



FORGING COMMERCIAL & CLINICAL PATHWAYS

TARGETING INFECTIOUS DISEASES WITH ORAL
IMMUNOTHERAPIES – DECEMBER, 2021

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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

- Review of Strategic Plan
- Review of R&D Project Pipeline
 - Travelan US Drug Development Plan
 - NMRC Drug Development Plan
 - IMM-529 US Drug Development Plan
 - IMM-124E SARS-COV-2 R&D

DEVELOPMENT PIPELINE



PRE-CLINICAL PHASE I PHASE II PHASE III MARKET

1

Commercial Products

Travelan® - commercial product Australia

Protectyn® - commercial product Australia

Travelan® - commercial product Canada

Travelan® - commercial product USA

2

IMM-124E

i) Travelers' Diarrhea FDA drug registration USA

ii) P4TD Travelers' Diarrhea Efficacy Field Trial

iii) COVID-19 research

3

IMM-529

Recurrent *C. difficile* infections

4

Naval Medical Research Center

Moderate to severe *Campylobacteriosis* infections

ETEC infections

5

Walter Reed Army Institute of Research

Evaluation of *Shigella* specific therapeutic drug candidates

Personal use only



TRAVELAN[®]: PLAN FOR EXPANDED USE

WITH PARTIAL SUPPORT BY US DOD FOR DOSE FINDING

- Immuron is pursuing a regulatory pathway to license Travelan[®] with the FDA via a Biologics License Application (BLA) with a proposed indication to prevent TD induced by ETEC
- We are seeking financial support to fund part of this initiative and develop a dosing regimen acceptable for use by the military

**DRUG CANDIDATE
IMM-124E**

**Status with FDA:
IND 14,933**

IND 15675 / IND 17066

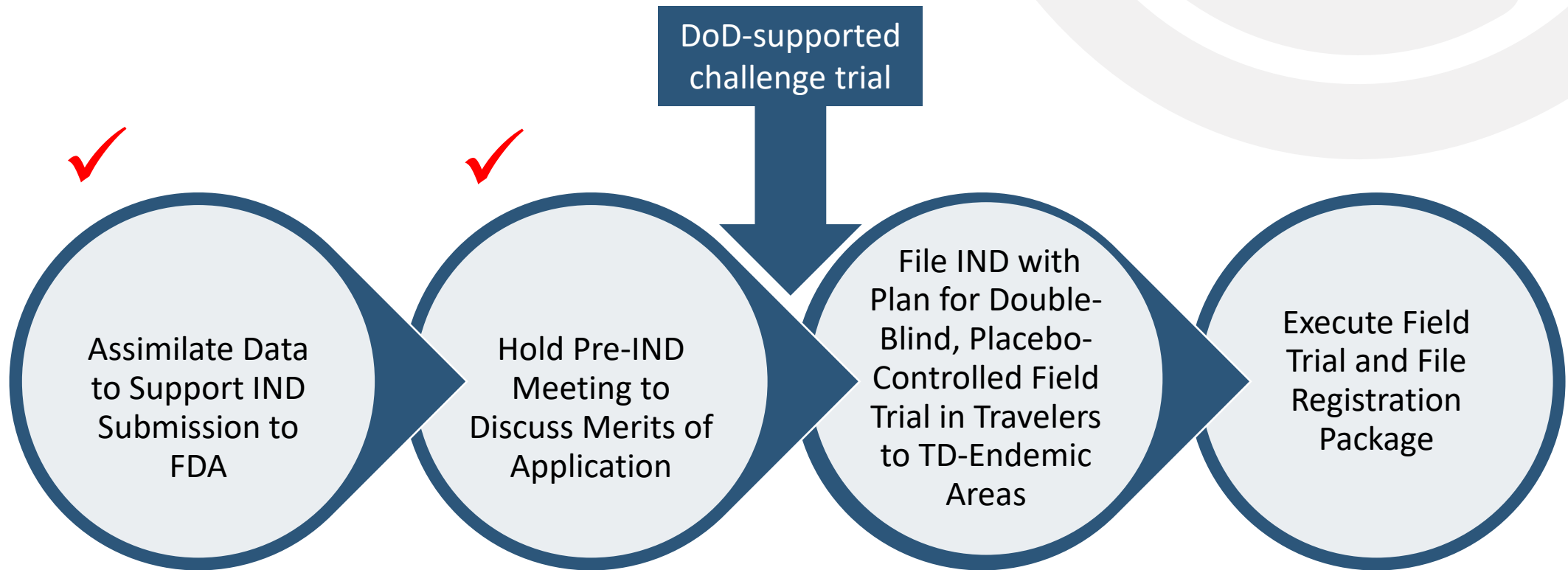


Plan to develop IMM-124E as an approved biologic in the USA targeting travelers' diarrhea



