Immuron Opens Clinical Site to Evaluate Safety and Efficacy of IMM-529 for Treatment of Clostridium Difficile Infection (CDI)

Key Highlights:

- ***Immuron's clinical study of IMM-529 initiated at Hadassah Medical Centre***
- ***First of 60 Clinical Study Patients to be enrolled by mid-September***
- ***Trial to evaluate Safety and Efficacy of IMM-529 drug product compared to placebo control***
- ***450,000 CDI cases reported annually in the USA resulting in 29,300 deaths in 2015***

Melbourne, Australia, August 28th, 2017: Immuron Limited (ASX: IMC; NASDQ: IMRN), an Australian microbiome biopharmaceutical company focused on developing and commercializing oral immunotherapeutics for the treatment of many gut mediated diseases, today announced the successful site initiation of its first-in-human, IMM-529 clinical study for the treatment of Clostridium Difficile Infection (CDI).

Immuron is pursuing the biopharmaceutical research and development of an effective and safe treatment of CDI which according to the Centre for Disease Control and Prevention (CDC), infects more than 450,000 patients causing over 29,000 deaths, per year in the United States alone. The IMM-529 drug product has been shown in pre-clinical tests to be an effective treatment. Success in this trial will provide a firm foundation to the Board and Management that the Company's IMM-529 drug product has significant potential for continued clinical development.

Following Immuron's announcement to the market on August 9th, 2017 advising receipt of approval from the Israeli Ministry of Health's (MoH) and the Hadassah Medical Center Ethics Committee to perform the clinical study, Immuron has now implemented the opening of the site to enroll the first of 60 patients by mid-September 2017.

This Phase I/II randomised, double-blind, placebo-control clinical study is designed to evaluate the safety and preliminary efficacy of Immuron's IMM-529 drug product for the treatment of CDI.

Eligible patients will be randomized and in addition to their standard of care treatment will receive either IMM-529 or placebo three times daily for a total of 28 days which will then be followed by two months of

monitoring for any recurrence of disease. The primary objective of the study is to assess patient safety and tolerability of IMM-529, while secondary endpoints will evaluate the preliminary efficacy of the product evaluated by determining duration and severity of symptoms, and the rate of recurrence. Topline results are anticipated in the fourth quarter of 2018.

The study will be conducted under the leadership of Professor Yoseph Caraco, who is the head of the Clinical Pharmacology Unit at Hadassah Medical Center in Jerusalem, which specializes in early stage clinical studies.

The protocol for the study was jointly developed by Immuron with Professor Caraco and Professor Allon Moses, Chairman of the Department of Clinical Microbiology and Infectious Diseases, and Professor Jacob Strahilevitz of the Department of Clinical Microbiology and Infectious Diseases at Hadassah.

"Immuron's IMM-529 compound is a unique combination of polyclonal antibodies, targeting all main virulence factors of CDI," said Dr. Dan Peres, Chief Medical Officer at Immuron. "We anticipate IMM-529 will exhibit the same level of safety as previously demonstrated with our other compounds, while its "one-of-a-kind" mechanism of action should relieve the diseased gut of the infectious and toxic burden to allow the microbiome to recuperate and reinstate homeostasis."

We believe there is a true void in the market for an effective treatment of CDI, and we are confident this compound presents a solution for the many patients diagnosed with CDI each year."

About IMM-529:

IMM-529 is an oral compound taken three times per day consisting of a combination of polyclonal antibodies targeting the *Clostridium-Difficile's* toxin B responsible for the clinical manifestation of the disease, as well as the spores and the vegetative cells which are thought to be the primary cause of the recurrences. The delivery of IMM-529 results in localized toxin B neutralization, while binding to the C-Diff spores and vegetative cells to prevent further colonization. IMM-529 antibodies have been shown to survive transit through the stomach and remain functional up through the large intestine.

In addition, the antibodies in IMM-529 have demonstrated to cross-react with a variety of human and animal C. *difficile* isolates and their associated toxin B vegetative cell and spore components. The antibodies in IMM-529 have also been shown to neutralize Toxin B from a historical C. *difficile* strain (630), and from a hypervirulent (HV) strain which caused the worldwide outbreaks in 2011.

In preclinical studies, IMM-529 demonstrated superiority in prophylactic use, treatment of disease, and the prevention of recurrence. All results were published in the Nature Journal Scientific Reports earlier this year (Hutton *et al* Scientific Reports 2017;7:3665).

About CDI:

Clostridium difficile is the causative organism of antibiotic-associated colitis. Colonization is facilitated by disruption of normal intestinal flora due to antimicrobial therapy. The organism is capable of elaborating exotoxins that bind to receptors on intestinal epithelial cells, leading to inflammation and diarrhea and, in severe cases, death. *Clostridium difficile* Infection (CDI) has become a major-medical concern causing an estimated annual economic burden of more than US$10 billion globally. The problem is especially acute in hospitals and in long-term in-patient care facilities. Over 453,000 cases of recurrence are recorded annually while an estimated 29,300 patients die each year from CDI infections in the USA alone (** CIDRAP Center for Infectious Disease Research and Policy (Feb 2015)*).

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ABOUT IMMURON:

Immuron Ltd (ASX: IMC) is a biopharmaceutical company focused on developing and commercialising oral immunotherapeutics for the treatment of many gut mediated diseases. Immuron has a unique and safe technology platform that enables a shorter development therapeutic cycle. The Company currently markets and sells Travelan® for the prevention of travellers' diarrhea whilst its lead product candidate IMM-124E is in Phase 2 clinical trials for NASH and ASH. These products together with the Company's other preclinical immunotherapy pipeline products targeting immune-related diseases currently under development, will meet a large unmet need in the market. For more information visit: **http://www.immuron.com**

FORWARD-LOOKING STATEMENTS:

Certain statements made in this release are forward-looking statements and are based on Immuron's current expectations, estimates and projections. Words such as "anticipates," "expects," "intends," "plans," "believes," "seeks," "estimates," "guidance" and similar expressions are intended to identify forward-looking statements. Although Immuron believes the forward-looking statements are based on reasonable assumptions, they are subject to certain risks and uncertainties, some of which are beyond Immuron's control, including those risks or uncertainties inherent in the process of both developing and commercialising technology. As a result, actual results could materially differ from those expressed or forecasted in the forward-looking statements. The forward-looking statements made in this release relate only to events as of the date on which the statements are made. Immuron will not undertake any obligation to release publicly any revisions or updates to these forward-looking statements to reflect events, circumstances or unanticipated events occurring after the date of this release except as required by law or by any appropriate regulatory authority.