



# FORGING COMMERCIAL & CLINICAL PATHWAYS

TARGETING INFECTIOUS DISEASES WITH ORAL IMMUNOTHERAPIES – OCTOBER, 2020

JERRY KANELLOS, Ph.D. CEO

> NASDAQ: IMRN ASX: IMC

#### DEVELOPMENT **PIPELINE** Comm

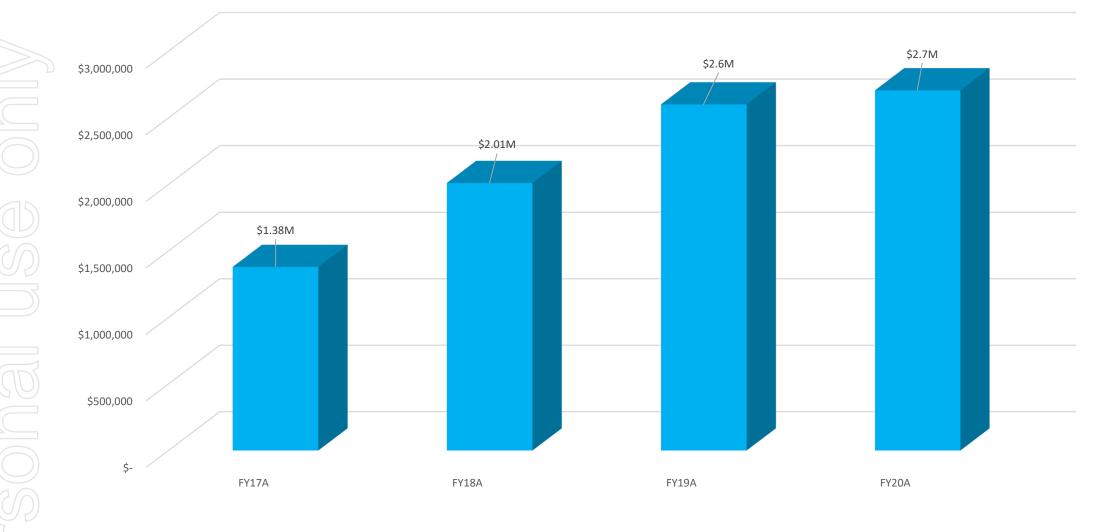
Walter Reed Army Institute of Research

| -                                | PRE-CLINICAL  | PHASE I           | PHASE II       | PHASE III | MARKET |
|----------------------------------|---|-------------------|----------------|-----------|--------|
|                                  | Travelan® - commercial product Australia                    |                   |                |           |        |
| Commercial<br>Products           |   |                   |                |           |        |
|                                  | Protectyn <sup>®</sup> - commercial product Australia       |                   |                |           |        |
|                                  | Travelan® - commercial product Canada                       |                   |                |           |        |
|                                  |   |                   |                |           |        |
|                                  | Travelan® - commercial product USA                          |                   |                |           |        |
| <b>2</b><br>IMM-124E             |   |                   |                |           |        |
|                                  | i) Travelers' Diarrhea FDA drug registration USA            |                   |                |           |        |
|                                  |   |                   |                |           |        |
|                                  | ii) P4TD Travelers' Di                                      | arrhea Efficacy F | ield Trial     |           |        |
|                                  |   |                   |                |           |        |
|                                  | iii) COVID-19 research                                      |                   |                |           |        |
|                                  |   |                   |                |           |        |
| ß                                | Recurrent C. difficile infections                           |                   |                |           |        |
|                                  |   |                   |                |           |        |
| IMM-529                          |   |                   |                |           |        |
|                                  | Moderate to severe  | Campylobacterio   | sis infections |           |        |
| Naval Medical<br>Research Center |   |                   |                |           |        |
|                                  | ETEC infections   |                   |                |           |        |
|                                  |   |                   |                |           |        |
|                                  | Evaluation of Shigella specific therapeutic drug candidates |                   |                |           |        |
|                                  |   |                   |                |           |        |

### **TRAVELAN® COMMERCIAL PROFILE:**



Global Immuron Sales (Gross) - AUD



Immur@n

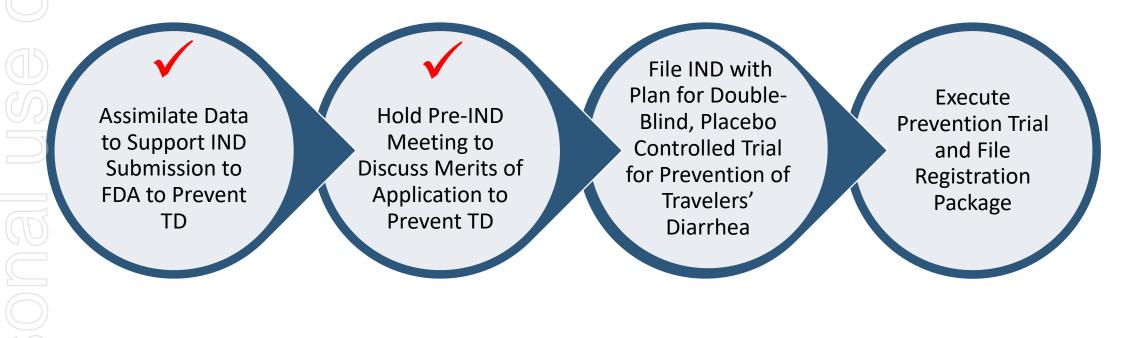
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## **IMM-124E DRUG DEVELOPMENT PLAN**

Immur@n



Plan to register Travelan<sup>®</sup> as a drug in the USA with the FDA to reduce the risk of Travelers' Diarrhea (TD) in travelers to endemic areas:



### US SALES FORECAST FOR TRAVELAN®: IF APPROVED AS DRUG



### **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<sup>®</sup> after seeking pre-travel advice.



 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.
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

## Immur@n

### A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED TRIAL EVALUATING THE EFFICACY OF NON-ANTIBIOTIC OTC PRODUCTS IN TRAVELERS' DIARRHEA (TD) PREVENTION (P4TD)



**CURRENT STATUS – PLAN TO COMMENCE ENROLMENT JUNE 2021** 

#### **Primary Objective:**

To evaluate the clinical efficacy of Travelan®, Florastor® and Bimuno® vs. placebo for maintenance of Gastrointestinal Health (GH) focusing on a 10 day window of prophylaxis during travel.