TRAVELAN[®] DRUG DEVELOPMENT PLAN

Travelan[®] for FDA approval as biologic to reduce the risk of travelers' diarrhea (TD) in travelers to endemic areas:



Personal use only



RATIONALE OF PHASE 2 TO BE SUPPORTED BY US DOD

- Travelan® efficacy studies were performed using two different doses (200 mg and 400 mg) 3 times a day
- Such a regimen is cumbersome for military troops deployed in austere environments and **military field studies have shown that compliance is low with products dosed more than once per day¹**
- We propose herein to test the efficacy of one large dose per day in a controlled human infection model (CHIM) trial using ETEC H10407 to inform the decision to move forward with a once per day dosing regimen in a Phase 3 study

¹Srivastava K, Arora A, Kataria A, Cappelleri JC, Sadosky A, Peterson AM. Impact of reducing dosing frequency on adherence to oral therapies: a literature review and meta-analysis. *Patient Prefer Adherence*. 2013;7:419-434 <https://doi.org/10.2147/PPA.S44646>

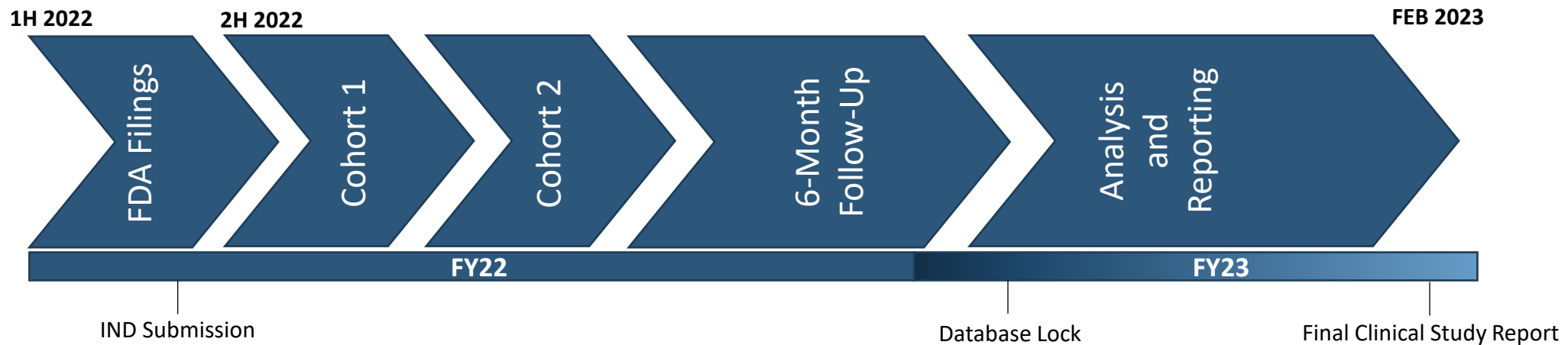


STUDY DESIGN & TIMELINE OF THE PHASE 2

➤ Randomized (1:1), double-blind, placebo-controlled trial in 60 healthy, adult subjects

- Admission to inpatient facility (two repetitive cohorts)
- Once daily dosing of Travelan®/placebo
- Challenge with 2×10^7 CFU of ETEC strain H10407 after two days of dosing
- Follow subjects in an inpatient setting for primary endpoint of moderate-severe diarrhea
- All subjects treated with antibiotics (ciprofloxacin) 5 days post-challenge (or earlier)
- Discharged when symptoms resolved/resolving and no longer shedding challenge organism

Product	N
Travelan® (IMM-124E), one dose (1.2 mg)	30
Placebo	30





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 APRIL 2022

Primary Objective:

To evaluate the clinical efficacy of Travelan®, Florastor® and Bimuno® vs. placebo for maintenance of GH as measured by the combined endpoint of incidence of GH deficiencies (defined as 3 or more unformed stools in a 24-hour period OR 2 or more unformed stools and one or more associated symptoms in a 24-hour period) or antibiotic treatment for diarrhea per subject report, 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.

