

PRESS RELEASE: May 10, 2017

# D Immuron Completes Manufacturing of IMM-529's Clinical Supplies for Treatment of CDI

- IMM-529 is Immuron's second therapeutic drug candidate to proceed toward clinical trials
- IMM-529 is targeting Clostridium difficile Infections (CDI), a disease with worldwide unmet need

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# Immuron Completes Manufacturing of IMM-529's Clinical Supply for Treatment of CDI

**Melbourne, Australia, 10 May 2017:** Australian microbiome biopharmaceutical company Immuron Limited (ASX: IMC) today announced that it has successfully completed manufacturing trial supplies of its clinical drug product candidate IMM-529, a first-in-class oral immunotherapeutic targeting the prevention of Clostridium *difficile* Infection (CDI) recurrence.

IMM-529 was manufactured by the Commonwealth Scientific and Industrial Research Organisation (CSIRO) Separations Science team and Pharmaceutical Packaging Professionals in part with a grant of \$50,000 from the Food Innovation Australia Limited (FIAL) Enterprise Solutions Centre Program.

Commented Thomas Liquard, CEO of Immuron:

"We are thrilled to have completed this very important milestone. **IMM-529 is the second therapeutic drug** candidate the Company is progressing toward clinical trials. This demonstrates that Immuron's platform has the potential to develop multiple therapeutics which may result in several revenue opportunities for the Company in the future."

Human safety and efficacy studies (Phase 1/2 clinical trial) of IMM-529 will start by the end of Q2-2017, and will be building on the positive pre-clinical results reported from a series of proof-of-concept efficacy studies completed by Dr. Dena Lyras and her research team from Monash University in Melbourne, Australia.

Immuron's Chief Operating & Research Officer Dr. Jerry Kanellos said:

"We are very pleased as we continue to takes steps to bring another compound into clinical trials from Immuron's extensive intellectual property portfolio. IMM-529 is the most advanced clinical program within our early-stage Research & Development portfolio and we are grateful for the financial support provided by FIAL.

Our planned Phase I/II clinical trials of IMM-529 will evaluate the safety and efficacy of this immunotherapy, in combination with existing standards of care, in 60 patients with acute and chronic CDI. We are planning to initiate the study by the end of 2Q2017 at Hadassah University in Israel, which is a major center for the treatment of CDI, and we anticipate that the results will be available in mid-2018."

CDI has become a major-medical problem causing an estimated annual economic cost of more than US\$10 billion globally. The problem is especially acute in hospitals and in long-term in-patient care facilities. An estimated 29,000 patients die each year from CDI in the U.S. alone. Recurrent CDI affects approximately 100,000 people in the U.S. annually.

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IMM-529 is a biological product which is intended to prevent and treat CDI without destroying the microbiome like antibiotic treatments, allowing the microbiome to return to a healthy state. The antibodies survive transit through the stomach and remain functional in the large intestine. The antibodies in IMM-529 result in localised toxin B neutralisation at the site of infection before significant damage is done, binding to spores and vegetative cells in the gut and preventing toxin B translocation into the blood supply.

The antibodies in IMM-529 have been demonstrated to be cross-reactive with a variety of human and animal C. *difficile* isolates and to their associated Toxin B, vegetative cell and spore components. The antibodies in IMM-529 have also been shown to neutralise Toxin B from a multi-drug resistant C. *difficile* strain (630) and from a hypervirulent (HV) strain which caused the recent worldwide outbreaks. In comparison to other clinical programs in CDI, Immuron's program is unique as it not only targets the Toxin B but also the spores and the vegetative cells which are thought to be the primary cause of the recurrences that make CDI so difficult to treat.

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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 forwardlooking 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.

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