

# Immuron



## Biologics License Application (BLA) of a Bovine Immunoglobulin Supplement that prevents Travelers' Diarrhea caused by Enterotoxigenic *Escherichia Coli* (ETEC).

Award number: MTEC-21-10-NavyMultiTopic-013 ESG: MT21010.013

### Company Overview:

Immuron Ltd (NASDAQ:IMRN) (ASX:IMC) is a globally integrated biopharmaceutical company focused on developing, and commercializing, oral immunotherapeutics for the treatment of gut mediated diseases.

Travelan® | Immuron's flagship product is an over-the-counter immune supplement that targets pathogenic bacteria



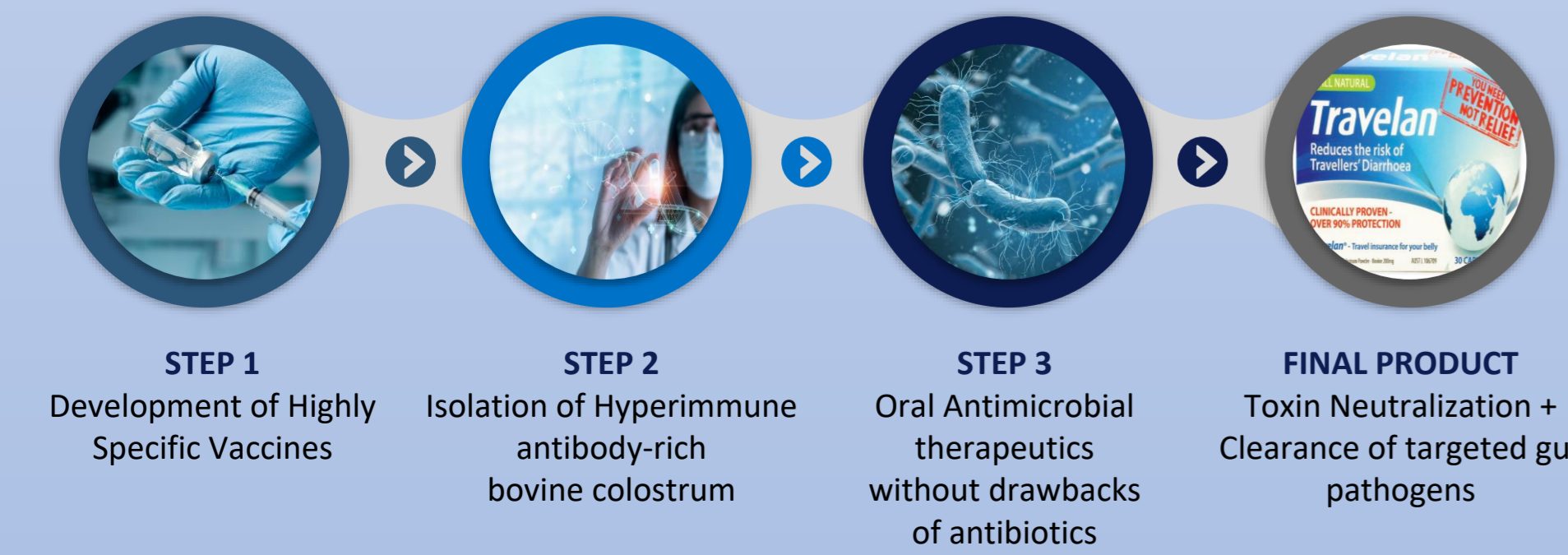
- ✓ World-first listed medicine to reduce risk of Travelers' Diarrhea AUST L 106709
- ✓ Natural health product NPN 80046016
- ✓ Dietary supplement



- ❖ >\$2.7 million AUD (net: A\$2.5M) sales (FY20)
- ❖ FY23 sales of A\$1.80 million up 136% on FY22
- ❖ Evaluating options to enter Asian and European markets through distributors
- ❖ Evaluating options to add to marketed products portfolio in FY24

### Platform Technology:

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.