THE EFFICACY OF NON-ANTIBIOTIC OTC PRODUCTS IN TRAVELERS' DIARRHEA (TD) PREVENTION (P4TD)

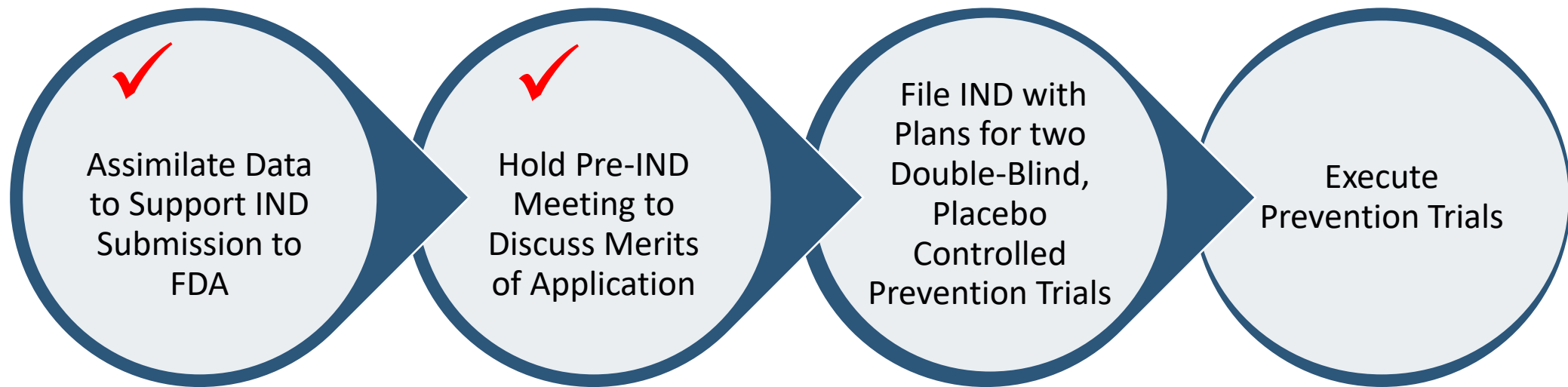


- The study products used in the clinical trial are considered dietary supplements not medicines approved by the FDA
- Clinical Trial Design approved by IRB not FDA
- Each product will be purchased commercially and packaged in sachets similar to placebo – subjects will be instructed to take 1 sachet twice a day with meals.
- Travelers and deployed personnel will be enrolled prior to departure and will begin taking the study product 3 days prior to arrival at destination, continuing for 10 days during travel.
- Enrollment will occur over a 24-month period



NMRC CAMPETEC DRUG DEVELOPMENT PLAN

Two Human Clinical Trials Planned: To evaluate the efficacy of the New Drug in Infectious Diarrhea Caused by ETEC and Moderate To Severe Campylobacteriosis



NMRC CAMPETEC DRUG DEVELOPMENT PLAN



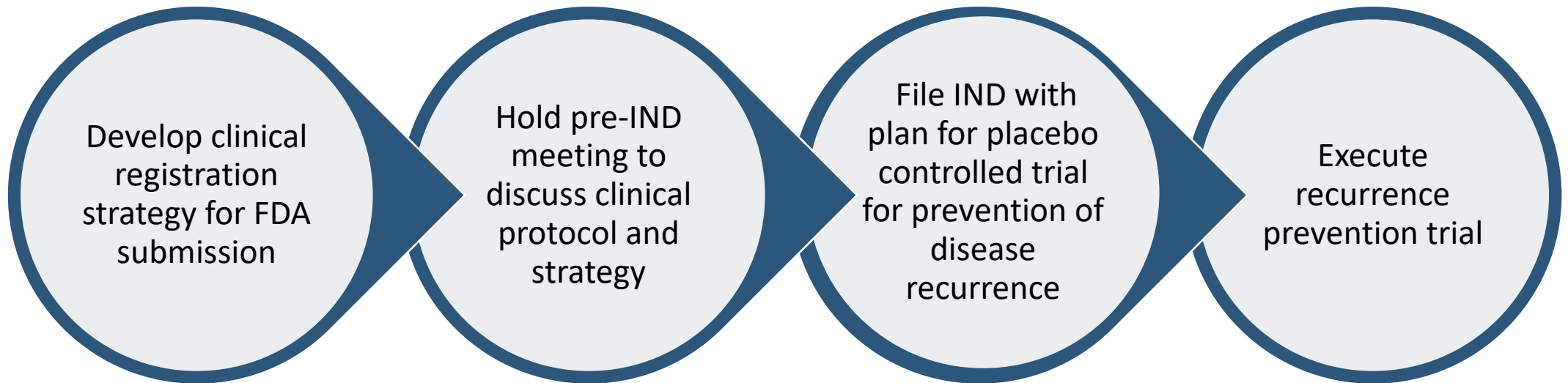
CURRENT STATUS

- **cGMP DRUG PRODUCT Manufacture**
 - Completed ✓
- **CLINICAL STUDY**
 - IND Application – In progress
 - FDA Review and Approval of IND – Q1 CY22
 - ETEC Study Initiation at John Hopkins – Q2 CY22



