

# Pre-Clinical Results of IMM-529 in C. *difficile* Infection (CDI) Published in Scientific Reports

**Melbourne, Australia, 3 July 2017:** Australian biopharmaceutical company Immuron Limited (ASX: IMC; NASDAQ: IMRN), announces that the results of its successful pre-clinical proof-of-concept (POC) program in Clostridium *difficile* Infection (CDI) have been published in Scientific Reports. Scientific Reports is an online multidisciplinary, open access journal from the publishers of Nature. The paper was peer-reviewed prior to publication.

The paper, which discusses the outstanding results of the studies, is titled "Bovine antibodies targeting primary and recurrent Clostridium difficile disease are a potent antibiotic alternative", and can be found on Immuron's website at: <a href="http://immuron.com/assets/Uploads/Hutton-et-al-2017-Scientific-Reports.pdf">http://immuron.com/assets/Uploads/Hutton-et-al-2017-Scientific-Reports.pdf</a> as well as on the Scientific Reports website. The abstract can be found at the end of this press release.

IMM-529 is a first-in-class biologic which contains highly specific antibodies to the C. difficile toxin B, the highly infectious C. difficile spores, and the C. difficile vegetative cells which colonise the gut. This unique triple-targeted mechanism of action (MOA) effectively neutralizes C. difficile, but does not negatively impact the rest of the microbiota. The antibodies in IMM-529 have been demonstrated to be cross-reactive to 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 was the cause recent worldwide outbreaks.

In 2016, Immuron and researchers at Monash University released the results of the Company's IMM-529 preclinical program in CDI which showed that IMM-529 was effective in all three phases of the disease including prevention of primary disease, treatment of primary disease and reducing recurrence of disease. Since these results in 2016, Immuron has been working on securing key academic partners for the clinical phase of the study, and on the manufacturing of the clinical supplies. The Company envisages it will commence a Phase I/II program of 60 CDI patients in early 3Q 2017, with results available in mid-2018.

# Immuron CEO Thomas Liquard, commented:

"We are pleased that these peer-reviewed results are now available to the broader scientific community. The quality of the studies, and the results, highlight the promise of IMM-529 as a potential treatment for CDI and we look forward to progressing our Phase I/II program as quickly as we can.

We would like to thank Dr. Dena Lyras and her team at Monash University, Melbourne, Australia for the outstanding design and execution of these studies, and we look forward to continuing our successful collaboration with her team at Monash University."





## Abstract:

The increased incidence of antibiotic resistant 'superbugs' has amplified the use of broad spectrum antibiotics worldwide. An unintended consequence of antimicrobial treatment is disruption of the gastrointestinal microbiota, resulting in susceptibility to opportunistic pathogens, such as Clostridium difficile. Paradoxically, treatment of C. difficile infections (CDI) also involves antibiotic use, leaving patients susceptible to re-infection. This serious health threat has led to an urgent call for the development of new therapeutics to reduce or replace the use of antibiotics to treat bacterial infections. To address this need, we have developed colostrum-derived antibodies for the prevention and treatment of CDI. Pregnant cows were immunised to generate hyperimmune bovine colostrum (HBC) containing antibodies that target essential C. difficile virulence components, specifically, spores, vegetative cells and toxin B (TcdB). Mouse infection and relapse models were used to compare the capacity of HBC to prevent or treat primary CDI as well as prevent recurrence. Administration of TcdB-specific colostrum alone, or in combination with spore or vegetative cell-targeted colostrum, prevents and treats C. difficile disease in mice and reduces disease recurrence by 67%. C. difficile-specific colostrum should be re-considered as an immunotherapeutic for the prevention or treatment of primary or recurrent CDI.

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#### **COMPANY CONTACT:**

Thomas Liquard Chief Executive Officer AUS Ph: +61 (0)3 9824 5254 thomasliquard@immuron.com

# **AUSTRALIA INVESTORS RELATIONS:**

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

#### **US INVESTORS RELATIONS:**

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

## **US PUBLIC RELATIONS:**

Eric Fischgrund
FischTank - Marketing and PR
US Ph: +1 (646) 699 1148
eric@fischtankpr.com

# **ABOUT IMMURON:**

Immuron Limited (NASDAQ: IMRN; ASX: IMC), is a biopharmaceutical company focused on developing and commercialising oral immunotherapeutics for the treatment of 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 and its lead clinical candidate, IMM-124E, is in Phase 2 clinical trials for NASH, ASH and Pediatric NAFLD. Immuron's second clinical stage asset, IMM-529, is targeting C. difficile Infections (CDI). 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 global immunotherapy market.

For more information visit: http://www.immuron.com





#### FORWARD-LOOKING STATEMENTS:

This press release may contain "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1934, each as amended. Such statements include, but are not limited to, any statements relating to our growth strategy and product development programs and any other statements that are not historical facts. Forward-looking statements are based on management's current expectations and are subject to risks and uncertainties that could negatively affect our business, operating results, financial condition and stock value. Factors that could cause actual results to differ materially from those currently anticipated include: risks relating to our growth strategy; our ability to obtain, perform under and maintain financing and strategic agreements and relationships; risks relating to the results of research and development activities; risks relating to the timing of starting and completing clinical trials; uncertainties relating to preclinical and clinical testing; our dependence on third-party suppliers; our ability to attract, integrate and retain key personnel; the early stage of products under development; our need for substantial additional funds; government regulation; patent and intellectual property matters; competition; as well as other risks described in our SEC filings. We expressly disclaim any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in our expectations or any changes in events, conditions or circumstances on which any such statement is based, except as required by law.

