Immuron Plans Phase 3 trial for IMM-124E to Prevent Travelers' Diarrhea

Key Points

- **Immuron completes first meeting with FDA on development of IMM-124E as product to specifically prevent Travelers' Diarrhea (TD)**
- **Phase 3 clinical trial of IMM-124E to prevent TD planned for 2020**
- **Previous clinical trial data on IMM-124E from earlier studies provides support for development as treatment to prevent TD**

Melbourne, Australia, November 21, 2019: Immuron Limited (ASX: IMC; NASDAQ: IMRN), an Australian biopharmaceutical company focused on developing and commercializing oral immunoglobulin therapeutics for the treatment of gut mediated diseases, today announced that the company recently completed a Pre-IND meeting with the U.S. Food and Drug administration (FDA) regarding its investigational drug IMM-124E which the company is developing to treat travelers' diarrhea (TD). Following the FDA's guidance and feedback, the Company now plans to file an investigational new drug (IND) application for IMM-124E to prevent TD during the first half of 2020, followed by a Phase 3 trial of IMM-124E to prevent TD in individuals traveling to areas where TD is endemic.

"We already have a great deal of clinical experience with IMM-124E due to an earlier clinical trial the Company conducted with this drug candidate in a clinical study in patients with nonalcoholic steatohepatitis under a separate IND," said Dr. Gary S. Jacob, CEO of Immuron Ltd. "Our recent interactions with FDA were exceedingly helpful in refining plans for this Phase 3 trial. To our knowledge, IMM-124E, once successfully shown to work in subjects traveling to endemic areas, and successfully approved, would be the first and only FDA-approved pharmaceutical product to specifically prevent diarrhea."

Travelan® and IMM-124E, Immuron's drug candidate presently in clinical development for TD, are one and the same active pharmaceutical ingredient. The Company currently markets and sells Travelan® as a Therapeutic Goods Administration (TGA) listed medicine for prevention of TD in Australia, and also markets Travelan® in the U.S. and Canada as a dietary supplement, and natural health product, respectively, for digestive tract protection.

ABOUT IMM-124E

IMM-124E is a first-in class, oral polyclonal antibody therapy currently being developed as a prophylactic treatment to prevent TD in individuals traveling to endemic areas for ETEC exposure. In an earlier study completed in 133 biopsy-proven NASH patients where patients were treated with either IMM-124E or placebo for 6 months, treatment with IMM-124E resulted in a statistically significant reduction of serum LPS levels when compared to placebo. In addition,

biomarkers associated with inflammation were also reduced by IMM-124E including ALT, AST and cytokeratin-18. IMM-124E was developed to target the endotoxin lipopolysaccharide (LPS) and other pathogenic bacterial components in the human gastrointestinal tract to potentially reduce LPS-related inflammation and systemic translocation.

ABOUT TRAVELAN®

Travelan® is a highly purified tabletized preparation of hyper-immune bovine antibodies and other factors, which when taken with meals is believed to bind to diarrhea-causing bacteria, preventing colonization and the pathology associated with TD. 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 TD, 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 TD. In the U.S., Travelan® is sold as a dietary supplement for digestive tract protection.

ABOUT TRAVELERS' DIARRHEA

Travelers' diarrhea (TD) affects between 30 and 70% of over one billion international travelers every year. TD 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 TD as they may be contracted while travelling and initial symptoms are often indistinguishable.

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 technology platform with one commercial asset Travelan® generating revenue. Immuron's lead clinical candidate, IMM-124E, is presently being developed as a drug to prevent TD. The Company also has a collaborative program with the U.S. Department of Defense (DoD) to develop treatments utilizing the Company's hyperimmune bovine colostrum technology against enteric acute infectious pathogens, including Shigella and Campylobacter. A recent USD $3.7 million grant was awarded by DoD to develop a product against Campylobacter utilizing this technology. Immuron's second clinical-stage asset, IMM-529, targets *Clostridium difficile* Infections (CDI). These products together with the Company's other preclinical pipeline products currently under development targeting immune-related and infectious diseases are anticipated to meet pressing needs in the global immunotherapy market.

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

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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.