Immuron Reports Results in Severe Alcoholic Hepatitis Clinical Trial

Melbourne, Australia, August 08, 2019: Immuron Limited (ASX: IMC; NASDAQ: IMRN), an Australian biopharmaceutical company focused on developing and commercializing oral immunotherapeutics for the treatment of gut mediated diseases, today announced the topline results of the clinical study conducted by the TREAT Consortium which was funded by the National Institute of Alcohol Abuse and Alcoholism (NIAAA).

The primary objective of the TREAT-003 study was to evaluate the safety and efficacy of IMM-124E at two oral dosage levels as compared with a placebo and provide proof of concept in human subjects for the Mechanism of Action (MoA) in patients with severe alcoholic hepatitis being treated with steroids. The study was conducted at three clinical sites in the USA and supported by a UO1 grant from NIAAA. A total of 57 patients with Severe Alcoholic Hepatitis (SAH) with a Model for End Stage Liver Disease (MELD) Score ranging from 21-28 were enrolled into the clinical study and were treated with either IMM-124E or placebo for 28 days (placebo N=20, IMM-124E 2400 mg/day N=18, IMM-124E 4800 mg/day N= 19). No Suspected Unexpected Serious Adverse Reactions (SUSAR) were reported and no differences in Serious Adverse Events (SAE) were observed across the three arms of the study and no SAE was considered related to the study drug by investigators. Both doses of IMM-124E in the study (2400mg and 4800mg) were well tolerated. The circulating endotoxin levels were variable but statistically similar across the study arms at baseline, day 7 and day 30. There were 9 deaths reported over a six-month period for the entire cohort and there were no significant differences across study groups. The MELD score and its components improved in survivors especially at day 30 onwards but there were no significant differences across study arms. These data indicate that IMM-124E is safe to use in patients with severe alcoholic hepatitis but does not reduce circulating lipopolysaccharide levels, mortality or have an impact on MELD score in the study population.

"***Alcoholic hepatitis occurs in a setting of altered intestinal permeability and high endotoxin load.***" said Arun Sanyal, Professor of Gastroenterology and Hepatology from the Virginia Commonwealth University in Richmond, USA and the study lead Principle Investigator.

"The IMM-124E drug candidate has been developed to target LPS in the gut and prevent it translocating into the portal circulation and the major objective was to determine if orally administered IMM-124E could reduce

endotoxemia in patients with severe alcoholic hepatitis being treated with steroids. In this extreme clinical setting in patients with established severe disease and very high endotoxin load, the study results demonstrated that during the 28-day treatment period there was no statistically significant reduction of serum endotoxin levels or markers of liver injury in the treatment groups when compared to placebo. The possibility of using IMM-124E prior to development of severe disease and its ability to reduce endotoxin load in that setting remains unexplored. This is a disease with a high mortality rate, nine patients enrolled in the study died due to complications associated with the disease. There remains an urgent medical need for new treatments."

Immuron CEO Dr. Gary Jacob commented:

"Immuron was pleased to support this important initiative which was funded by the NIAAA to conduct research and develop potential new treatments for severe alcoholic hepatitis patients. The Company remains focused on its own clinical development pipeline and pursuing the registration of Travelan® with the FDA as the only approved drug to prevent Travelers Diarrhea, IMM-529 to prevent Clostridium difficile infection recurrence and expanding our anti-infective preclinical programs with the US Department of Defense."

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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). The company now has plans to develop a U.S. registration dossier for IMM-124E for Travellers' Diarrhea. Immuron's second clinical-stage asset, IMM-529, targets *Clostridium difficile* Infections (CDI), and is presently in a clinical trial in CDI patients. These products together with the Company's other preclinical immunotherapy pipeline products currently under development targeting immune-related and infectious diseases are anticipated to meet pressing needs in the global immunotherapy market.

For more information visit: http://www.immuron.com

About the TREAT003 Study
This study was conducted by the TREAT Consortium which is funded by the National Institute of Alcohol Abuse and Alcoholism (NIAAA) to purse translational investigations in alcoholic hepatitis. The TREAT Consortium is made up of investigators from Indiana University School of Medicine (Indianapolis, IN), Mayo Clinic (Rochester, MN) and Virginia Commonwealth University (Richmond, VA). The IMM-124E study drug and matching placebo were provided by Immuron Limited. The study is a Phase II proof of concept multicenter,

randomized, double-blind study comparing 2 doses of IMM-124E to placebo for the treatment of patients with Severe Alcoholic Hepatitis. The trial enrolled 57 patients at 3 clinical sites in the United States of America (Indiana University School of Medicine, Indianapolis, IN, Mayo Clinic, Rochester, MN and Virginia Commonwealth University, Richmond, VA).

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.