Immuron Aims to Secure FDA Approval for IMM-124E to Prevent Travelers' Diarrhea

Key Points

- **Immuron to develop U.S. registration dossier for IMM-124E for Travelers' Diarrhea**
- **Company anticipates significant inflection in sales with successful FDA registration of IMM-124E**
- **Company to pursue rapid path for clinical development of IMM-124E**
- **Travelan® safely and effectively marketed for well over 10 years in Australia and currently sold in U.S. and Canada as dietary supplement and natural health product, respectively, with limited marketing**

Melbourne, Australia, April 11, 2019: Immuron Limited (ASX: IMC; NASDAQ: IMRN), an Australian biopharmaceutical company focused on developing and commercializing oral immunoglobulin therapeutics for the treatment of gut mediated diseases, today announced plans to pursue clinical development of IMM-124E, its bovine polyclonal antibody drug candidate, through a formal FDA registration pathway as a drug to prevent travelers' diarrhea (TD).

The Company currently markets and sells Travelan® as a Therapeutic Goods Administration (TGA) listed medicine for prevention of travelers' diarrhea in Australia, and also markets Travelan® in the U.S. and Canada as a dietary supplement, and natural health product, respectively, for digestive tract protection. Travellers diarrhea affects between 30 and 60% of over one billion international travellers every year and symptoms of nausea, vomiting, fever, stomach cramps and diarrhea, can last up to 7 days. Travelan® has been shown in clinical studies to be an effective preventative against TD when taken as instructed.

"This is an important strategic initiative towards enhancing commercialization of the Travelan®/IMM-124E franchise," said Dr. Gary S. Jacob, CEO of Immuron Limited. "It is important to note that Travelan® and IMM-124E, our drug candidate presently in clinical development in gut mediated diseases, are one and the same. We believe seeking FDA registration for IMM-124E as a drug to prevent travelers' diarrhea offers the potential for substantial sales benefits to Immuron. We are moving aggressively forward to develop IMM-124E through the FDA by planning to file an Investigational New Drug (IND) application for prevention of travelers' diarrhea, and pursuing with FDA a rapid path for its clinical development."

Immuron forecasts IMM-124E's potential peak annual sales at over USD $100 million annually as an FDA approved drug to prevent TD.

IMM-124E recently completed a non-alcoholic steatohepatitis (NASH) trial and is currently being evaluated in ongoing clinical trials in alcoholic steatohepatitis (ASH) and pediatric non-alcoholic fatty liver disease (NAFLD). The Company expects top-line data from the clinical trial of IMM-124E in ASH patients to be released by late 2Q 2019. Immuron is focused on establishing whether statistically-significant reductions in systemic lipopolysaccharide (LPS) endotoxin, observed in the completed Phase 2 trial in NASH patients, are observed in the ASH trial where lowering systemic LPS is the primary endpoint for the trial. Together with the completed trial in NASH patients, the Company will be looking to determine IMM-124E's potential in treating conditions where systemic LPS is believed to play a critical role.

About IMM-124E

IMM-124E is a first-in class, oral polyclonal antibody therapy developed to target the endotoxin lipopolysaccharide (LPS) and other pathogenic bacterial components in the human gastrointestinal tract reducing LPS-related inflammation and systemic translocation. In a recent study completed in 133 biopsy-proven NASH patients where patients were treated with either IMM-124E or placebo for 6 months, treatment with IMM-hjjj124E resulted in a statistically significant reduction of serum LPS levels when compared to placebo. In addition, biomarkers associated with inflammation were also reduced by IMM-124E including ALT, AST and cytokeratin-18. In addition to the adult NASH study, IMM-124E is also being evaluated in two NIH funded Phase II proof-of-concept studies of IMM-124E in children with pediatric NAFLD and adults with alcoholic steatohepatitis.

About Immuron

Immuron Limited (ASX: IMC, NASDAQ: IMRN), is an Australian microbiome biopharmaceutical company focused on developing and commercializing orally delivered targeted polyclonal antibodies for the treatment of inflammatory mediated and infectious diseases. Immuron has a unique and safe technology platform that enables a shorter development therapeutic cycle. The Company currently markets Travelan® in Australia for the prevention of Travelers' Diarrhea, and markets Travelan® in the U.S. and Canada as a dietary supplement for digestive tract protection. Immuron's lead clinical candidate, IMM-124E, is presently in Phase II trials in Severe Alcoholic Hepatitis (SAH) and Pediatric Nonalcoholic Fatty Liver Disease (NAFLD). Immuron's second clinical-stage asset, IMM-529, targets *Clostridium difficile* Infections (CDI), and is presently in a clinical trial *in C. difficile* patients.

- - - END - - -

COMPANY CONTACT:

Gary S. Jacob, Ph.D.
Chief Executive Officer
Ph: +61 (0)3 9824 5254
info@immuron.com

AUS INVESTOR RELATIONS:

Peter Taylor
NWR Communications
Ph: +61 (0)4 1203 6231
peter@nwrcommunications.com.au

USA INVESTOR RELATIONS:

Dave Gentry - CEO
RedChip Companies, Inc.
US Ph: +1 (407) 491 4498
dave@redchip.com

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.