

Immuron Announces Statistically Significant Results of Triple-Action Anti-Infective IMM-529 in Pre-Clinical Clostridium difficile Recurrence Studies

Melbourne, Australia, 12 January 2016: Australian microbiome biopharmaceutical company Immuron Limited (ASX: IMC) today announced that IMM-529, a first-in-class oral therapeutic, successfully demonstrated prevention of Clostridium difficile (C. difficile) infection recurrence in over 77.8% of infected mice.

The mouse model developed by Associate Professor Dena Lyras and her team at Monash University was designed to evaluate the effectiveness of IMM-529 when used in conjunction with standard of care antibiotic treatment. Combination therapy with IMM-529 and vancomycin significantly reduced disease recurrence and mortality to 22.2% compared to 88.9% mortality in the control, vancomycin only group. The results were statistically significant.

The team now aims to publish these results as soon as possible and will present these results at a conference later this year.

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

"We are delighted with these findings. This is a key proof of concept study which confirms the clinical potential for this class of drug in the treatment of C. difficile. We now have successfully demonstrated in three preclinical models that IMM-529 can be utilized as a therapeutic in all three aspects of the disease including prevention, treatment of primary disease and recurrence, the latter representing a growing unmet need in the fight against C. difficile."

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 causing 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*, 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 a biologic which is intended to prevent and treat C. difficile infections and does not destroy the microbiome like antibiotic treatments, allowing the microbiome to return to a healthy state. 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 historical C. difficile strain (630) and *from a hypervirulent (HV) strain which caused the recent worldwide outbreaks*.

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

"Our IMM-529 is a first-in-class program and a potential paradigm-changing new anti-infective product. The successful completion of our preclinical studies has demonstrated that IMM-529 could be the first oral non-antibiotic therapeutic against C. difficile, and we look forward to progressing this asset to the clinic in 2016."

"These studies are yet another proof of the robustness and versatility or Immuron's platform. We now have a growing OTC product in several markets, a recruiting Phase II program in NASH, a recruiting Phase II in ASH that is full funded by the NIH and now a successful pre-clinical program in C. difficile. Immuron's future is very bright and we look forward to continuing to produce results for our shareholders."

Three major products development milestones have now successfully been achieved with the Immuron proprietary platform including (1) Travelan, which is the only preventive treatment for Travellers' Diarrhoea, (2) IMM-124E which is in Phase II for the treatment of NASH (fatty-liver disease) as well as in Phase II for ASH (alcoholic steatohepatitis), a trial that is 100% funded by the NIH and (3) IMM-529 for the treatment of *C. difficile*.

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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.