Immuron Approved to Commence Clinical Study in C.Difficile Infection (CDI)

Key Highlights

- **Final approval for key first in-human Clinical Study for CDI treatment, by Israeli Ministry of Health**
- **An estimated 28,000 patients die each year from CDI infections in the USA alone**
- **Study of 60 CDI patients to commence at Jerusalem's Hadassah Medical Centre in Sept 2017**
- **Study designed to demonstrate Safety, Tolerability and Preliminary Efficacy of IMM-529**
- **IMM-529 shows effectiveness against a range of clinically relevant C. *difficle* bacteria strains**
- **Top line results from the clinical trial expected in Q4 2018**

Melbourne, Australia, August 9th, 2017: Australian microbiome biopharmaceutical company Immuron Limited (ASX: IMC; NASDQ: IMRN) today announced it has been granted final approval to commence its first in-human, IMM-529 clinical study for the treatment of Clostridium Difficile Infection (CDI). Approval was received from both the Hadassah Medical Center Ethics Committee, as well as the Israeli Ministry of Health's (MoH) office.

Immuron's CDI clinical trial is designed to study a total of 60 patients diagnosed with CDI and have received standard of care antibiotic treatment. Patients will be enrolled within three weeks of their diagnosis and will be randomized into either IMM-529 three times daily, or placebo, for 28 days. The primary objective of the study is to assess IMM-529's safety and tolerability, while secondary end points are to evaluate the preliminary efficacy of IMM-529 as evaluated by duration and severity of symptoms and rate of disease recurrence.

The study is to be conducted at Hadassah Medical Center in Jerusalem, Israel and is scheduled to be initiated within the next few weeks. This is the Immuron's first human clinical study using IMM-529 following the outstanding results reported from a series of proof-of-concept pre-clinical efficacy studies completed by Dr Dena Lyras and her research team at Monash University. The results from the Monash University study were recently published in the Nature Journal Scientific Reports in June 2017.

Dan Peres, MD, Immuron's Chief Medical Officer commented;

> *"The approval process conducted by both the Ethics Committee, and the Israeli Ministry of Health, demonstrates that the regulators deem our product's safety profile favorably. We are excited to take the Monash University team's extensive and successful results into human subjects to help these patients overcome CDI. IMM-529 offers a novel and safe solution to a growing problem and we hope this preliminary data will lead us to the next stage of the clinical development process."*

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Immuron's program is unique as it not only targets the toxin B, secreted by the bacteria causing the clinical manifestations of disease, epithelial cell death and extensive colonic inflammation but also the spores and the vegetative cells which are thought to be the primary cause of the recurrences making C. *difficile* so difficult to treat.

About Immuron's IMM-529:

IMM-529 is a naturally produced polyclonal antibody biological product intended to prevent and treat C. *difficile* infections and designed to spare the gut microbiome from the effects of "classic" antibiotic treatments, allowing the microbiome to recuperate to its healthy state. IMM-529 antibodies have been shown to survive transit through the stomach and remain functional in the large intestine. The delivery of IMM-529 results in localized toxin B neutralization at the site of infection and prevents severe damage occurring to the gut while also binding to C-Diff spores and vegetative cells preventing further colonization.

In addition, the antibodies in IMM-529 have demonstrated cross-reactions 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 recent worldwide outbreaks.

About CDI:

CDI has become a major-medical problem 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 due to bacteria produce toxins causing inflammation of the colon resulting in severe diarrhea and, in severe cases, death. An estimated 28,000 patients die each year from CDI infections in the USA alone, while recurrent CDI affects ~100,000 people in the U.S. annually.

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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.