Immuron Expands on Preliminary Success of Phase II Study in NASH Treatment with IMM-124E

Melbourne, Australia, 13 July 2017: Australian biopharmaceutical company, Immuron Limited (ASX:IMC; NASDAQ:IMRN), is pleased to expand on the preliminary announcement of the interim analysis results recently reported from the IMM-124E Phase II study in NASH (ASX Announcement, 10 July 2017).

Immuron's aim is to illustrate that IMM-124E has the potential to play a differentiated role in the management of NASH which may form the cornerstone of NASH combination treatment strategies, both as a single agent treatment and in combination with other agents.

Key Highlights

- **Interim Analysis report achieves main goals – Safety, Tolerability and Futility**
- **Proof of concept for a biological effect demonstrating decrease in liver injury**
- **Highest dose levels show no indication of toxicity, succeed primary safety hurdles**
- **Interim Analysis Committee determines study should progress to next stage**
- **Immuron on schedule to complete clinical trial of all remaining active participants in time to report top line results by the end of 2017**

Commenting on the results of the study, Immuron's Head of Medical, Dr Dan Peres, MD said:

> *"The study results so far have been extremely encouraging for us as IMM-124E is demonstrating the expected safety and data to show it's potential to treat NASH as a non-absorbable drug. We expect the remaing data coming in through until the end of the year will demonstrate additional pathways making IMM-124E a strong candidate for the treatment of NASH either on its own, or in combination with other therapies."*

The primary objective of the interim analysis was to evaluate the safety of the product, and search for signals of efficacy from the primary, secondary and exploratory endpoints at two dosage levels of IMM-124E under evaluation when compare with a placebo. As expected there were no indications of safety concerns or adverse events, serum biochemistry, hematology, vital signs, or physical examination findings for both treatment groups.

As previously reported, the interim analysis succeeded in meeting its primary goals,safety and tolerability, and accordingly the Company's Medical Advisory Committee reviewing the interim analysis results determined the study should proceed to completion as planned.

The higher evaluated dose of IMM-124E was well tolerated with a significant safety margin to allow the evaluation of even higher doses in the future if required.

Other parameters evaluated were liver fat (using MRI compared with placebo), Liver enzymes (focusing on ALT), Hemoglobin A1c, metabolic markers, immunological markers, serum bovine Ig (pharmacokinetics), and serum LPS levels.

In order to be included in the interim analysis, patients needed to have attended at least one post-baseline visit. The Full Analysis Set (FAS population) had 122 patients who met this criterion. To be included in the Per Protocol (PP population), patients had to have completed the entire 24-week treatment period, have valid Baseline and Week 24 MRI values prior to 28 February 2017 for hepatic fat fraction, be 80% - 120% compliant with study treatment and not have any major protocol deviations. A total of 69 patients met these criteria. Due to the small cohort of participants included in the analysis no significance was expected to be reported at this early stage.

The Company is very pleased to be able to report the efficacy signals on liver enzymes (ALT and AST) which demonstrated a dose related reduction in both treatment doses at 24 weeks, though not significantly different than placebo.

The inherent wax and wane of these parameters over time and the significant affect of the baseline values led us to run the AUC analysis to account for all data contrary to only 2 time points. Such analysis translated into a near-significant reduction of these parameters over time (AUC ANCOVA analysis). Additional modeling emphasized this effect further to the point of statistical significance.

A dose-related treatment effect trend was reported in both treatment groups compared to placebo. The greatest decrease occurred in the highest dose group, with the low dose group decreasing by an intermediate amount compared with the placebo group.

The Company believes that this documented effect within the entire study population, together with the established correlation of both liver enzymes, with liver injury, is the proof of concept for a biological effect demonstrating decrease in liver injury by IMM-124E.

The study's failure to meet a signal on Fat Fraction was not surprising due to the wide range of results reported across the participant cohort analyzed, where readings ranged from 2% FF up to 40% FF. The interim analysis was not powered to achieve a statistical end point in this area.

We are currently on track to complete the NASH clinical trial for all remaining active study participants in order to report top line trial results for the entire study by the end of 2017.

Exploratory endpoints as outlined in the study protocol include mean serum concentrations of: lipopolysaccharide (LPS), C-reactive protein (CRP), cytokeratin (CK)-18 fragments, C-peptide , glucagon-like peptide (GLP)-1 and adiponectin and subsets of inflammatory cytokines: interleukin (IL)-6, IL-1α, IL1β, IL-2, IL-4 IL-10, IL-13, IL-12, IL-17, IL-23 interferon gamma (IFNγ), Transforming Growth Factor Beta (TGF-β) and tumor necrosis factor alpha (TNFα); These parameters are currently being analyzed by our contract research organizations and we hope to have the final interim report compiled by the end of August 2017.

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ABOUT IMMURON:

Immuron Limited (NASDAQ: IMRN; ASX: IMC), is a biopharmaceutical company focused on developing and commercialising oral immunotherapeutics for the treatment of 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 and its lead clinical candidate, IMM-124E, is in Phase 2 clinical trials for NASH, ASH and Pediatric NAFLD. Immuron's second clinical stage asset, IMM-529, is targeting C. *difficile* Infections (CDI). 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 global immunotherapy 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.

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.