Immuron IMM-529 IND approved by FDA

Key Points

- **Immuron receives U.S. Food and Drug administration (FDA) approval for IMM-529 Investigational New Drug (IND) application and clinical study may proceed**
- **FDA assigned an IND number (032095) for the IMM-529 application**
- **IND 32095 is Immuron's Investigational new drug (IND) application for clinical development of IMM-529 as product to specifically prevent or treat *Clostridioides difficile* infection (CDI) and is now active**

Melbourne, Australia, November 5, 2025: Immuron Limited (ASX: IMC; NASDAQ: IMRN), is pleased to announce that the United States Food and Drug Administration (FDA) has approved Immuron's Investigational New Drug application for IMM-529 and the Phase 2 clinical trial may proceed.

The Company plans to initiate a Phase 2 clinical trial for IMM-529 in individuals with *Clostridioides difficile* infection (CDI) during the first half of 2026.

The Phase 2 clinical trial will be a randomized, double blind, placebo-controlled clinical study of IMM-529 with Standard of Care (SOC) for the treatment of CDI in subjects with first episode CDI or recurrent CDI. Up to 60 subjects will be enrolled in the study. Subjects will be randomly assigned to IMM-529 + SOC or placebo + SOC in a 2:1 ratio at multiple sites in Australia. The primary objective will be to evaluate the safety and tolerability of IMM-529 together with SOC in patients with CDI or recurrent CDI. Determination of efficacy will be assessed by the measurement and comparison of mortality rate, disease symptoms and recurrence rate for each treatment group.

Opportunity assessment by Lumanity indicates that if efficacious, IMM-529 will be positioned as early in treatment algorithm as payers will allow. It is anticipated that first-episode and recurrent patients will be recruited in the IMM-529 Phase 2 clinical trial design. Up to ~98k patients would be eligible if IMM-529 is positioned at the first recurrence. Based on the estimated market size, anticipated payer restrictions, pricing, and competition, base case yearly revenue for IMM-529 is projected at US$400M. Oral dosing of IMM-529 was viewed as a positive by infectious disease experts.

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 *Clostridioides difficile* (C. diff). Paradoxically, treatment of *Clostridioides difficile* infection (CDI) also involves antibiotic use, and the heavy reliance on antibiotics to control C. diff does not allow for the gut flora to regenerate and predisposes the patient to relapsing CDI. C. diff is currently the most common pathogen in healthcare-associated infections and was deemed an urgent threat in the Center for Disease Control and Prevention's report on antibiotic resistance threats in the United States (CDC, 2019). CDI affects over 400,000 people in

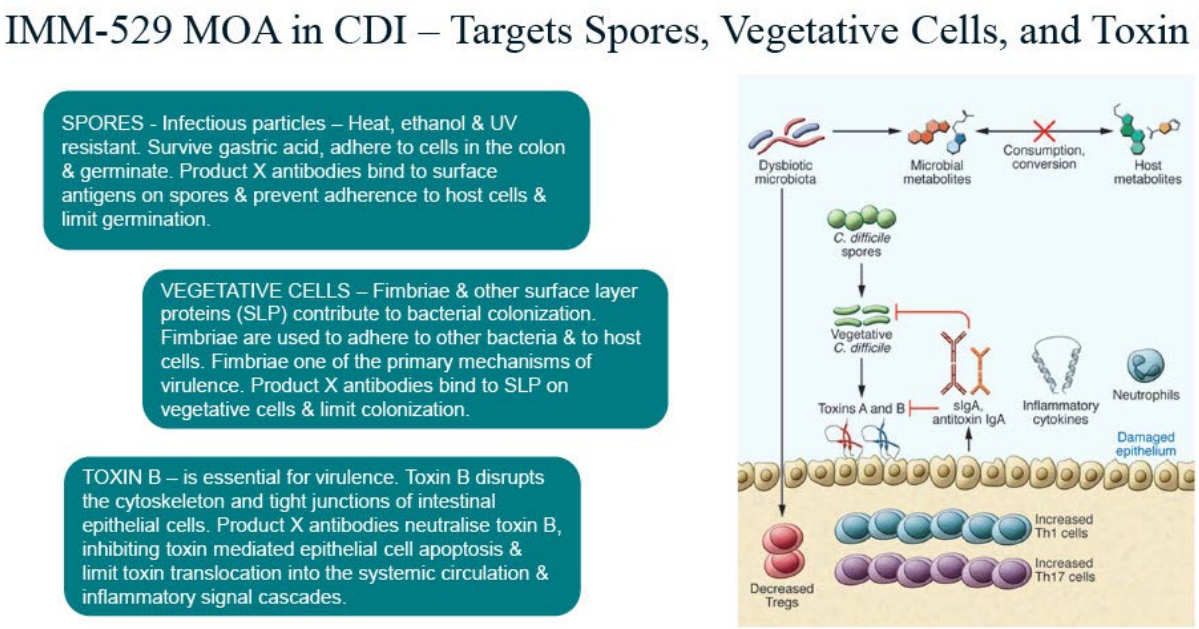
the US on a yearly basis, contributing to over 30,000 deaths in the US alone annually. This serious health threat has led to an urgent call for the development of new therapeutics to reduce or replace the use of antibiotics to treat bacterial infections.

To address this need, Immuron is developing IMM-529 as an adjunctive therapy in combination with standard of care antibiotics for the prevention and/or treatment of recurrent CDI. IMM-529 antibodies targeting C. diff may help to clear CDI infection and promote a quicker re-establishment of normal gut flora, providing an attractive oral preventative for recurrent CDI.

Immuron is collaborating with Dr. Dena Lyras and her team at Monash University, Australia to develop vaccines to produce bovine colostrum-derived antibodies. Dairy cows were immunised to generate hyperimmune bovine colostrum (HBC) that contains antibodies targeting three essential C. diff virulence components. IMM-529 targets Toxin B (TcB), the spores, and the surface layer proteins of the vegetative cells (refer to MOA schematic - below).

This unique 3-target approach has yielded promising results in pre-clinical infection and relapse models, including **(1) Prevention of primary disease (80% *P* =0.0052); (2) Protection of disease recurrence (67%, *P* <0.01) and (3) Treatment of primary disease (78.6%, P<0.0001; TcB HBC).** Importantly IMM-529 antibodies cross-react with whole cell lysates of many different human strains of C. diff including hypervirulent strains.

To our knowledge, IMM-529 is, to date, the only investigational drug that has shown therapeutic potential in all three phases of the disease. https://doi.org/10.1038/s41598-017-03982-5



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.

Immuron Platform Technology

Immuron's proprietary technology is based on polyclonal immunoglobulins (IgG) derived from engineered hyper-immune bovine colostrum. Immuron has the capability of producing highly specific immunoglobulins to any enteric pathogen and our products are orally active. Bovine IgG can withstand the acidic environment of the stomach and is resistant to proteolysis by the digestive enzymes found in the Gastrointestinal (GI) tract. Bovine IgG also possesses this unique ability to remain active in the human GI tract delivering its full benefits directly to the bacteria found there. The underlying nature of Immuron's platform technology enables the development of medicines across a large range of infectious diseases. The platform can be used to block viruses or bacteria at mucosal surfaces such as the Gastrointestinal tract and neutralize the toxins they produce.

For more information visit: https://www.immuron.com.au/ and https://www.travelan.com
Sign up to Immuron's Investor Hub: Here

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.