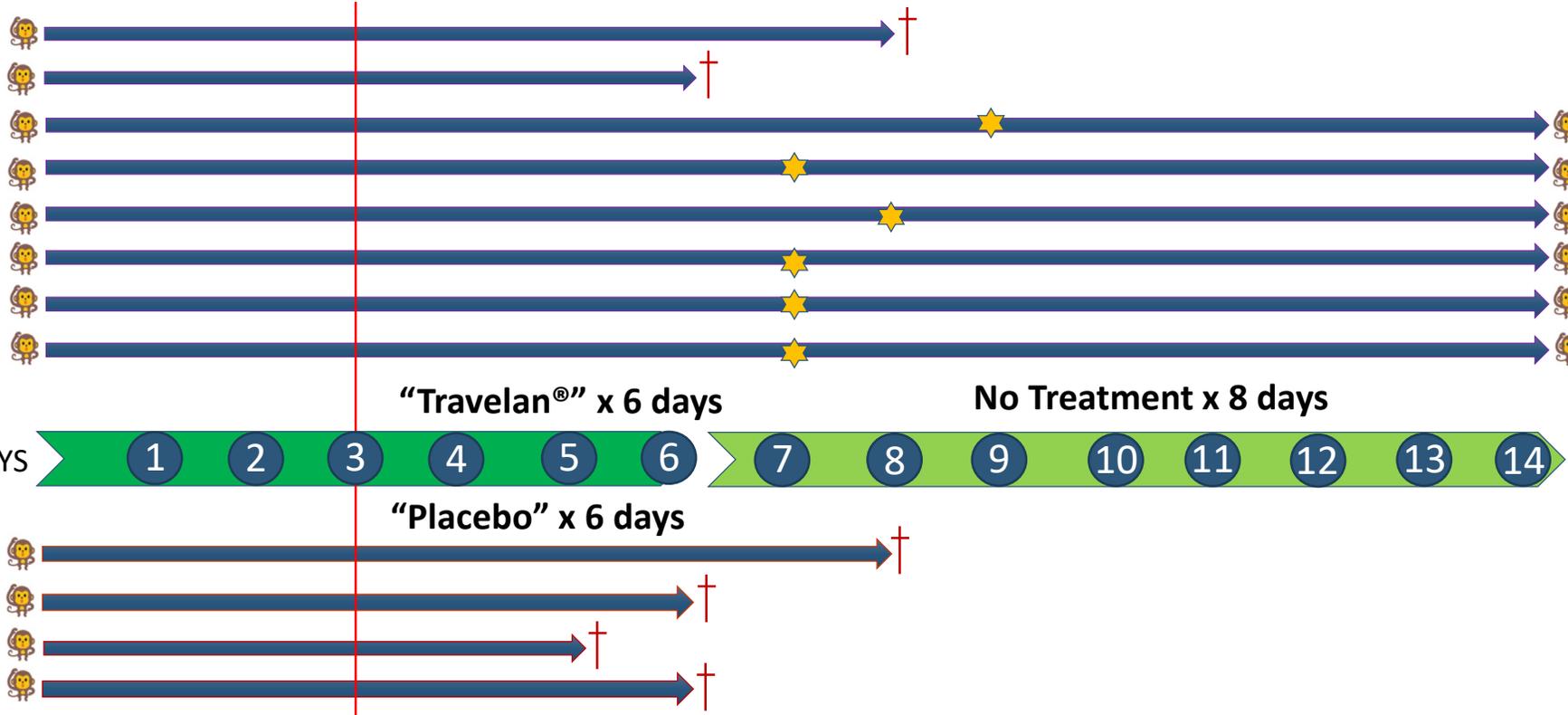
**\*Collaborative animal model study with AFRIMS & WRAIR**



# RESULTS OF TRAVELAN® SHIGELLA CHALLENGE STUDY\*



3 x 10<sup>9</sup>  
*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



## **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.



# KEY MILESTONES EXPECTED TO DRIVE VALUE



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



- Initiate Phase 3 Clinical Trial on IMM-124E TD prevention study

- Phase 3 IMM-124E TD Clinical Data Available

- Pre-IND Meeting on IMM-529 *C. difficile* program

- Plan to File BLA for IMM-124E TD prevention study

Results from US Army Shigella animal studies expected in 2020

*In vitro* results from US Navy NMRC studies expected 2020