Immuron Enrols First Patients in Clinical Study of IMM-529 for Treatment of Clostridium Difficile Infection (CDI)

Key Highlights:

- *First patients enrolled in Immuron's IMM-529 clinical study at Hadassah Medical Center in Israel*
- *Trial will treat 60 confirmed patients over 28 days to evaluate safety and efficacy of IMM-529 for the treatment of CDI*
- *CDI is one of the top superbugs challenging the healthcare industry as its germs spread easily, often requires antibiotic treatment, and leaves patients vulnerable to infections*
- *450,000 CDI cases reported annually in the USA increasing healthcare costs from $3K to $10K per patient*

Melbourne, Australia, January 31, 2018: Immuron Limited (ASX: IMC; NASDQ: IMRN), an Australian microbiome biopharmaceutical company focused on developing and commercializing oral immune-therapeutics for the treatment of gut mediated diseases, today announced the enrollment of the first patients into the first-in-human IMM-529 clinical study for the treatment of *Clostridium Difficile* Infection (CDI). Most commonly affecting older adults after use of antibiotic medications, CDI can cause symptoms that range from diarrhea to life-threatening gut inflammation.

The Immuron CDI clinical study is a Phase I/II placebo-controlled study focusing on the safety, tolerability, and preliminary efficacy of IMM-529. Preliminary efficacy will be assessed by duration and severity of symptoms, as well as the rate of disease recurrence when compared to administered placebo. A total of 60 confirmed CDI patients will be randomized to receive either IMM-529 or a placebo three times a day for a total of 28 days. Patients will then be monitored for two additional months to determine any recurrence of disease.

The study is led by Professor Yoseph Caraco, head of the Clinical Pharmacology Unit at Hadassah Medical Center in Jerusalem. It is the Company's first in-human clinical study using IMM-529 for the treatment of CDI, as its previous pre-clinical efficacy studies completed by Dr. Dena Lyras and her research team at Monash University showed significant potential in all disease phases. Topline results are anticipated in the first quarter of 2019.

The Study's Principle Investigator (PI) Professor Yoseph Caraco commented:

"Clostridium-difficile is posing a growing risk amongst a greater population of patients, including those recently treated with antibiotics, the elderly, institutionalized and hospitalized. Since 2000, dramatic

increases in the incidence and severity of healthcare-associated C. difficile infection have occurred, particularly in patients over the age of 65.

Immuron's proposed approach of targeting the main virulence factors of the disease with only a minor disturbance to the natural microbiome would potentially be extremely valuable in treating CDI. In view of the preclinical work performed on IMM-529, I am optimistic that IMM-529's mechanism of action might be the answer we're all looking for. "

According to the Centers for Disease Control and Prevention (CDC) [1], Clostridium-difficile infects more than 450,000 patients causing over 29,000 deaths per year in the United States alone. There is a high likelihood for recurrence of symptoms, which nearly triples the healthcare costs per patient, resulting in annual healthcare costs of nearly $4.5 billion. The CDC also cites the importance of developing new treatments including the need for improved antibiotic use and infection control.

IMM-529 uses a combination of polyclonal antibodies to target and neutralize the three main virulence factors of CDI without negatively impacting the microbiome. The drug is unique in that it targets the spores and vegetative cells that are thought to be the primary cause of the recurrences, alongside the Toxin B which is targeted by most therapeutics in development today. The compound, which is delivered orally three times a day, provides a solution that is easily tolerable to patients to treat and prevent recurrence of CDI.

Immuron's Chief Medical Officer Dr. Dan Peres commented:

"We are excited to enrol our first patients into the IMM-529 study, a drug that has shown promise in successfully treating Clostridium-difficile. Our technology's unique delivery of antibodies clearly differentiates it from other Clostridium-difficile treatments on the market or in development.

We believe the results of this approach, as already reflected in our pre-clinical studies, will continue to garner attention from the pharmaceutical industry and the medical community. We look forward to the top line results in the beginning of 2019."

[1] https://www.cdc.gov/media/releases/2015/p0225-clostridium-difficile.html

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 *Clostridium-Difficile* 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 cells 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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COMPANY CONTACT:

Jerry Kanellos
Chief Executive Officer (Interim)
Ph: +61 (0)3 9824 5254
jerrykanellos@immuron.com

AUS INVESTOR RELATIONS:

Peter Taylor
NWR Communications
Ph: +61 (0)4 1203 6231
peter@nwrcommunications.com.au

USA MEDIA CONTACT:

Kate Caruso-Sharpe
FischTank Marketing and PR
US Ph: + 1 646 699 1414
kate@fischtankpr.com

USA INVESTOR RELATIONS:

Jon Cunningham
RedChip Companies, Inc.
US Ph: +1 (407) 644 4256, (ext. 107)
jon@redchip.com

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.