Immuron Receives U.S. Patent on Drug Composition to Treat *Clostridium difficile*

Company Provides Update on Status of IMM-529 Clinical Trial and New Strategic Focus

Key Points

- ***C. difficile* remains a major medical problem, causing an estimated annual economic burden of more than USD $10 billion globally, with 28,000 deaths per year in the U.S. alone**
- **U.S. Patent Office issues patent covering Immuron's drug composition for treatment of *C. difficile***
- **Australian clinical sites to be opened for *C. difficile* trial**
- **Immuron plans to file an investigational new drug (IND) application with the Food and Drug Administration (FDA) in the U.S.**

Melbourne, Australia, March 19, 2019: Immuron Limited (ASX: IMC; NASDAQ: IMRN), an Australian biopharmaceutical company focused on developing and commercializing oral immuno-therapeutics for the treatment of gut mediated diseases, today announced the issuance of a patent by the United States Patent and Trademark Office (USPTO) for a method to treat *Clostridium difficile* infections. The patent (USPTO No. 10144775) entitled "Methods and compositions for the treatment and/or prophylaxis of *Clostridium difficile* associated disease" describes a targeted drug composition comprising an enriched, hyperimmune polyclonal antibody preparation of bovine colostrum for use in treating *C. difficile*, a bacterium that causes life threatening diarrhea. The Company's drug candidate IMM-529, which is based on this technology, is presently in a Phase 1/2a clinical trial in *C. difficile* patients.

"The claims of this new U.S. patent provide broad coverage of the application of our proprietary technology to the treatment of *C. difficile* Infection (CDI)," said Gary S. Jacob, Ph.D., CEO of Immuron Ltd. "CDI remains a major-medical problem causing an estimated annual economic burden of more than USD $10 billion globally. The problem is especially acute in hospitals and in long-term in-patient care facilities. Moreover, the problem is compounded by the high rate of recurrence in patients treated with front-line antibiotics. Immuron's drug candidate IMM-529 is not an antibiotic. It is comprised of a hyperimmune polyclonal antibody colostrum agent that is capable of binding and inactivating not only the *C. difficile* toxin B but also spore antigens and vegetative cell antigens. We plan to focus our efforts moving forward on developing IMM-529 to treat patients with recurrent *C.*

difficile with the filing of an IND with FDA. This will enable us to include clinical sites in the U.S. as well as in the rest of the world."

Immuron's phase I/IIa clinical trial of IMM-529 in patients with *C. difficile* presently being conducted in two clinics in Israel has not met the patient enrolment numbers which the Company anticipated. As a result, Immuron has addressed this issue by making changes to the current enrolment protocol. A feasibility and Australian-site identification process is now complete, and the Company expects to have Australian clinical sites open for recruitment of patients shortly. The Company's strategic plan to file an IND with FDA, to further develop the drug candidate and to specifically focus on treating patients with recurrent disease, is intended to pursue a major unmet medical need in treatment of patients suffering with *C. difficile* infections, as well as significantly enhance patient enrolment by adding sites located in the U.S.

About Clostridium difficile

C. difficile is a Gram-positive, spore-forming, anaerobic bacterium that infects the gastrointestinal tract and causes an array of clinical symptoms ranging from mild diarrhoea to more severe, often fatal, gastrointestinal disease such as pseudomembranous colitis and toxic megacolon. The infection cycle of *C. difficile* is complex because this bacterium produces spores that are highly resistant to environmental assaults, enabling persistence in unfavourable environments. Spores are the infectious particles ingested by the host, where they germinate into vegetative cells, colonise the large intestine and establish infection. The bacteria produce toxins causing inflammation of the colon resulting in severe diarrhea and, in severe cases, death. An estimated 28,000 patients die each year from CDI infections in the USA alone, while recurrent CDI affects ~100,000 people in the U.S. annually. *C. difficile* infection is most often associated with antibiotic use as the alteration to the endogenous gastrointestinal microbiota results in increased susceptibility to CDI. Paradoxically, the standard of care treatment of (CDI) also involves antibiotic use, leaving patients susceptible to re-infection.

About IMM-529

IMM-529 is a polyclonal antibody biological product intended to prevent and treat *C. difficile* infections and has been developed to spare the gut microbiome from the effects of "classic" antibiotic treatments. The delivery of IMM-529 results in localized toxin B neutralization at the site of infection and prevents severe damage occurring to the gut while also binding to *C. difficile* spores and vegetative cells preventing further colonization. In addition, the antibodies in IMM-529 have demonstrated cross-reactions with a variety of human and animal *C. difficile* isolates and their associated Toxin B, vegetative cell 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 a worldwide outbreak of the disease.

About Immuron

Immuron Limited (ASX: IMC, NASDAQ: IMRN), is an Australian microbiome biopharmaceutical company focused on developing and commercializing orally delivered targeted polyclonal antibodies for the treatment of inflammatory mediated and infectious diseases. Immuron has a unique and safe technology platform that enables a shorter development therapeutic cycle. The Company currently markets Travelan® in Australia for the prevention of Travelers' Diarrhea, and markets Travelan® in the U.S. and Canada as a dietary supplement for digestive tract protection. Immuron's lead clinical candidate, IMM-124E, is presently in Phase II trials in Severe Alcoholic Hepatitis (SAH) and Pediatric Nonalcoholic Fatty Liver Disease (NAFLD). Immuron's second clinical-stage asset, IMM-529, targets *Clostridium difficile* Infections (CDI), and is presently in a clinical trial *in C. difficile* patients.

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FORWARD-LOOKING STATEMENTS:

This press release may contain "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange 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.