Immuron Announces New Research Collaboration targeting Antimicrobial Resistance

Highlights:

- **New Research Collaboration with Monash University**
- **One proposal will target Antimicrobial Resistant Pathways to develop broad spectrum therapeutic drug products**
- **Second project proposal will focus on the Develop of new therapeutic drug candidates against Vancomycin-resistant enterococci (VRE)**

Melbourne, Australia, January 15, 2025: Immuron Limited (ASX: IMC; NASDAQ: IMRN), an Australian based and globally integrated biopharmaceutical company is pleased to announce a new research collaboration agreement with Monash University.

The major objective of this research collaboration is to develop new therapeutic drug candidates which target antimicrobial resistant pathogens. This work will utilize the Immuron technology platform, and the extensive experience of the Biomedicine Discovery Institute research team lead by Professor Dena Lyras.

The research collaboration is effective and will continue whilst there are relevant research activities being performed under the research plan. No additional or new funding is required for the initial activities by Immuron for the strategic collaboration. The funding of Immuron's research activities is allowed for in the Company's existing research budget.

After the results from this research agreement are known, the parties will negotiate in good faith (and without obligation) whether to jointly develop or commercialise the outcomes of these research collaborations on commercially reasonable terms.

The first project proposal will focus on the underlying mechanisms which bacteria utilise to share and transfer their DNA. A process which can rapidly alter the functional capacity and characteristics of a bacterium, resulting in the emergence of antimicrobial resistance (AMR) with the aim to develop broad spectrum therapeutic drug products.

Antimicrobial resistance (AMR) poses a significant threat to healthcare systems worldwide. AMR can lead to more severe and harder-to-treat infections in healthcare settings, such as hospitals and nursing homes. These infections often result in longer hospital stays, higher medical costs, and increased mortality rates. In the U.S., the estimated national cost to treat these infections exceeds $4.6 billion annually (CDC Antimicrobial Resistance Facts and Stats: https://www.cdc.gov/antimicrobial-resistance/data-research/facts-stats/index.html).

The second project proposal will specifically target Vancomycin-resistant enterococci (VRE) and as the name suggests VRE are bacteria that are resistant to the antibiotic vancomycin. VRE are opportunistic nosocomial pathogens that have emerged as a major healthcare problem worldwide. The two most clinically significant enterococci, *Enterococcus faecalis* and *Enterococcus faecium*, are associated with a range of nosocomial infections in elderly and immunosuppressed patients. VRE complicates outcomes for at-risk patients, increasing their risk of developing subsequent infections and/or transmitting VRE to other patients. VRE colonisation has been associated with an increased risk of bacteremia, infections at other body sites and can also lead, in severe cases, to mortality.

The global market for antibiotics is projected to reach $57.0 billion by 2026 with a compound annual growth rate (CAGR) of 4.0%. The rising prevalence of drug-resistant infections, including VRE, is expected to drive the demand for new and innovative treatments in this space.

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 Travelan®

Travelan® is an orally administered passive immunotherapy that prophylactically reduces the likelihood of contracting travelers' diarrhea, a digestive tract disorder that is commonly caused by pathogenic bacteria and the toxins they produce. Travelan® is a highly purified tabletized preparation of hyper immune bovine antibodies and other factors, which when taken with meals bind to diarrhea-causing bacteria and prevent colonization and the pathology associated with travelers' diarrhea. In Australia, Travelan® is a listed medicine on the Australian Register for Therapeutic Goods (AUST L 106709) and is indicated to reduce the risk of Travelers' Diarrhea, reduce the risk of minor gastro-intestinal disorders and is antimicrobial. In Canada, Travelan® is a licensed natural health product (NPN 80046016) and is indicated to reduce the risk of Travelers' Diarrhea. In the U.S., Travelan® is sold as a dietary supplement for digestive tract protection.

Travelers' diarrhea (TD)

TD is generally defined as the passage of ≥ 3 unformed stools per 24 hours plus at least one additional symptom (such as nausea, vomiting, abdominal cramps, fever, blood/mucus in the stools, or fecal urgency) that develop while abroad or within 10 days of returning from any resource-limited destinations (Leung et al., 2006). Diarrhea continues to be the most frequent health problem among travelers to destinations in lower- and middle-income regions (Steffen, 2017). Deployed US military personnel, essentially representing a long-term traveller population, are particularly affected given their population dynamics and the context in which they seek care and treatment (Connor et al., 2012). Diarrhea is the leading infectious disease threat to the overall health and preparedness of deployed US armed forces, with diarrheagenic E. coli, Campylobacter spp., and Shigella spp. among the most commonly reported etiologies (Riddle et al., 2006).

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.

IMM-124E (Travelan®)

IMM-124E was developed using Immuron's platform technology. IMM-124E is produced from the colostrum of birthing cattle that have been immunised during pregnancy with a vaccine containing the outer antigens of multiple human derived ETEC. A total of 13 ETEC strains are used in the vaccine to produce high levels of antibodies against selected surface antigens from the most common strains of ETEC.

The resultant hyperimmune colostrum IMM-124E from ETEC vaccinated cows contains significant levels of polyclonal antibodies specific for ETEC antigens LPS, CFA-I and Flagellin (Sears et al., 2017).

The antibodies produced in IMM-124E have been found to have a stronger binding and neutralizing activity (than the antibodies of unvaccinated cattle) against a wide range of LPS antigens including both the variable O-polysaccharide region and the preserved oligosaccharide core 'R' region of LPS from the 13 serotypes used in the ETEC vaccine.

IMM-124E is manufactured into a tablet form referred to as Travelan®.

IMM-529

Immuron is developing IMM-529 as an adjunctive therapy in combination with standard of care antibiotics for the prevention and/or treatment of recurrent Clostridioides difficile infection (CDI). IMM-529 antibodies targeting Clostridioides difficile (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.

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 (Hutton et al., 2017).

References

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