



## Immuron Presents NASH Interim Results at BioShares Conference

**Melbourne, Australia, 7 August 2017:** Australian biopharmaceutical company, Immuron Limited (ASX:IMC; NASDAQ:IMRN), is please to provide investors with a copy of its recent presentation slide deck showcased at the 2017 BioShares Biotech Summit conference held in Queenstown, New Zealand.

CEO, Dr Jerry Kanellos, presented clinical data from the Company's recent interim analysis report from the IMM-124E Phase II study in NASH during the Fibrosis session entitled "*Insights to Fibrosis Drug Discovery and Development*".

A copy of the presentation slide deck is appended to this announcement.

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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>



**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.



# Immuron Limited

*Developing Therapies that Fundamentally  
Change the Paradigms of Care*

July 2017

Immuron

ASX:IMC NASDAQ:IMRN

# Oral Immunotherapy: Scalable, Disruptive Technology



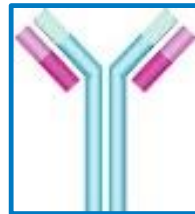
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## Vaccines Are Developed



2

## Antibodies Are Harvested from Colostrum



Antigen Specific  
Antibodies  
(IgG and IgG1)

+



Adjuvants

3

## Broad Therapeutic Effect

Induction of  
regulatory  
T-cells

+

Clearance of  
Targeted GUT  
Pathogens

- Reduced gut and blood pathogens responsible for initiating inflammation
- Reduces systemic inflammation
- Lowers organ injury
- Not associated with general immune suppression
- Generally Regarded as Safe (GRAS)

