Immuron Reports Neutralizing activity Against SARS-CoV-2

Key Points

- **Immuron's IMM-124E used to manufacture Travelan® and Protectyn® demonstrates antiviral activity against the COVID-19 virus in laboratory studies**
- **Immuron's technology platform offers a potential new oral therapeutic approach to target SARS-CoV-2 in the GI Tract**

Melbourne, Australia, July 21, 2020: Immuron Limited (ASX: IMC; NASDAQ: IMRN), an Australian biopharmaceutical company focused on developing and commercialising oral immunotherapeutics for the prevention and treatment of gut mediated pathogens, today is pleased to announce that IMM-124E used to manufacture the company's flag ship commercially available and over-the-counter gastrointestinal and digestive health immune supplements Travelan® and Protectyn® has demonstrated neutralizing activity against the severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2), the virus that causes COVID-19.

The cytopathic effect inhibition cell-based assay was established and performed by 360 biolabs, a Melbourne based Contract Research Organization using the SARS-CoV-2 hCoV-19/Australia/VIC01/2020 virus obtained from Melbourne's Peter Doherty Institute for Infection and Immunity. The in-vitro assessment of the neutralization of SARS-CoV-2 was performed on four production lots of product used to manufacture Travelan® and Protectyn®. The In-vitro susceptibility of the virus to IMM-124E was determined using the quantitative assay which measures virus replication in the presence of increasing concentrations of the product compared to replication in the absence of the product. The effective concentration of IMM-124E was reported as the concentration of the product at which virus replication is inhibited by 50 percent (EC_{50}) or 90 percent (EC_{90}).

All four production lots produced mean EC_{50} values of 40.5 to 91.9 ug/mL and inhibited viral replication at concentrations which there was no observed cell toxicity. The concentration of IMM-124E at which virus replication was inhibited by 90 percent (EC_{90}) produced mean EC_{90} values ranging from 48.7 to 155.4 ug/mL for all four lots tested again at concentrations at which there was no observed cell toxicity. A commercially available high protein milk powder product was used as a placebo in the studies and produced EC_{50} values greater than the observed cellular cytotoxicity concentration of >4800 ug/mL. The control milk powder inhibited viral replication at doses >25,000 ug/mL and more importantly did not inhibit viral replication at doses which it was cytotoxic to cells.

Another major finding made during the study was that cell viability in the presence of IMM-124E was greatly enhanced when compared to placebo. IMM-124E improved cell viability by 180 to 260% relative to controls. These results indicate that IMM-124E at concentrations which inhibited SARS-CoV-2 replication improved cell viability.

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Bovine coronavirus is widely prevalent in dairy cows and is transmitted by infected feces being taken in via the mouth or nose. The virus initially infects cells in the small intestine, and then spreads through to the colon. The major source of coronavirus is adult cattle carriers shedding the virus in their feces and thereby exposing the newborn calves.

Bovine coronaviruses (BCoVs) cause respiratory and enteric infections in cattle including;

- severe diarrhea in newborn calves
- winter dysentery in adult cows
- bovine infectious respiratory disease (BIRD) in calves and adult cattle

Prophylaxis of BCoV enteric disease in newborn calves is usually obtained by means of vaccination of pregnant cows to enhance the level of maternal antibodies that are transferred to their offspring through colostrum, thus exerting a local protective effect against BCoV-induced enteritis. Specific treatment and prevention of coronavirus also involves the feeding of antibodies against coronavirus. This can be achieved by feeding the antibody rich colostrum from coronavirus vaccinated animals, to calves for the first few weeks of life. Therefore, the possibility of producing a Hyper-immune Bovine Colostrum to severe acute respiratory syndrome (SARS)-like coronavirus (SARS-CoV-2) is quite high. However, the prevalence and prognosis of digestive system involvement and gastrointestinal symptoms in patients with COVID-19 remains largely unknown.