### Travelan® / IMM-124E:

- ❖ IMM-124E is a hyperimmune bovine colostrum produced by immunisation of cows during gestation with a vaccine consisting of multiple Enterotoxigenic *E. coli* (ETEC) strains known to cause Travelers' diarrhea.
- ❖ Colostrum is harvested at birthing and manufactured to form a spray-dried powder enriched with anti-ETEC antibodies (>35% w/w), which bind and remove ETEC from the digestive system.
- ❖ Clinical studies demonstrated >90% protection in man against infection with ETEC in two phase 2 placebo-controlled clinical challenge studies (Otto et al., 2011)

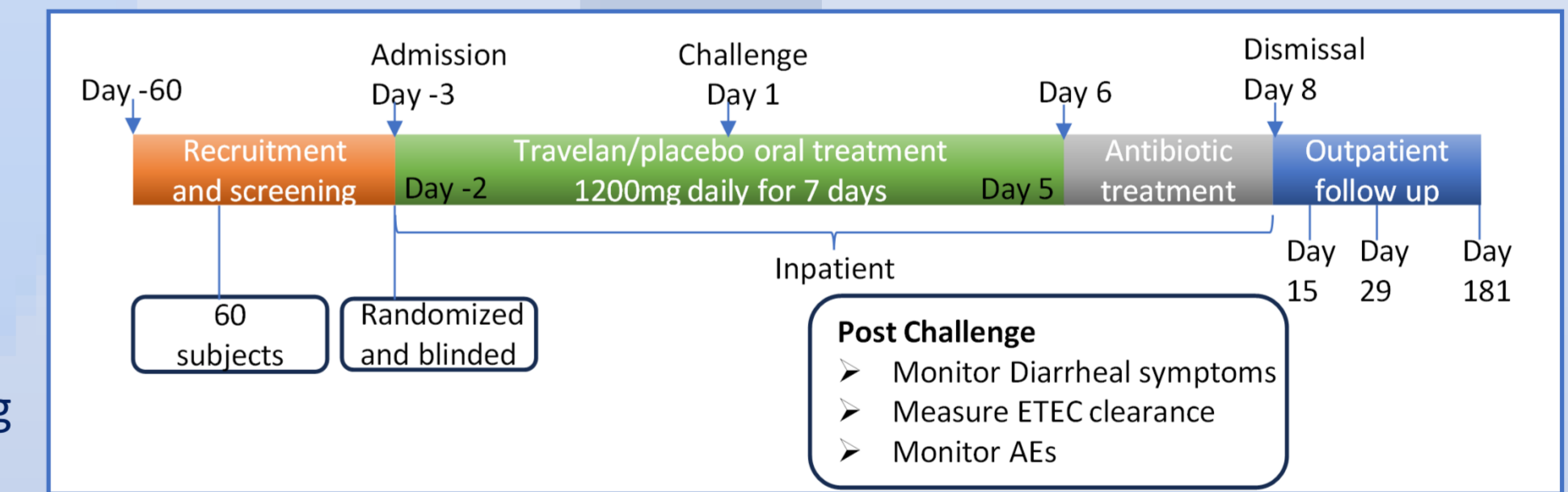


### Strategy for FDA approval of Travelan® for prevention of Travelers' Diarrhea:

**DRUG CANDIDATE IMM-124E**  
 FDA granted INDs:  
 014933, 015675  
 017066, 029087

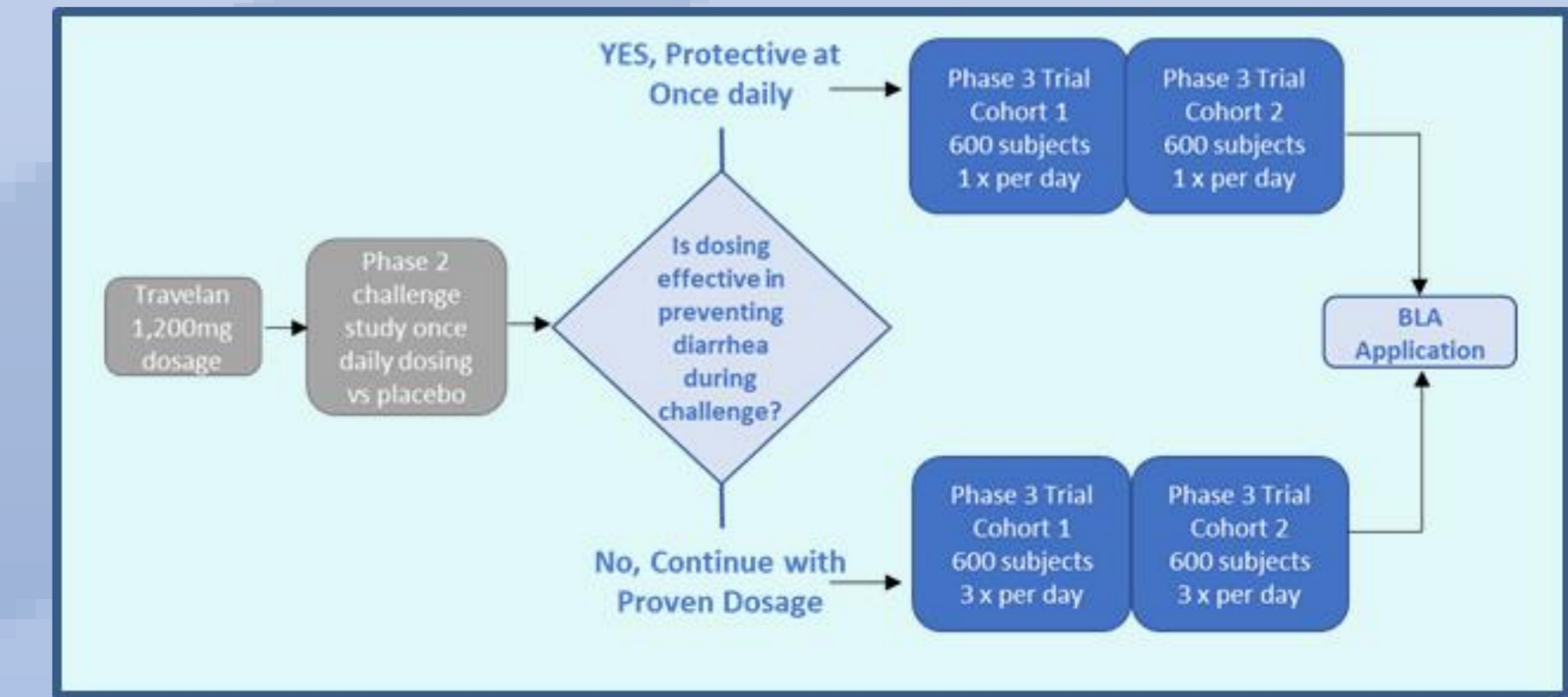
Plan to develop IMM-124E as an approved biologic in the USA targeting travelers' diarrhea

MTEC award granted to perform a controlled human infection model (CHIM) with a dosing schedule better suited to the military to assess the efficacy of Travelan® against moderate-to-severe diarrhea following challenge with ETEC strain H10407.