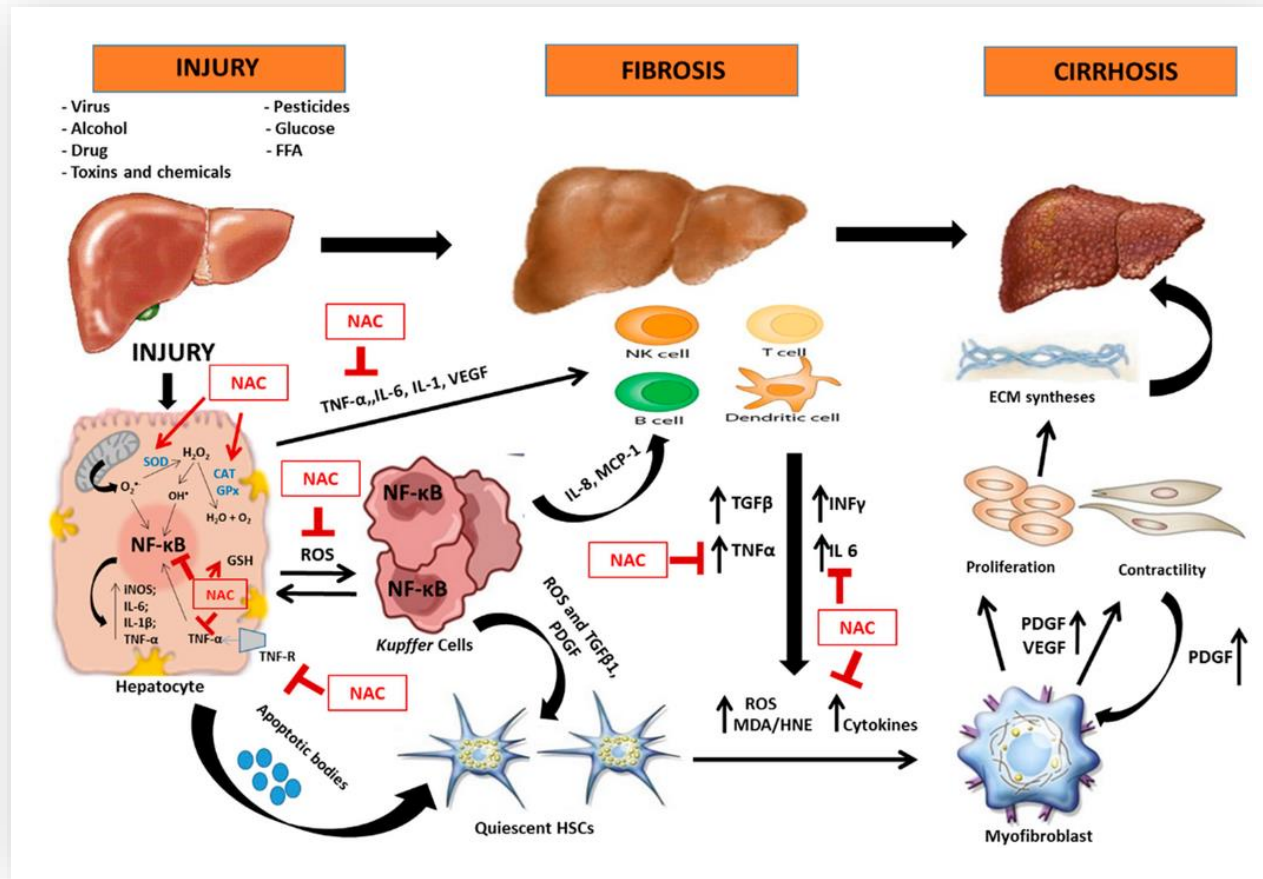
## Competitive Advantage

- **Platform capable of spawning multiple drugs** → Long-term value creation
- **Regulated as biologics by the FDA** → 12 years exclusivity in the US for each approval
- **Significant hurdles to generic biosimilar entry** → No pharmacokinetic baseline; Mixture (e.g., Copaxone)
- **Safety established** → Generally Regarded As Safe (GRAS)

# NASH (Non-Alcoholic Fatty Liver) Pathophysiology



## NASH – Pathophysiology



- Blood derived antigens (including circulating LPS) determines tolerance vs. inflammation
- Kupffer cells play a key role in liver inflammation and fibrosis
- Tregs hold a key role in tolerance (homeostasis)
- Much like hepatic tolerance the gut immune system can promote anti-inflammatory effect

Source: Adapted from Cohen-Naftaly; Scott L. Friedman, 2011



# IMM-124E in NASH (Non-Alcoholic Fatty Liver)



- **Targeted antibodies mediate broad anti-inflammatory mechanism of action**
  - Upstream Effect: **LPS-TLR4 pathway**
  - Downstream: **Anti-inflammatory through both innate and adaptive immune systems** (e.g., the induction of regulatory T-cells to control and inhibit excess inflammation)
- Strong **anti-fibrotic effect** demonstrated with CCl4 model
- **Unique competitive profile due to safety/MOA:**
  - Addresses **multi-factorial** nature of NASH
  - Potential for **broad combination use**
  - Safety profile supporting of **long-term chronic use**
  - Potential to **expand to mild/moderate** populations
- **Market exclusivity** (biologics; High barriers to generic biosimilar entry)

# IMM-124E – Summary of Data

Prevention of Fibrosis and Improvement in Metabolic & Inflammatory Markers



## CCl4 Fibrosis Studies

- **Carbon-Tetrachloride (CCl4) a non-disease related fibrosis model**
- **Aim:** To demonstrate effects of IMM-124E on Fibrosis caused by Intraperitoneal CCl4
- **Results:**
  - Marked **reduction in Liver Fibrosis and Inflammation** on Histology
  - Marked reduction on Liver Damage markers (i.e. ALT, Bilirubin etc.)
  - Marked **reduction in Liver Activated Macrophages (F4/80 high)**