Colostrum is a complex biological fluid that is rich in nutritional components (vitamins, minerals, and amino acids), immune regulating compounds (immunoglobulins, lactoferrin, cytokines and antimicrobial peptides) and growth factors. The main functions of colostrum are to provide essential nutrients, strengthen the natural defense system, modulate immune response, balance intestinal microbiota, promote tissue growth and maturation of the digestive tract in newborns. Colostrum also has antiviral, antifungal and antibacterial properties which enable it to kill different pathogens like Escherichia coli, rotavirus and Cryptosporidium.

Bovine coronaviruses belong to the family Coronaviridae in the order Nidovirales and are members of subgroup 2a along with swine hemagglutinating encephalomyelitis virus (HEV), canine respiratory CoV, and human CoV-OC43 and HKU1. HEV, which causes wasting disease, is an exception; the others all cause enteric and/or respiratory disease. The severe acute respiratory syndrome (SARS)-CoVs, which are associated with respiratory and enteric infections in humans and animals (eg, civet cats, raccoon dogs, bats), belong to the CoV subgroup 2b.1.

“Armed with the knowledge of Bovine coronavirus enteric disease we were interested in testing IMM-124E against SARS-CoV-2” said Dr Jerry Kanellos, CEO of Immuron Limited.

“We know that SARS-CoV-2 causes an influenza-like disease that is primarily thought to infect the lungs with transmission through the respiratory route ranging from mild respiratory symptoms to severe lung injury, multiorgan failure, and death. Respiratory symptoms have dominated the clinical focus, however gastrointestinal symptoms such as diarrhea, vomiting, and abdominal pain are also observed in a growing subset of patients often presenting with no respiratory symptoms. In the United States the Centers for Disease Control and Prevention recently updated the symptoms of coronavirus to include diarrhea. This growing clinical evidence suggests that the Gastrointestinal

tract may present another viral target organ. The virus RNA has been detected in anal swabs of patients even after nasopharyngeal testing has turned negative, and cells in the inner-gut lining express high amounts of the angiotensin-converting enzyme 2 (ACE2) receptor that SARS-CoV-2 uses to gain entry to cells implying the potential for gastrointestinal infection and a fecal–oral transmission route. If fecal–oral transmission is a significant factor in the pandemic then the consequences for an oral therapeutic would be significant, however the research is still inconclusive. The preliminary data set we have generated potentially offers a new oral therapeutic approach to target and directly inhibit the virus in the Gastrointestinal tract and warrants further evaluation to identify the inhibitory substances in our products. The company has filed a provisional patent application in respect of the findings."

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 inflammatory mediated and infectious diseases. Immuron has a novel and safe technology platform with one commercial asset generating revenue. In Australia, Travelan® is a listed medicine on the Australian Register of Therapeutic Goods (AUST L 106709) and is indicated to reduce the risk of Travellers' Diarrhea, reduce the risk of minor gastro-intestinal disorders and is antimicrobial. In Canada, Travelan® is a licenced natural health product (NPN 80046016) and is indicated to reduce the risk of Travellers' Diarrhea. In the U.S., Travelan® is sold as a dietary supplement for digestive tract protection in accordance with section 403 (r)(6) of the Federal Drug Administration (FDA).

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.

About Travelers' diarrhea
Travelers' diarrhea is a gastrointestinal infection with symptoms that include loose, watery (and occasionally bloody) stools, abdominal cramping, bloating, and fever, Enteropathogenic bacteria are responsible for most cases, with enterotoxigenic *Escherichia coli* (ETEC) playing a dominant causative role. Campylobacter spp. are also responsible for a significant proportion of cases. The more serious infections with Salmonella spp. the bacillary dysentery organisms belonging to Shigella spp. and Vibrio spp. (the causative agent of cholera) are often confused with travelers' diarrhea as they may be contracted while travelling and initial symptoms are often indistinguishable.

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.