Overview of the IMM-124E clinical study

MTEC-funded clinical study will assist the overall strategy for Biologics License application of IMM-124E in the U.S. for prevention of Travelers' diarrhea



Clinical strategy for Biologics License application of Travelan®

### Immuron & U.S. Department of Defense Collaborations:

#### Clinical studies – current



**Phase 2 clinical study to evaluate a dosing regimen for Travelan® more suited for the military (MTEC#21010.013)**

- IMM-124E – FDA approved IND (Dec 2022)
- Initiated clinical trial May 2023: [NCT05933525](#)



**Phase 2 randomized field study (USU)**

- Evaluate the effectiveness of IMM-124E or placebo for prophylaxis during deployment or travel to a high travelers' diarrhea risk region
- Recruitment goal 868, current 284 [NCT04605783](#)



**CampETEC clinical study - colostrum specific for Campylobacter and enterotoxigenic *E.coli* (ETEC)**

- Immuron manufactured colostrum and sponsored Toxicology study (2022)
- FDA approved IND (May 2023)
- Clinical challenge study planned (Dec 2023)

#### Collaborative studies – current

	NMRC	AFRIMS	WRAIR	
Travelan® (ETEC)	✓	✓	✓	✓ Established
Campylobacter	✓			✓ Developing
Shigella	✓		✓	