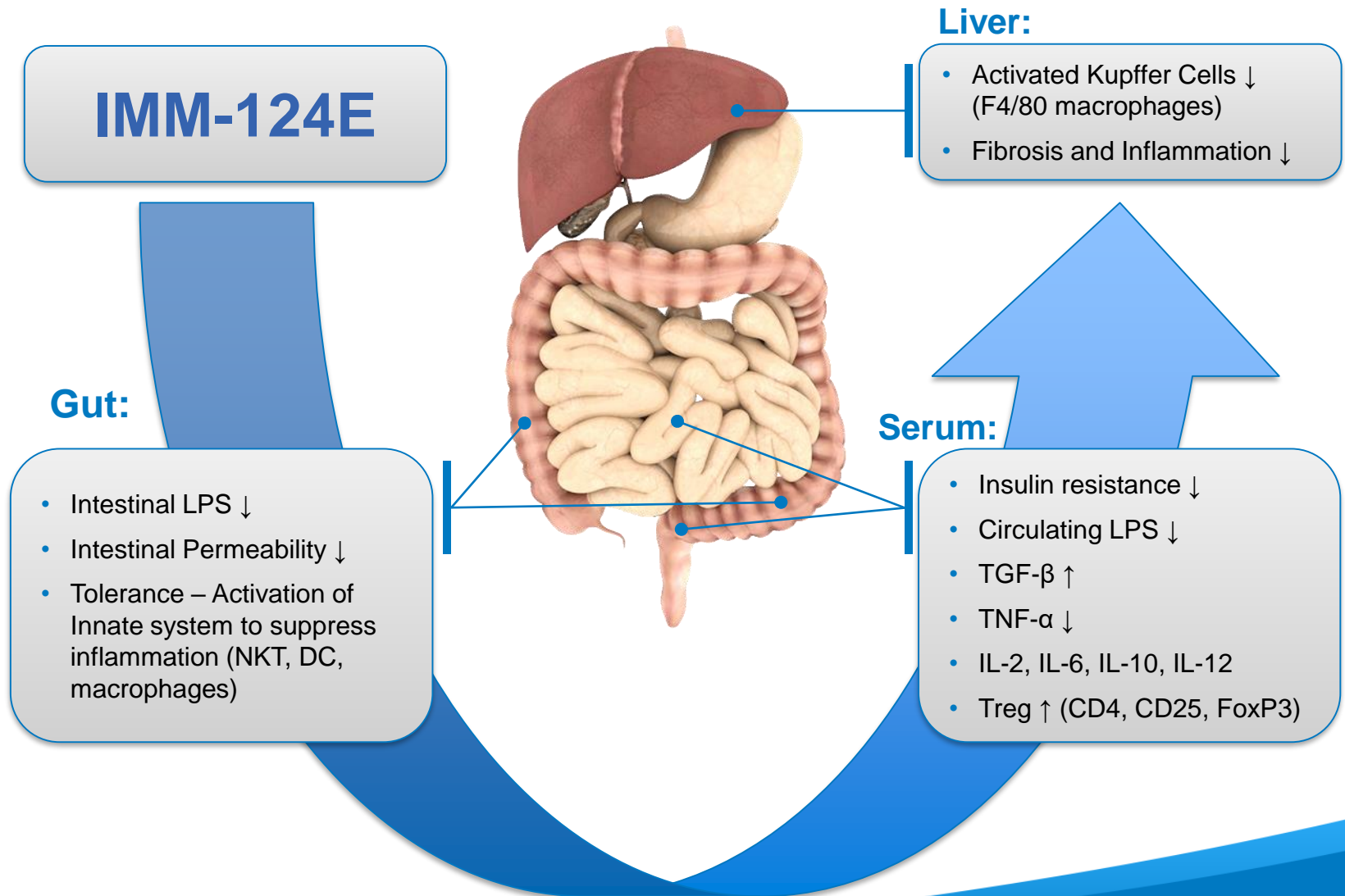
## Ob-Ob Mice

- **Model represents the Metabolic syndrome**
- **Aim:** To demonstrate the effect of IMM-124E or **anti-LPS IgG** (derived from IMM-124E)
- **Results:**
  - Anti-LPS IgG considerable reduces ALT level
  - Improved metabolic status for IG and IMM-124E treated mice (i.e. TG, Fasting Glucose and OGTT)
  - **Anti-inflammatory shift: Decreased TNF- $\alpha$  and increase splenic NKT cells**

## Phase 1/2 Clinical Studies

- **Aim: To show safety and efficacy of IMM-124E Biopsy Proven NASH Patients**
- **Population:** 10 subjects with biopsy proven NASH and Type 2 Diabetes
- **Results:**
  - Improved Metabolic status (e.g. HbA1c, HOMA OGTT) GLP1 and Adiponectin
  - Improved Liver status (e.g. ALT)
  - **Proof of concept: increase in Circulatory Regulatory T-Cell**

# IMM-124E in NASH (Non-Alcoholic Fatty Liver)





# IMM-124E: Fatty-Liver Portfolio – 3 Phase II Trials



## Three Ongoing Phase 2 Programs: NASH, ASH and Pediatric NAFLD

### NASH

- Lead Principal Investigator: Arun Sanyal; Former President of AASLD (American Association for the Study of Liver Diseases) and current Chair of the Liver Study Section at the NIH (National Institute of Health)
- Multi-center, double-blinded, placebo controlled trial; 25 sites running in US, Australia and Israel
- Fully recruited: 134 patients with biopsy proven NASH
- Primary endpoint: changes in liver fat content confirmed by MRI; changes in ALT (liver enzymes)
- 3 arms: placebo, high dose and low dose
- Timing: topline results by 4Q 2017

### ASH

- NIH funded; sponsored by University of Virginia
- Expected enrollment: 66 patients
- Endpoint: ALT
- Timing: topline results in 2018

### Pediatric NAFLD

- NIH funded; sponsored by Emory University
- Expected enrollment: 40 patients
- Endpoint: ALT; 3 months treatment
- Timing: topline results in 1H 2018



## IMM-124E-2001 Interim Analysis – No Safety Issues Reported

### NASH Study

- The study has 12 scheduled visits over the study duration of 28 weeks (24 weeks treatment and 4 weeks follow-up).
- The interim analysis was triggered when 80 patients (two thirds of the planned study population) had completed the entire 24-week treatment period and had verified Baseline and week 24 MRI data.
- The purpose of the interim analysis was to determine whether any signals exist regarding; safety of the study treatment and to search for signals of efficacy from primary, secondary and exploratory endpoints.

