



Immuron Limited

Oral Immunoglobulins

Changing the Paradigms of Care

September 2018

Forward Looking Statement

Certain statements made in this presentation 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 commercializing 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 presentation 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 presentation except as required by law or by any appropriate regulatory authority.

Company Highlights



- **Clinical stage biopharmaceutical** company targeting inflammatory-mediated and infectious diseases with **oral immunotherapies**
- **Validated technology platform – with one registered asset generating revenue**
- **2 Lead clinical assets in Phase 2 development** for the treatment of multiple high value indications, **Fat Liver Disease and CDI**.
- **Excellent safety profile, GRAS by FDA, expedited regulatory review and approval process**
- **High-value peer licensing deals and M&A underscore potential upside**
- **Experienced** Management Team and **strong support** from leading **KOLs and institutions (NIH, DoD)**
- **Company listed on NASDAQ in 2Q 2017**

Prominent Scientific Advisory Board and Leading Research Partners



Advisory Board

Dr. Arun Sanyal (MD)

University of Virginia

Former President of the AASLD. Current Chair of the Liver Study Section at the NIH. IMM-124E lead PI.

Dr. Stephen Harrison (MD)

*San Antonio Military Medical Center
Brooke US Army Medical Center*

Internationally renowned expert in NASH. Lead PI of Galectin's GR-MD-02's Phase II trial.

Dr. Manal Abdelmalek (MD)

Duke University Medical Center

Dr. Abdelmalek is a leading investigator in the field of NASH.

Dr. Gerhard Rogler (MD, PhD)

Zurich University

Professor Rogler is a leader in the field of Colitis and has authored more than 200 original peer-reviewed articles.

Dr. Miriam Vos (MD)

Emory University

Dr. Vos specializes in the treatment of gastrointestinal disease in children as well as fatty liver disease and obesity.

Dr. Dena Lyras (PhD)

Monash University

Dr. Lyras is one of the world's leading experts in *C. difficile*.

Organizations



Universität
Zürich^{UZH}

Platform Overview: Oral Immunoglobulins



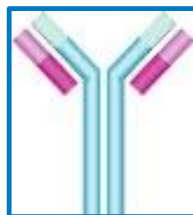
1

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
- Strong anti-toxin properties
- Decrease toxin levels results in decrease gut damage
- Generally Regarded as Safe (GRAS)

Competitive Advantage

- **Platform capable of producing multiple drug candidates** → Long-term value creation
- **Bovine IgG possesses a unique ability to remain active in the human GI tract** → delivering its full benefits to the bacteria found there
- **Bovine IgG is capable of withstanding the acidic environment of the stomach and is resistant to proteolysis by the digestive enzymes in the GI tract**
- **Safety established** → Not absorbed into the blood

Immunotherapy Targeting Pathogenic Bacteria



Technology Platform Capable of Producing High Levels of Antibodies against specific pathogenic and antigenic determinants

Targeting Virulence Factors;

- Spores
- Lipopolysaccharide
Endotoxins
- Exotoxins
- Fimbriae & Molecules which facilitate adhesion
- Surface Layer Proteins which contribute to Colonisation
- Flagella (Flagellin)

Antigens Important For;

- Outer Membrane Stability
- Host Immune Evasion
- Motility
- Host Cell Adherence
- Colonization
- Cellular Invasion

Immunotherapy Targeting Pathogenic Bacteria



Proprietary Technology to “Weed” Harmful Bacteria

Direct Protective MOA

- Toxin Neutralization
- Suppression of Germination
- Suppression of Adhesion
- Suppression of Motility
- Suppression of Colonization

Indirect Protective MOA

- Inhibition of Toxin Induced Inflammatory Signal Cascades
- Anti-Inflammatory Effect via Stimulation of the Innate Immune Response
- Enhancement of Gut Barrier Function
- Inhibition of Epithelial Cell Apoptosis

