



## Immuron Successfully Completes NASH Phase II Clinical Study Milestone

**Melbourne, Australia, November 9, 2017:** Immuron Limited (ASX:IMC) (NASDAQ:IMRN), an Australian microbiome biopharmaceutical company focused on developing and commercialising oral immunotherapeutics for the treatment of gut-mediated diseases, announced today that it has completed its Last Patient Last Visit (LPLV) for its IMM-124E Phase II study for the treatment of NASH, and expects data due in the first quarter of next year (Q1 CY2018).

The last patient in the Company's NASH clinical study conducted the final scheduled visit on October 9, following a 28-week study period. The study enrolled a total of 133 patients with biopsy-proven NASH. On October 18, the same study site conducted its Close-Out Visit (COV), the last on-site monitoring visit conducted for the study. This effectively concludes patient dosing and research activities at all study sites for the IMM-124E Phase II study.

Immuron will report its top line clinical trial results in the Q1 CY2018, once all data is finalised and reviewed by the Company and its Scientific Advisory Board. Once reported, the Company will continue its partnering and business development efforts to reach the next phase of clinical studies.

In July 2017, the Company announced its interim analysis results conducted by analysing a total of 122 patients, 80 of which completed their 24-week treatment of IMM-124E. In this report, IMM-124E demonstrated good safety features compared to the placebo. Additionally, the Data and Safety Monitoring Board (DSMB) reported that IMM-124 demonstrated a statistically-significant reduction in ALT – an enzyme most commonly found in the liver – over time when the two treatment doses were compared to the placebo arm. The same effect was noted for AST – another enzyme found in the liver – and a correlation between these two enzymes was also reported. These preliminary results suggest a reduction in liver injury (necro-inflammation) over the duration of treatment compared to the placebo.

*"We are now working diligently to analyse and collate all remaining data from our contracted laboratories and CROs,"* said Immuron Head of Medical, Dr Dan Peres.

*"Following thorough analysis, we expect to report our top line results in Q1 CY2018. Based on the safety profile and the efficacy signal we reported earlier this year, we believe that the results generated by this analysis position IMM-124E as a unique product for treating NASH patients on its own, or in combination with other promising treatments."*

*“The completion of these patient studies marks a pivotal inflection point for Immuron, as we now look forward to analysing and reporting the data results,” said Jerry Kanellos, CEO of Immuron Ltd.*

*“The pharmaceutical quest to treat NASH that many call the ‘Dash to NASH’ is one that represents tremendous market opportunity and high-growth potential. We hope to continue advancing through later stages of clinical trials, and ultimately making a difference for NASH patients and the medical community, as well as realizing value for shareholders.”*

\* Data Safety and Monitoring Board

\*\* Alanine transaminase – measured levels of ALT assist in liver function evaluation

--- END ---

**COMPANY CONTACT:**

**Jerry Kanellos**

Chief Executive Officer

Ph: +61 (0)3 9824 5254

jerrykanellos@immuron.com

**USA MEDIA CONTACT:**

**Kate Caruso-Sharpe**

FischTank Marketing and PR

US Ph: + 1 646 699 1414

kate@fischtankpr.com

**AUS INVESTOR RELATIONS:**

**Peter Taylor**

NWR Communications

Ph: +61 (0)4 1203 6231

peter@nwrcommunications.com.au

**USA INVESTOR RELATIONS:**

**Jon Cunningham**

RedChip Companies, Inc.

US Ph: +1 (407) 644 4256, (ext. 107)

jon@redchip.com

**ABOUT IMMURON:**

Immuron Ltd (ASX: IMC) is a biopharmaceutical company focused on developing and commercialising oral immunotherapeutics for the treatment of 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’ diarrhea whilst its lead product candidate IMM-124E is in Phase 2 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: <http://www.immuron.com>

**About the IMM-124E Study**

The IMM-124E study is a Phase 2 proof of concept multinational, randomized, double-blind study comparing 2 doses IMM-124E to placebo for the treatment of NASH in adults with any stage biopsy-proven NASH. The trial enrolled 133 patients and is still on going. The primary endpoint is the improvement of liver steatosis as assessed by MRI comparing the mean values), as measured at the 24 weeks’ time point. The key secondary endpoints are: change in ALT as well as other liver enzymes and metabolic markers.

IMM-124E enrolled adults with all-stage biopsy proven NASH up to 12 months of randomization.

For personal use only

#### **About IMM-124E**

IMM-124E is an oral, three-times-daily, non-absorbable compound containing poly-clonal anti-LPS immunoglobulins proposed to interact with the gut LPS and immune system to achieve an immunomodulatory effect reducing LPS-related inflammation and inducing tolerance. Because of this unique mechanism of action, targeting multiple pathways, IMM-124E has the potential to play a differentiated role in the management of NASH and may form the cornerstone of NASH combination treatment strategies, both as a single agent and in combination with other agents.

In addition to the adult NASH study, IMM-124E is also being evaluated in the pediatric population in a Phase 2 proof-of-concept study of IMM-124E in children with Pediatric NAFLD.

#### **About Non-Alcoholic Steatohepatitis (NASH)**

NASH is a severe type of non-alcoholic fatty liver disease (NAFLD), which is characterized by the accumulation of fat in the liver with no other apparent causes. NASH occurs when the accumulation of liver fat is accompanied by inflammation and cellular damage. The inflammation can lead to fibrosis (scarring) of the liver and eventually progress to cirrhosis, portal hypertension, liver cancer, and eventual liver failure.

NASH is an emerging health crisis impacting 3% to 5% of the U.S. population and 2% to 4% globally, and is the fastest growing cause of liver cancer and liver transplant in the U.S. The increasing prevalence of NASH is attributed to the growing obesity epidemic and the disease is often diagnosed in patients who have diabetes, high cholesterol or high triglycerides. There is currently no approved treatment for NASH.

#### **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.

For personal use only