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US DoD Naval Medical Research Center Requests Meeting with FDA for Guidance on two Phase 2 trials to Prevent Acute Infectious Diarrhea

Key Points

- **NMRC requests Pre-IND meeting with FDA on the development of a new oral therapeutic targeting Campylobacter and ETEC**
- **Two human phase II clinical trials to be conducted in 2021**
- **One trial will focus on the ability of the hyperimmune product to protect volunteers against moderate to severe campylobacteriosis**
- **The second trial will focus on ETEC infections**

Melbourne, Australia, June 9, 2020: Immuron Limited (ASX: IMC; NASDAQ: IMRN), an Australian biopharmaceutical company focused on developing and commercializing oral immunotherapeutics for the prevention and treatment of gut mediated pathogens, today is pleased to provide shareholders with an update on the company's research collaboration with the Naval Medical Research Center (NMRC) to develop and clinically evaluate a new therapeutic against campylobacter and ETEC (E-Coli). The NMRC recently requested a Pre-IND meeting with the U.S. Food and Drug administration (FDA) regarding its new investigational drug which the company is developing to treat moderate to severe campylobacteriosis and ETEC infections.

The FDA on the 26 May 2020 issued guidance explaining how the coronavirus disease public health emergency is impacting the conduct of formal meetings and its review of certain user fee-funded applications. The FDA will focus its resources on applications and submissions related to Covid-19 and other life-threatening conditions. The FDA will still aim to conduct initial investigational new drug application (IND) 30-day safety reviews and respond to "other important safety issues that may emerge during IND development". The agency will provide written comments on the non-clinical information in the Pre-IND information package which is planned to be submitted on the 10th of June 2020. Following the FDA's guidance and feedback, the NMRC plans to file an investigational new drug (IND) application later this year and commence the Phase 2 clinical studies during the first half of 2021.

"We received a formal start work notification and approval at the end of January 2020 from the Henry Jackson Foundation for the Advancement of Military Medicine to commence work on the sub award" said Dr. Jerry Kanellos, CEO of Immuron Ltd.

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"The Australian Importation permit required to ship the vaccines from the NMRC was approved by Biosecurity Australia and the NMRC vaccines were shipped to our contract research partner to commence the project. The COVID-19 pandemic put the brakes on this and all our research and development activities. We have been monitoring the situation closely and I am please to say with the easing of restrictions around Australia work on the development of the clinical product can now recommence. The plan is to have the product completed by the end of this year and have it ready for clinical evaluation next year."

The COVID-19 pandemic has also impacted the IMM-124E pediatric clinical study in Nonalcoholic Fatty Liver Disease. The study's Principle Investigator Dr Miriam Vos from the Emory University School of Medicine closed the study earlier this year with only 22 subjects out of a target 40 completed the study protocol. The study findings were reported as negative as there was no substantial changes in ALT (Primary study end point) in the active arm of the study when compared to placebo.

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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.

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

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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).

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.

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