NASH Phase II Interim Analysis Reveals Improvement in Liver Enzymes (AST and ALT) with Good Safety and Tolerability

DSMB Recommends Trial to Continue to Completion

Melbourne, Australia, 10 July 2017: Australian biopharmaceutical company, Immuron Limited (ASX: IMC; NASDAQ: IMRN), is pleased to announce safety and efficacy results of the interim analysis of its ongoing IMM-124E Phase II study in NASH. The objectives of this analysis was to establish the safety of the compound and to provide a preliminary read on efficacy signals.

The NASH Phase II trial has enrolled 133 patients with the top-line results expected in 4Q2017. The pre-planned analysis was triggered when 80 subjects completed treatment.

The demographics of the population analyzed in the interim analysis were balanced in all three groups (placebo, low dose -600mg- and high dose -1200mg-) including sex, race, age, height, weight, BMIs, HbA1c and baseline hepatic fat fraction (HFF).

Highlights from the interim analysis are as follows:

- IMM-124E was safe and there were no safety signals when compared to placebo.
- The treatment was well tolerated and no subjects discontinued therapy due to side effects.
- The IMM-124E 1200mg and 600mg groups, as well as the placebo group, all demonstrated a significant change of ALT at 24 weeks compared to baseline (p=0.0038, p=0.016 and p=0.0337). However, no statistical difference was noted between the groups.
- When accounting for all ALT values thoughout the study period, the area under the curve (AUC) was calculated, and when correcting for ALT baseline values (using ANCOVA), a trend (p=0.067) in improvement in ALT was noted in the 1200 mg group when compared to placebo .
- When using the predicted ALT-AUC values, the overall AUC for ALT was statistically significantly lower for the 1200mg and 600mg groups (p=0.0036 and p=0.0075, respectively) when compared to placebo.
- The overall AUC for AST values, when corrected for baseline values, was also significantly lower in the 1200mg and 600mg dose groups (p=0.0036 and p=0.0098, respectively) when compared to placebo.
- There was no evidence of systemic absorption of IMM-124E as assessed by circulating bovine immunoglobulin.

- At the time of this interim analysis, no difference was noted in the hepatic fat fraction (HFF), which is the study's primary endpoint between the groups. This is most likely attributable to the small sample size in this analysis.

Based on the results of the interim analysis, IMM-124E has demonstrated to be a non-absorbable, safe and tolerable compound in patients with NASH. Early biochemical improvements in liver enzymes are noted, suggesting potential therapeutic benefit for treatment of NASH***. The DSMB recommendation was to continue the trial to completion, as there is no concern for safety or futility .***

Dan Peres, Immuron's Head of Medical commented:

"We are encouraged as both ALT and AST demonstrated strong correlation, suggesting an improvement of liver injury in the IMM-124E treated patients.

We are looking forward to completing the IMM-124E study and reporting the final results with the entire body of data by the end of the year. We believe the additional MOA data we are generating in partnership with Duke University and SanyalBio will further strengthen our prior data to support IMM-124E's unique mechanism of action which will assist us to design of the next phase in our clinical program."

Immuron CEO Thomas Liquard, added:

"We are encouraged by the results of this interim-analysis and are pleased by the DSMB's recommendation to continue the study to completion. NASH is increasingly viewed as a multifactorial disease whereby the approval of several chronic therapies, with different MOAs and used in combination, will be needed to control its long-term effects. These results support our belief that IMM-124E is a compound with a complex MOA that has the potential to have a beneficial impact in hard-to-treat fatty-liver diseases including NASH, ASH and Pediatric NAFLD."

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

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

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

US PUBLIC RELATIONS:
Eric Fischgrund
FischTank - Marketing and PR
US Ph: +1 (646) 699 1148
eric@fischtankpr.com

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

FORWARD-LOOKING STATEMENTS:

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