Immuron Advances IMM-529 (*Clostridioides difficile* infection) Partnering Strategy

Key Points

- **Immuron Engages Pullan Consulting to Advance IMM-529 Partnering Strategy**
- **Immuron is seeking a partner to support clinical development through regulatory approval and commercialization**
- **Immuron has U.S. Food and Drug administration (FDA) approval for IMM-529 Investigational New Drug (IND) application**
- **IND 32095 is Immuron's Investigational new drug (IND) application for clinical development of IMM-529 as a product to specifically prevent or treat Clostridioides difficile infection (CDI)**

Melbourne, Australia, July 6, 2026: Immuron Limited (ASX: IMC; NASDAQ: IMRN) is pleased to announce that it has engaged Pullan Consulting to provide business development services to assist in securing a strategic partnership for IMM-529.

Pullan Consulting is a highly regarded life sciences advisory firm with a strong track record of executing between five and twelve partnering transactions annually over the past 20 years. The firm specializes in guiding biotechnology and pharmaceutical companies through the partnering process, from strategy development and partner identification to negotiation and transaction execution. Pullan Consulting's expertise is expected to support Immuron in maximizing the value of IMM-529 while advancing the program toward commercialization.

Immuron has U.S. Food and Drug administration (FDA) approval for IMM-529 Investigational New Drug (IND) application (IND 32095) for clinical development of IMM-529 as a product to specifically prevent or treat Clostridioides difficile infection (CDI) in a Phase 2 clinical trial.

IMM-529 has a validated biological target. FDA-approved monoclonal antibody Bezlotoxumab was developed as a first-in-class therapy designed to prevent recurrence of Clostridioides difficile infection (CDI) by neutralizing toxin B, the major driver of recurrent disease. IMM-529's polyclonal antibodies offer multivalent defense compared with monoclonal single-epitope antibodies (Bezlotoxumab). IMM-529 also has an advantage over current standard of care antibiotic treatments that disrupt microbiota. IMM-529 decolonizes the gut facilitating clearance of the pathogen, recovery of the microbiome and prevention of recurrent infection.

Immuron has completed an Investigational Brochure and clinical protocol and has secured a principal investigator and three Australian sites. This trial is eligible for Australia's Clinical Trial Notification (CTN) scheme, a fast-track method for initiating trials.[1] Immuron has manufactured and released drug product for supply of a clinical trial.

The trial protocol is for 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 would be randomly assigned to IMM-529 + SOC or placebo + SOC in a 2:1 ratio at multiple sites. The primary objective would be to evaluate the safety and tolerability of IMM-529 together with SOC in patients with CDI or recurrent CDI. Determination of efficacy would 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 Company is seeking partners to advance clinical development of IMM-529. Under a licensing model, the licensee typically funds development, registration, and commercialization costs. Common licensing agreements include upfront fees upon execution of the document, as well as developmental milestone payments and royalties on product sales. Terms from select historical CDI-focused deals that show a range of possible transaction structures are shown below. With upfront payments ranging from USD$1-$50 million, milestone payments ranging from USD$25-$570 million, and typical royalties on sales in the mid-to-high single digit percentage range, a successful development partnership for its IMM-529 asset could prove transformational for Immuron.

Year	Licensor / Asset Owner	Licensee / Acquirer	Licensed Asset	Financial terms (public)	Stage at deal	Status
2023	Destiny Pharma	Sebela Pharmaceuticals	NTCD-M3 (nontoxigenic C. difficile strain, live biotherapeutic)	Upfront $1M; up to $570M milestones (incl. $19M development and up to $550M sales) plus royalties. (FT Markets)	Phase 3 ready	Phase 3 preparation continues, including work on a more patient friendly capsule formulation and regulatory alignment on Phase 3 design. (AMR Bio)
2017	Summit Therapeutics	Eurofarma	Ridinilazole (small molecule antibiotic)	$2.5M upfront; up to $25M milestones plus royalties. (BioSpace)	Phase 2/3	Phase 3 program did not meet superiority vs vancomycin; Summit later focused its strategy on oncology (ivonescimab). (Fierce Biotech)
2017	Assembly Biosciences	Allergan (later AbbVie)	Microbiome GI programs (often cited as ABI-M201, ABI-M301; not CDI specific)	$50M upfront plus milestones and royalties (per deal announcement coverage). (BioSpace)	Preclinical	Partnership was later unwound and the microbiome candidates returned; Assembly ultimately exited microbiome work. Note: public deal descriptions emphasize UC and Crohn's, not CDI. (Fierce Biotech)

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.

Immuron collaborated 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.

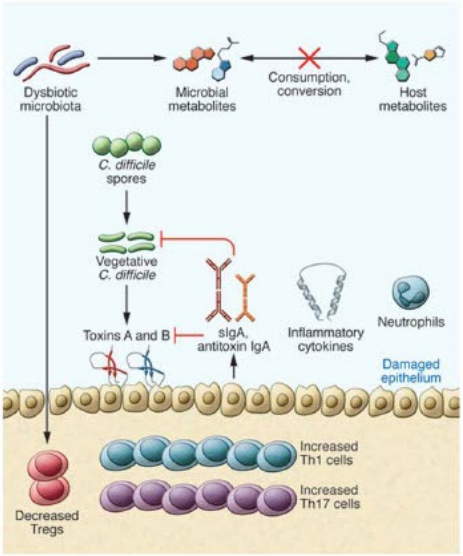
To our knowledge, IMM-529 is, to date, the only investigational drug that has shown therapeutic potential in all three phases of the disease. https://doi.org/10.1038/s41598-017-03982-5

IMM-529 MOA in CDI – Targets Spores, Vegetative Cells, and Toxin B

SPORES - Infectious particles – Heat, ethanol & UV resistant. Survive gastric acid, adhere to cells in the colon & germinate. Product X antibodies bind to surface antigens on spores & prevent adherence to host cells & limit germination.

VEGETATIVE CELLS – Fimbriae & other surface layer proteins (SLP) contribute to bacterial colonization. Fimbriae are used to adhere to other bacteria & to host cells. Fimbriae one of the primary mechanisms of virulence. Product X antibodies bind to SLP on vegetative cells & limit colonization.

TOXIN B – is essential for virulence. Toxin B disrupts the cytoskeleton and tight junctions of intestinal epithelial cells. Product X antibodies neutralise toxin B, inhibiting toxin mediated epithelial cell apoptosis & limit toxin translocation into the systemic circulation & inflammatory signal cascades.



This release has been authorized 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.

References

1. The Clinical Trial Notification (CTN) pathway is Australia's primary, fast-track method for initiating trials with unapproved therapeutic goods. It involves HREC ethics approval and institutional governance review, followed by an online notification to the TGA (4-8 week process), rather than direct regulatory review, facilitating rapid start-up.

Hutton, M.L., Cunningham, B.A., Mackin, K.E. et al. Bovine antibodies targeting primary and recurrent Clostridium difficile disease are a potent antibiotic alternative. Sci Rep 7, 3665 (2017). https://doi.org/10.1038/s41598-017-03982-5

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