

## Immuron Reports Highly Successful Completion of Pre-Clinical Proof-of-Concept Program in Clostridium Difficile

**Melbourne, Australia, 22 December 2015:** Australian microbiome biopharmaceutical Company Immuron Limited (ASX:IMC), today announces that it has successfully completed its pre-clinical proof-of-concept (POC) program in *Clostridium difficile* (*C. difficile*) with outstanding efficacy results.

Earlier this year, Immuron and researchers at Monash University, commenced testing IMM-529 *C. difficile* vaccines for characterisation and pre-clinical POC studies for animal efficacy trials. The vaccines were shown to contain highly specific antibodies to either toxin B, the highly infectious spores, or the vegetative cells which colonise the gut. **The results of these pre-clinical studies showed 80% efficacy in both the treatment and the prevention of *C. difficile* infections without the use of antibiotics.**

*"We are very pleased with these results and with our strong collaboration with Associated Professor Lyras and her team at Monash University,"* said Dr Jerry Kanellos, Immuron's Chief Operating and Scientific Officer.

*"Associate Professor Lyras is a world-renowned *C. difficile* expert and is the first researcher to report the clinical importance of toxin B in the pathology of the disease. These studies are an important validation of the strategic approach taken by Immuron and Monash University in the design of our oral immunotherapeutic products for *C. difficile* infections."*

In commenting on the recent pre-clinical results Associate Professor Lyras said:

*"We are thrilled to have been able to generate these outstanding results and I am excited by the potential of these therapeutics in treating patients with both the acute, and the relapse phase, of the disease. **It is difficult to obtain such promising outcomes without resorting to antibiotic use and these results are a testament to the strength of the Immuron platform and the potency of these vaccines.** *C. difficile* is an increasingly hard disease to treat and new treatment modalities are desperately needed."*

Immuron and Monash University will continue to analyse the results of the studies and additional announcements will be forthcoming. The team aims to publish these results as soon as possible and to present these results at a conference in 2016.

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*C. difficile* infections have 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 long-term care facilities because the bacteria produce toxins that cause inflammation of the colon resulting in severe diarrhea and in serious cases, death. An estimated 28,000 patients die each year from such infections in the USA alone. Recurrent CDI affects ~100,000 people in the U.S. annually.

Current therapies are based on antibiotics that have limited efficacy and cause an imbalance in the microbiome that may result in the recurrence of the disease. Several companies\* are pursuing new therapeutics to combat *C. difficile*, including Merck's recently completed pivotal Phase III Bezlotoxumab intravenous program which targets toxin B with a monoclonal antibody designed to prevent recurrence of *C. difficile*.

However, Immuron's program is unique as it is not only targets toxin B, but also the spores and the vegetative cells which are thought to be the primary cause of the recurrences that make *C. difficile* so difficult to treat. IMM-529 is also a natural product and does not destroy the microbiome like antibiotic treatments, allowing the microbiome to return to a healthy state.

Immuron's Chief Executive Officer, Mr Thomas Liquard, added;

*"These POC results further highlight the strength of Immuron's outstanding technology platform.*

*IMM-529 program is comprised of first-in-class and highly differentiated compounds that have the potential to fundamentally change the treatment paradigm for patients afflicted with C. difficile. We are now focused on assembling a clinical development plan for IMM-529 with the objective to take this program into the clinic as quickly as possible."*

Immuron is also pursuing animal recurrence studies and these are progressing as planned. Results will be available in January 2016. Positive results would mean that IMM-529 could be utilised in all three phases of the disease include prevention, initial treatment and recurrence, the later representing the largest unmet need in the fight against *C. difficile*.

\* Seres Therapeutics (US\$1.6B market cap); Synthetic Biologics (US\$224M market cap); Assembly Biosciences (US\$140M market cap); Summit Therapeutics (US\$125M market cap); All figures as of December 21, 2015.

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**About Immuron:**

Immuron Ltd (ASX: IMC; OTCQB: IMROY) is a microbiome company focused on developing and commercialising oral immunotherapeutics for the treatment of a 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' diarrhoea, whilst its lead product candidate IMM-124E is in Phase 2b 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.

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