IMM-529 DRUG DEVELOPMENT PLAN

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



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IMM-529 DRUG DEVELOPMENT PLAN



CURRENT STATUS

- **COLOSTRUM PRODUCTION**
 - Completed ✓
- **DRUG SUBSTANCE**
 - cGMP manufacture – Q1 CY22
- **DRUG PRODUCT**
 - cGMP manufacture – Q2 CY22
- **CLINICAL DEVELOPMENT**
 - Clinical Protocol - Completed ✓
 - Clinical Sites & Principal Investigators – Identified ✓
 - Engaging with suitable CROs to support Clinical Development – In progress
- **REGULATORY**
 - Pre-IND Meeting on IMM-529 – 2H CY22

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



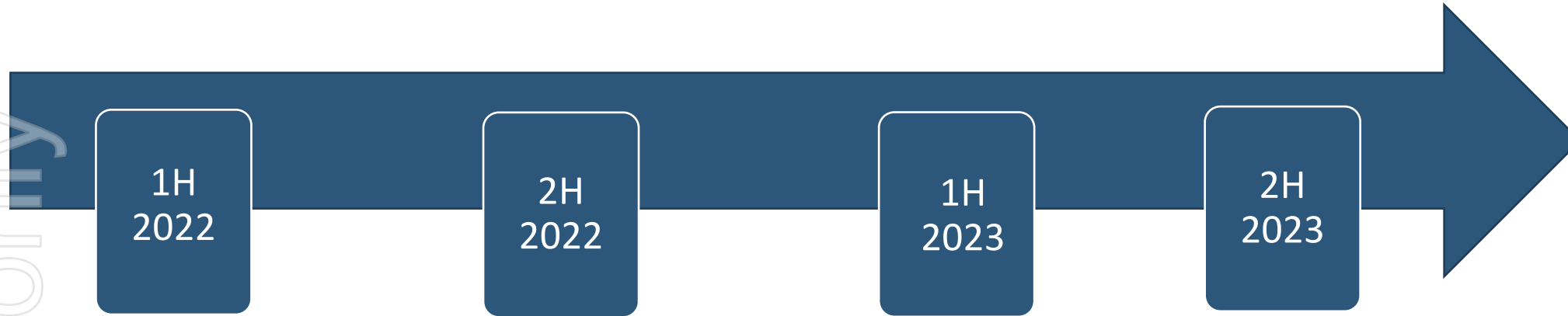
CURRENT STATUS

RESEARCH & DEVELOPMENT

- **Monash Research Services Agreement – Completed**
- **Research Agreement with Doherty Institute - Executed**
- The Aims of this work are as follows:
 - Testing of the neutralizing activity of the various fractions isolated by Monash University against the severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) in the cytopathic effect inhibition cell-based assay to be performed by The Doherty Institute – Study initiated December 2021 ✓
 - R&D Work to be expanded to include variants of concern – Draft protocols In progress
 - Murine mouse model for preclinical evaluation – Draft protocols in development



KEY MILESTONES EXPECTED TO DRIVE VALUE



- NMRC IND Submission (Q1 CY22)
- Initiate NMRC Phase 2 ETEC challenge study (Q2CY22)

- IMM-124E IND Submission
- IMM-529 cGMP Manufacture

- Topline Results NMRC ETEC Study
- Initiate NMRC Phase 2 Campylobacter challenge study
- Initiate IMC Phase 2 ETEC challenge study
- Pre-IND Meeting on IMM-529
- IMM-529 IND Submission

- Topline Results NMRC Campylobacter Study
- Topline Results IMM-124E ETEC Study
- Initiate Phase 2 CDI clinical study

- IMM-124E Infectious diarrhea pivotal field clinical study

Results from
US Grant application & COVID-19
Research Program expected YE2021

THANK YOU



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.