



## Immuron Travelers' Diarrhea Market Update

### Key Points

- **Immuron's IMM-124E IND Program recommences**
- **Uniformed Services University to recommence planned Travelers' Diarrhea clinical study**
- **COVID-19 - Consultancy Agreement with Infectious Disease Epidemiologist at Wayne State University**

Melbourne, Australia, October 12, 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 provide shareholders and the market with an update on the planned clinical programs in Travelers' Diarrhea (TD).

The Board of Immuron has approved company plans to recommence the CMC related activities regarding its investigational drug IMM-124E required to support an investigational new drug (IND) application to the FDA and the proposed phase III clinical study in TD.

The company has recently been advised by the Uniformed Services University (USU) that it has recommenced the planned clinical trial program to evaluate the efficacy of non-antibiotic OTC products in Travelers' Diarrhea and will provide a purchase order for IMM-124E. USU's Infectious Diseases Clinical Research Program (IDCRP), the UK Ministry of Defense and the New York City Travel Clinic are jointly conducting a randomized clinical trial to evaluate the efficacy of these nutraceutical products for TD and inform strategies for Force Health Protection. The P4TD study is a randomized, double-blind, placebo controlled multicenter clinical trial designed to evaluate the effectiveness of 3 commercially available nutraceuticals: A prebiotic (Bimuno®), a probiotic (Florastor®) and IMM-124E (Travelan®) passive immunoprophylaxis versus a placebo, for prophylaxis during deployment or travel to a high-TD risk region. All study participants (1336 in total) will be randomized to one of the three active products or placebo (334 per arm).

The company is also pleased to announce that it has executed a consultancy agreement with Professor Teena Chopra, Professor of Medicine Wayne State University School of Medicine, Detroit Michigan. Professor Chopra is an Infectious Disease Epidemiologist with a specific interest in *Clostridioides difficile* (*C.difficile*) infections. Professor Chopra and her team recently published their research findings on patients at a hospital associated with the Detroit Medical Center presenting with both SARS-CoV-2 and *C.difficile*<sup>1</sup>. Both infections can manifest as digestive symptoms and merit screening when assessing patients with diarrhea. The hospitals associated with the Detroit Medical

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<sup>1</sup> <https://doi.org/10.3201/eid2609.202126>

Centre treated over 600 patients presenting with COVID-19 during the peak of the pandemic. Professor Chopra and her team noted most predominantly included pulmonary symptoms but a small subset of less than 10% of the cases also included gastrointestinal events. 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 and will be an invaluable resource to access.

“*C. difficile* infection (CDI) is a challenging disease, with a recurrence rate of 15%–20% and a mortality rate of 5%. When CDI is present as a co-infection with COVID-19, CDI therapy can be difficult to monitor if diarrhea persists because of COVID-19. Our most recent research findings highlight the importance of judicious use of antibiotics for potential secondary bacterial infection in patients with COVID-19. Antibiotics are known to have unintended consequences, such as *C. difficile* infection. We recently identified 9 patients in our study who were elderly, an age group at higher risk for complications from overuse of antibiotics, such as adverse events, antibiotic resistance, and concomitant infections like CDI. Immuron’s technology platform is intriguing because it potentially offers a non-antibiotic solution to this debilitating disease” said Professor Chopra.

This release has been authorised by the directors of Immuron Limited.

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#### About Immuron

Immuron Limited (ASX: IMC, NASDAQ: IMRN), is an Australian biopharmaceutical company focused on developing and commercializing orally delivered targeted polyclonal antibodies for the treatment of inflammatory mediated and infectious diseases. Immuron has a novel and safe technology platform with one commercial asset generating revenue. In Australia, Travelan® is a listed medicine on the Australian Register of Therapeutic Goods (AUST L 106709) and is indicated to reduce the risk of Travellers’ Diarrhea, reduce the risk of minor gastro-intestinal disorders and is antimicrobial. In Canada, Travelan® is a licenced natural health product (NPN 80046016) and is indicated to reduce the risk of Travellers’ Diarrhea. In the U.S., Travelan® is sold as a dietary supplement for digestive tract protection in accordance with section 403 (r)(6) of the Federal Drug Administration (FDA).

#### About Travelan®

Travelan® is an orally administered passive immunotherapy that prophylactically reduces the likelihood of contracting travelers’ diarrhea, a digestive tract disorder that is commonly caused by pathogenic bacteria and the toxins they produce. Travelan® is a highly purified tabletized preparation of hyper immune bovine antibodies and other factors, which when taken with meals bind to diarrhea-causing bacteria and prevent colonization and the pathology associated with travelers’ diarrhea. In Australia, Travelan® is a listed medicine on the Australian Register for Therapeutic Goods (AUST L 106709) and is indicated to reduce the risk of Travelers’ Diarrhea, reduce the risk of minor gastro-intestinal disorders and is antimicrobial. In Canada, Travelan® is a licensed natural health product (NPN 80046016) and is indicated to reduce the risk of Travelers’ Diarrhea. In the U.S., Travelan® is sold as a dietary supplement for digestive tract protection.

#### About Travelers’ diarrhea

Travelers’ diarrhea is a gastrointestinal infection with symptoms that include loose, watery (and occasionally bloody) stools, abdominal cramping, bloating, and fever, Enteropathogenic bacteria are responsible for most cases, with enterotoxigenic *Escherichia coli* (ETEC) playing a dominant causative role. *Campylobacter* spp. are also

responsible for a significant proportion of cases. The more serious infections with *Salmonella* spp. the bacillary dysentery organisms belonging to *Shigella* spp. and *Vibrio* spp. (the causative agent of cholera) are often confused with travelers' diarrhea as they may be contracted while travelling and initial symptoms are often indistinguishable.

For more information visit: <http://www.immuron.com>

**FORWARD-LOOKING STATEMENTS:**

This press release may contain "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, each as amended. Such statements include, but are not limited to, any statements relating to our growth strategy and product development programs and any other statements that are not historical facts. Forward-looking statements are based on management's current expectations and are subject to risks and uncertainties that could negatively affect our business, operating results, financial condition and stock value. Factors that could cause actual results to differ materially from those currently anticipated include: risks relating to our growth strategy; our ability to obtain, perform under and maintain financing and strategic agreements and relationships; risks relating to the results of research and development activities; risks relating to the timing of starting and completing clinical trials; uncertainties relating to preclinical and clinical testing; our dependence on third-party suppliers; our ability to attract, integrate and retain key personnel; the early stage of products under development; our need for substantial additional funds; government regulation; patent and intellectual property matters; competition; as well as other risks described in our SEC filings. We expressly disclaim any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in our expectations or any changes in events, conditions or circumstances on which any such statement is based, except as required by law.