#### **STUDY DESIGN**

This is a randomized (1:1:1:1 allocation), double-blind, placebo controlled multicenter clinical trial comparing three dietary supplements, Travelan®, Florastor® and Bimuno®, individually against placebo to determine efficacy for maintenance of GH.

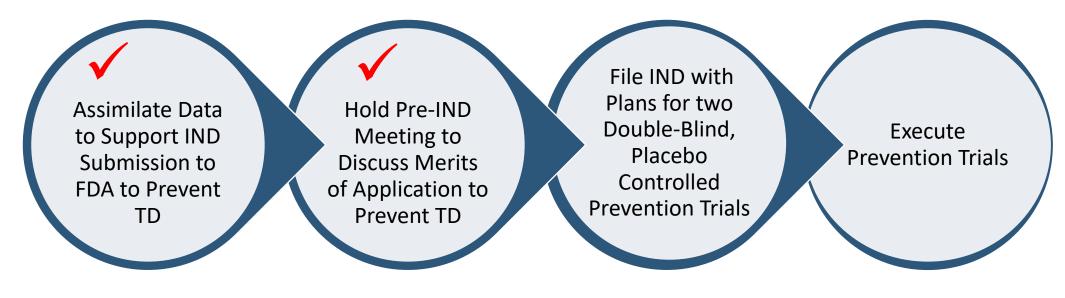
A total of 1320 subjects (330/arm) will be enrolled from the following populations: active duty US and UK military personnel, US DoD beneficiaries and US civilians deploying or traveling to intermediate or high GH disruption risk destinations.

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## US NAVEL MEDICAL RESEARCH CENTRE DRUG DEVELOPMENT PLAN



Two Human Clinical Trials Planned: New Drug to Reduce the risk of Infectious Diarrhea Caused by Campylobacter and by ETEC

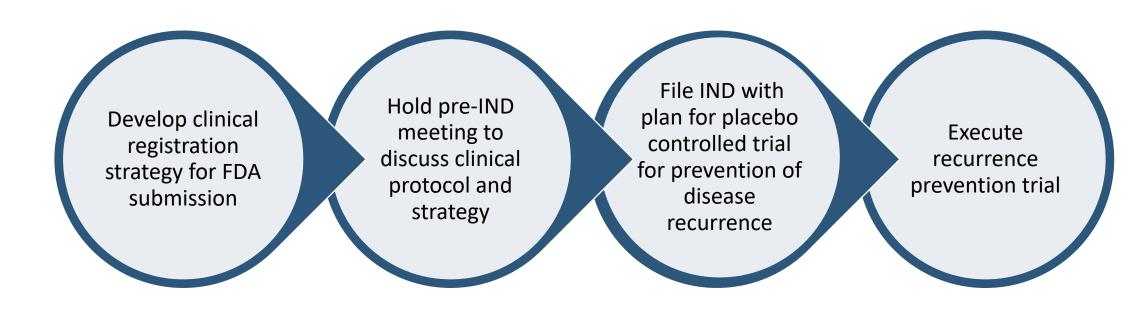


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## **IMM-529 DRUG DEVELOPMENT PLAN**



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





### Immuron Reports Neutralizing activity Against SARS-CoV-2

#### **Key Points**

- Immuron's Hyper-immune Bovine Colostrum used to manufacture Travelan<sup>®</sup> and Protectyn<sup>®</sup> 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 hype-Immune bovine colostrum used to manufacture the company's flag ship commercially available and over-the-counter gastrointestinal and digestive health immune supplements Travelan<sup>®</sup> and Protectyn<sup>®</sup> has demonstrated neutralizing activity against the severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2), the virus that causes COVID-19.

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# IMM-124E SARS-COV-2 RESEARCH & DEVELOPMENT PROPOSAL

#### **CURRENT STATUS**

### **RESEARCH & DEVELOPMENT**

Reached out to local, national, and international potential research collaborators to advance this work and assist in the further characterization of the neutralization activity of SARS-CoV-2 observed with IMM-124E

- Research Services Agreements
  - > To identify the inhibitory substance/s in IMM-124E

#### • Preclinical Development

- > Access application form for a contract research project submitted
- The project aims to assess the effect of IMM-124E in ex-vivo and animal models infected with SARS-CoV-2

# IMM-124E SARS-COV-2 RESEARCH & DEVELOPMENT PROPOSAL

#### **CURRENT STATUS**

### **CLINICAL PROPOSALS**

- **Consultancy agreement** executed with Professor Teena Chopra, Professor of Medicine Wayne State University School of Medicine, Detroit
  - Professor Chopra is building a registry of the patients presenting with gastrointestinal events to better understand this cohort and the unique medical challenges they present
- Clinical protocol development
  - Reviewing several proposals to assess the efficacy of IMM-124E to treat patients with COVID-19