

# US NIH Grants Funding for Second Fatty Liver Trial; Pediatric NASH Study with Emory University

**Melbourne, Australia, 18 August, 2016:** Australian microbiome biopharmaceutical company, Immuron Limited (ASX: IMC), today announced that Emory University has been provided with a grant from the US National Institutes of Health (NIH) to conduct a Phase II clinical study of Immuron's IMM-124E in pediatric Non-Alcoholic Steato-Hepatitis (NASH) patients.

This is Immuron's second NIH grant targeting fatty liver diseases, with the other being the Company's ongoing Phase II trial in ASH (Alcoholic SteatoHepatitis) in cooperation with the University of Virginia.

Mr Thomas Liquard, CEO of Immuron commented:

"This second grant received from the NIH illustrates the importance the agency attributes to Immuron's IMM-124E as a potential treatment for fatty-liver diseases. The competition for NIH grants is fierce and this grant was classified in the Top 1% of all grant requests, highlighting the quality of the proposal and high level of unmet need. Pediatric NASH is a growing health crisis with no approved treatments available and represents a \$billion+ opportunity for Immuron.

With this new program, Immuron now has one of the most **compelling portfolios** of fatty-liver programs in the industry with **three current Phase II trials** in NASH, ASH and Pediatric NASH. Having such a breadth of programs in this space increases the Company's likelihood of success, which not only enhances the chance of economic value for our shareholders, but also diversifies their investment, and sends a clear indication that Immuron is a leader in the field of NASH clinical research.

Immuron is delighted to be partnering with pediatric metabolic diseases key opinion leader Dr Miriam Vos, and her excellent team at Emory University to bring this unique asset to pediatric patients. Dr Vos and her team are at the forefront of pediatric NASH research."

## Added, Dr Miram Vos, the trial's Principal Investigator:

"We are excited to be working with Immuron on this Phase II trial. Pediatric Non-alcoholic Fatty Liver Disease (NAFLD) is the most important liver disease today, and IMM-124E shows great potential for treating children due to its unique safety profile and its mechanism of action which targets the underlying mechanisms of the disease, on multiple levels." This Phase II trial aims to enroll 40 patients with treatment of IMM-124E for 3 months, with 2 major objectives:

- 1. Determine if a three-month treatment with IMM-124E, in combination with standard of care lifestyle advice (SOC) is safe, and results in greater improvement in hepatic inflammation, insulin sensitivity and blood lipids when compared to placebo with SOC; and
- 2. Define the mechanism of action related endpoints in response to three-month treatment of IMM-124E in children with the aim of reducing the above outcomes as well as: stool microbiome, metabolomics, intestinal inflammation, systemic inflammation, transcriptomics, and correlate these with changes in clinical measurements.

Pediatric NASH is a progressive form of liver disease associated with excessive fat storage in the liver together with inflammation, which can then lead to liver fibrosis and cirrhosis. Pediatric NASH is believed to affect up to 5% - 10% of the US pediatric population. A US landmark study <sup>1,2</sup> that examined the incidence of disease in 742 autopsy children who had died of an accident, found that 17.3% of the children aged 15 to 19 years had NAFLD<sup>1,2</sup>. There are currently no approved drug therapies for pediatric NASH.

- 1. Mencin AA, Lavine JE. Advances in pediatric nonalcoholic fatty liver disease. Pediatr Clin North Am. 2011;58(6):1375-1392.
- 2. Schwimmer JB, Deutsch R, Kahen T, Lavine JE, Stanley C, Behling C. Prevalence of fatty liver in children and adolescents. Pediatrics. 2006;118(4):1388-1393.

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### **Company Contact:**

Thomas Liquard Chief Executive Officer AUS Ph: +61 (0)3 9824 5254 thomasliquard@immuron.com

#### **Immuron US Investor Relations:**

Jon Cunningham RedChip Companies, Inc. US Ph: +1 (407) 644 4256, (ext. 107) jon@redchip.com

#### About Immuron:

Immuron Ltd (ASX: IMC; OTCQB: IMROY) is a microbiome company focused on developing and commercialising oral immunotherapeutics for the treatment of a many gut mediated diseases. Immuron has a unique and safe technology platform that enables a shorter development therapeutic cycle. The Company currently markets and sells Travelan® for the prevention of travellers' diarrhoea, whilst its lead product candidate IMM-124E is in Phase 2b clinical trials for NASH and ASH. These products together with the Company's other preclinical immunotherapy pipeline products targeting immune-related diseases currently under development, will meet a large unmet need in the market.

For more information visit: <u>http://www.immuron.com/</u>

#### Forward-Looking Statements:

Certain statements made in this release are forward-looking statements and are based on Immuron's current expectations, estimates and projections. Words such as "anticipates," "expects," "intends," "plans," "believes," "seeks," "estimates," "guidance" and similar expressions are intended to identify forward-looking statements. Although Immuron believes the forward-looking statements are based on reasonable assumptions, they are subject to certain risks and uncertainties, some of which are beyond Immuron's control, including those risks or uncertainties inherent in the process of both developing and commercialising technology. As a result, actual results could materially differ from those expressed or forecasted in the forward-looking statements. The forward-looking statements made in this release relate only to events as of the date on which the statements are made. Immuron will not undertake any obligation to release publicly any revisions or updates to these forward-looking statements to reflect events, circumstances or unanticipated events occurring after the date of this release except as required by law or by any appropriate regulatory authority.