



Immuron Receives European Patent on Drug Composition to Treat *Clostridioides difficile* Associated Disease

Melbourne, Australia, January 17, 2023: Immuron Limited (ASX: IMC; NASDAQ: IMRN), an Australian based and globally integrated biopharmaceutical company that has developed two commercially available oral immunotherapeutic products for the treatment of gut mediated diseases, is pleased to announce that has been granted a European Patent for compositions and methods for the treatment and/or prophylaxis of *Clostridioides difficile* associated disease.

Notification of the decision to grant European Patent 14784945.9, entitled "Methods and Compositions for the treatment and/or prophylaxis of *Clostridium difficile* associated disease," was formally received yesterday, and grant of this application will be published in the European Patent Bulletin on 25 January 2023 under European Patent No. 2986316. The company previously reported it had received notification from the European Patent Office of the intent to grant in July last year (ASX announcement July 7, 2022).

The European registration adds to Immuron's patent position for compositions and methods for the treatment and/or prophylaxis of *Clostridioides difficile* associated disease in Australia, New Zealand and the United States.

Clostridioides difficile (previously known as *Clostridium difficile*) infection (CDI) is a disease of the large intestine caused by toxins produced by the spore forming bacterium *Clostridioides difficile*. CDI can also result in serious disease complications including bowel perforation, toxic megacolon and sepsis, and it can prove fatal in the most severe cases. In recent years, increases in the frequency and severity of CDI have been observed worldwide, as well as an increased risk of community-associated CDI, and CDI in persons previously thought to be low risk. It is estimated that CDI affects up to 1.2% of hospitalized patients in the United States, representing an estimated cost of USD 4.8 billion per year (source: CDC). In Europe, the estimated cost is approximately 3 billion per year, which is likely to increase concomitantly with a more elderly society; more than 134 million Europeans will be >65 years by 2050.

This release has been authorised by the directors of Immuron Limited.

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About Immuron

Immuron Limited (ASX: IMC, NASDAQ: IMRN), is an Australian biopharmaceutical company focused on developing and commercializing orally delivered targeted polyclonal antibodies for the treatment of infectious diseases.

About IMM-529

IMM-529 is a polyclonal antibody biological product intended to prevent and treat *Clostridioides difficile* (*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 *Clostridioides Difficile* Infection

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 diarrhea 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 unfavorable environments. Spores are the infectious particles ingested by the host, where they germinate into vegetative cells, colonize 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.

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 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.