Immuron's Clinical Programs

Multiple Near-Term Inflection Points



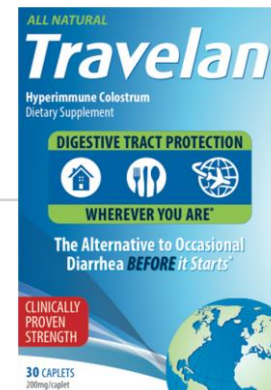
Program	Indications	Development Stage				Program Highlights
		Pre-Clinical	Phase 1	Phase 2	Phase 3	
Anti-Inflammatory Programs						
IMM-124E	NASH					- Topline results reported 1Q 2018
IMM-124E	ASH					- NIH Funded; UVA - Topline results expected 2019
IMM-124E	Pediatric NAFLD					- NIH Funded; Emory University - Topline results expected 1Q 2019
IMM-124E	Colitis					Collaboration with Dr. Rogler, Zurich University - results reported 2Q 2018
IMM-124E	Autism					Murdoch Childrens Research Institue, La Trobe & RMIT Universities
Anti-Infective Programs						
IMM-529	<i>C. difficile</i>					- Phase 1/2 initiated 4Q 2017 - Topline results expected 1H 2019
IMM-124E / Shigella Vaccine	Shigella Infections					Collaboration with US Army - results reported 1Q 2018
IMM-124E	Campylobacter; ETEC Infections					Collaboration with US Navy - - results reported 2Q 2018

TRAVELAN

- Hyperimmune bovine IgG powder 200mg (30 caplets, 30 month shelf life)
- Reduces the risk of TD, reduces the symptoms of minor GI disorders



Australian Packaging



US Packaging

Regulatory Authority	Regulatory Pathway	Indications
TGA	Listed Medicine	<ul style="list-style-type: none"> • Reduces the risk of travellers' diarrhoea • Reduces the symptoms of minor gastro-intestinal disorders • Antimicrobial
Medsafe (New Zealand)	Not marketed in New Zealand	Not marketed in New Zealand
FDA (USA)	Self-affirmed generally regarded as safe (GRAS) Dietary supplement. FDA does not review dietary supplements for safety and effectiveness	Hyperimmune colostrum dietary supplement
Health Canada	Natural Health Product	Travelan helps reduce the risk of traveller's diarrhea.
EMA (Europe)	Not marketed in Europe	Not marketed in Europe