### Patient Populations

- A total of 133 patients have been randomized into the study.
- To be included in the interim analysis patients were required to have attended one post baseline visit.
- The Full Analysis Set population had 122 patients who met this criterion.
- To be included in the Per Protocol population patients had to complete the 24-week treatment period, have valid Baseline and Week 24 MRI values. A total of 69 patients met this criteria.

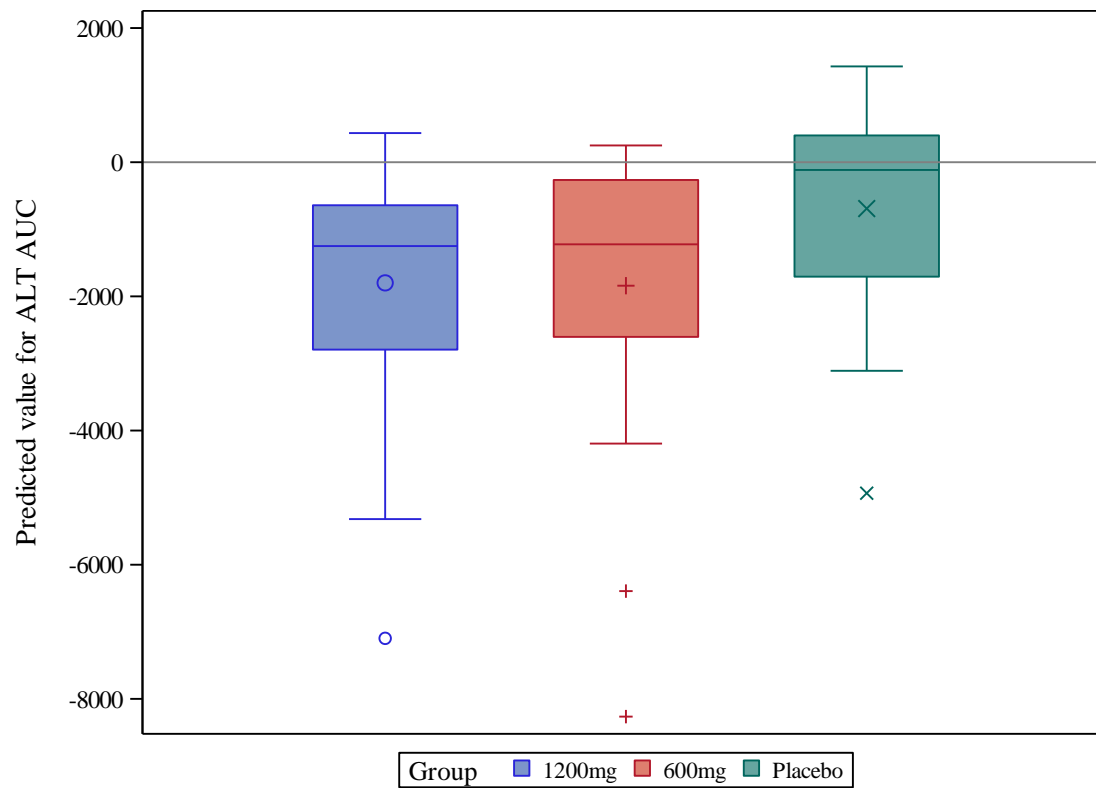
### Results

- Baseline participant characteristics across the 3 treatment groups are similar
- Baseline LPS 1000 – 10,000 times level reported for healthy blood donors
- Primary endpoint, change in HFF from Baseline to Week 24 did not show any treatment signals, in either FAS or PP populations
- There was a trend for serum ALT to decrease throughout 24 weeks.
- Exploratory analysis of changes in ALT values taking into account all time points by calculating area under the curve and correcting for baseline values demonstrated a dose-related effect.

# Phase II: Interim Analysis Report - Improves Liver Function



## Box plot for predicted ALT AUC from ANCOVA (FAS population) Improved Liver Enzymes



Predicted value adjusted for Baseline ALT

Analysis showed that the 1200 mg treatment group approached a significant difference to Placebo and that a dose effect became evident with the 600 mg group

The 1200 mg and 600 mg groups were not different from one another ( $p=0.3589$ ) but each approached significant difference compared to placebo ( $p=0.0036$  and  $p=0.0075$ )

**Thank You**