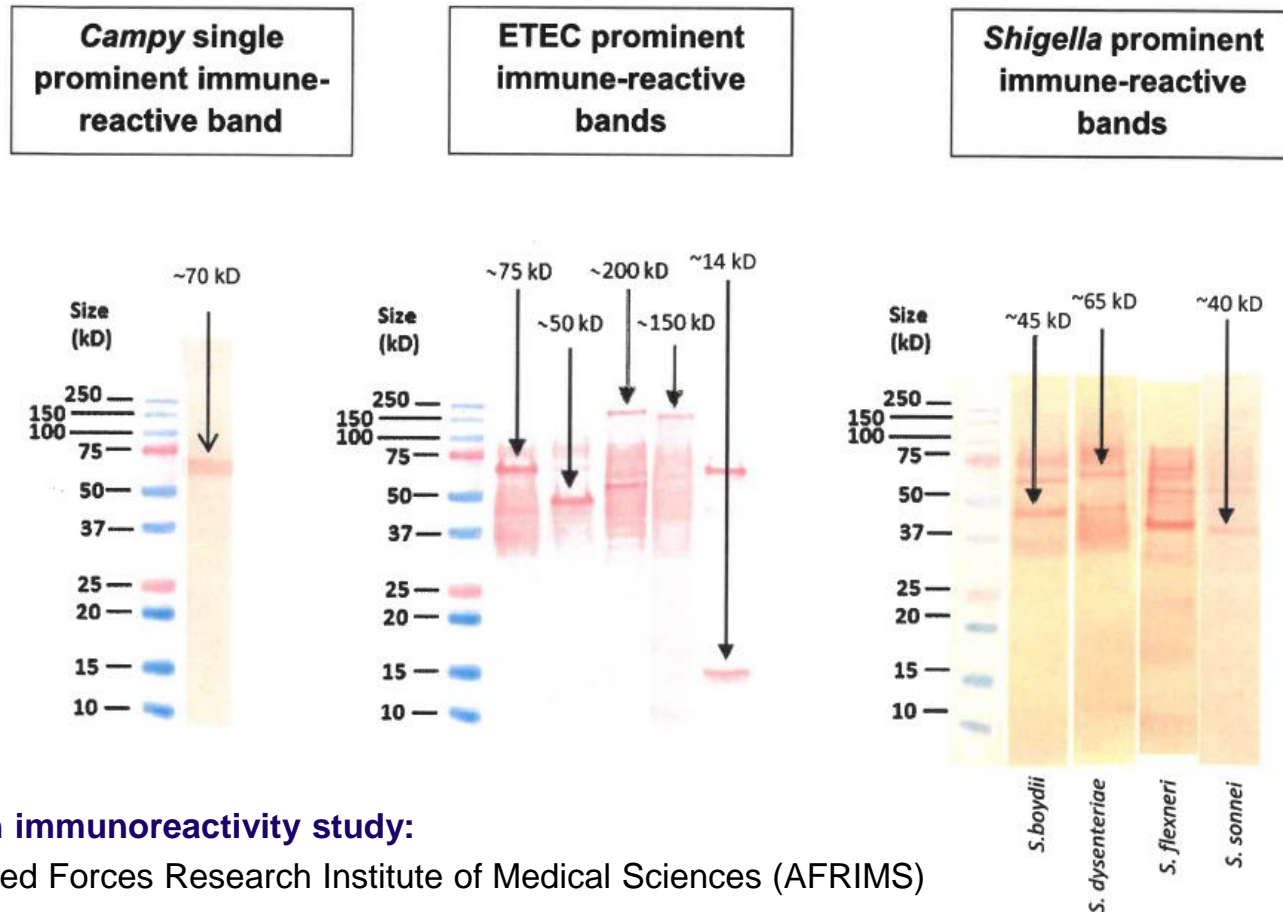
ARTG Listing for Travelan

<http://www.travelanusa.com/>

Prominent immune-reactive bands of *Campylobacter*, ETEC and *Shigella* isolates



from Bhutan, Cambodia, Nepal and Thailand



Travelan immunoreactivity study:

- Armed Forces Research Institute of Medical Sciences (AFRIMS)
- Walter Reed Army Institute of Research (WRAIR)
- US Naval Medical Research Centre (NMRC)

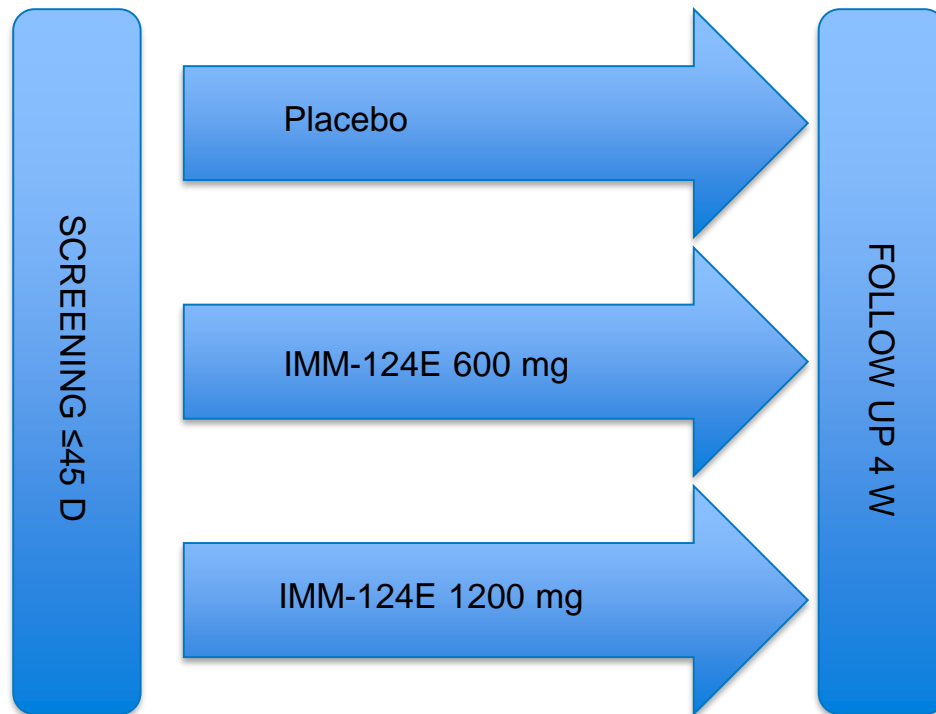
Immuron Limited



*IMM-124E-2001 NASH Clinical Trial
Top Line Results*

March 2018

STUDY DESIGN IMM-124E-2001



120 patients, 3-arms, Randomized, double blind, Placebo – 2dose, balanced 1:1:1 design

Major Inclusion Criteria

Histologically proven NASH (≤ 12 months)

- NASH activity score (NAS) ≥ 4
- Cytologic ballooning score of at least 1
- 10% or more macrovesicular steatosis
- HBA1C of ≤ 9.0

STUDY ENDPOINTS



PRIMARY

- Safety
- Hepatic Fat Fraction

SECONDARY

- liver enzymes – ALT, AST, GGT
- Glucose homeostasis and serum lipid profile
- Serum Bovine Ig – Pharmacokinetics
- Establish recommended dose

MoA

- Lipopolysaccharides (LPS)
- CK-18
- Cytokines
- Adiponectin and GLP-1

STUDY POPULATIONS



Patients Screened: N = 237

Screening Failure n =
104

Patients Randomized: N = 133

Early Discont. n = 21
Non-compliance n=8
Major deviations n=2

Study Analysis Sets:

PP: 102 FAS: 133 ITT: 133

Definitions:

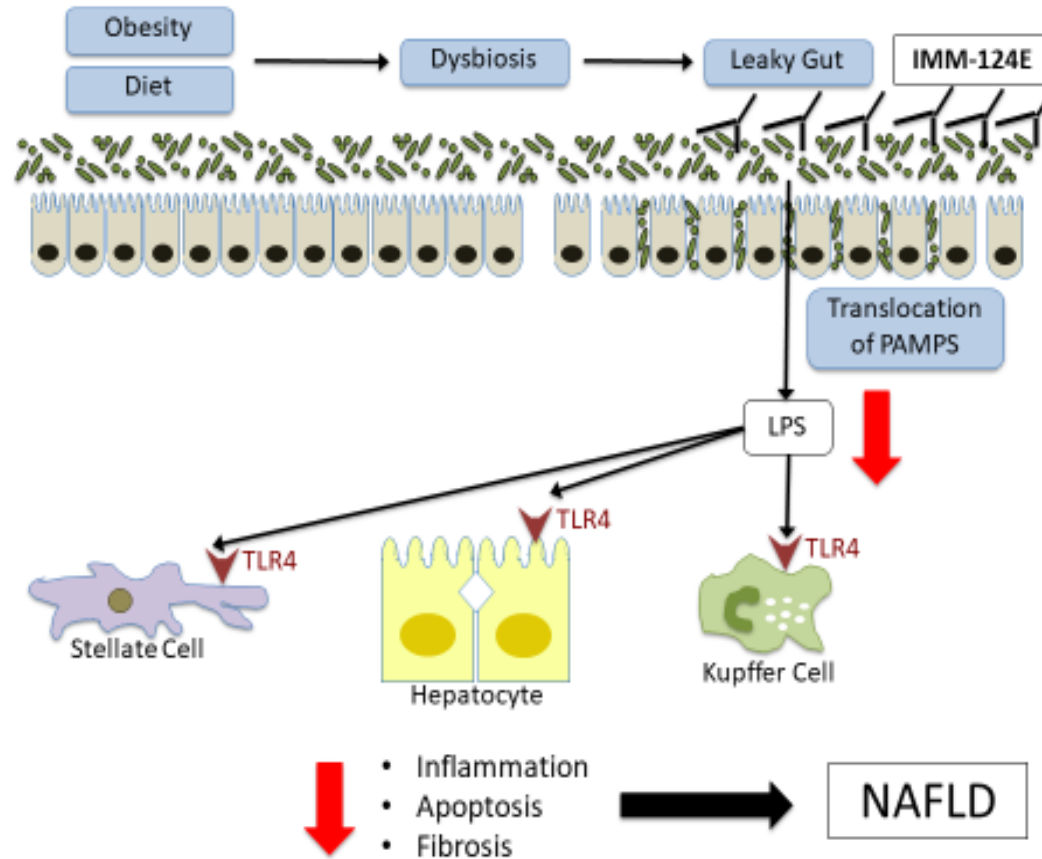
ITT = Intention to Treat
FAS = Full analysis set
PP = Per Protocol

SUMMARY: IMM-124E Clinical Trial Results



- **First-In Class Anti-LPS Mechanism of Action confirmed for IMM-124E**
- **Results demonstrate excellent safety and tolerability**
- **Statistically significant reduction in serum endotoxin/ Lipopolysaccharide (LPS) levels compared to placebo**
- **Statistically significant reduction in mean serum ALT in patients with elevated pre-treatment ALT**
- **Statistically significant Reduction of additional serum NASH biomarkers associated with liver damage – AST and CK-18**
- **IMM-124E retained within the GI tract and not absorbed into the bloodstream, contributing to favourable safety profile**
- **No effect on liver steatosis**

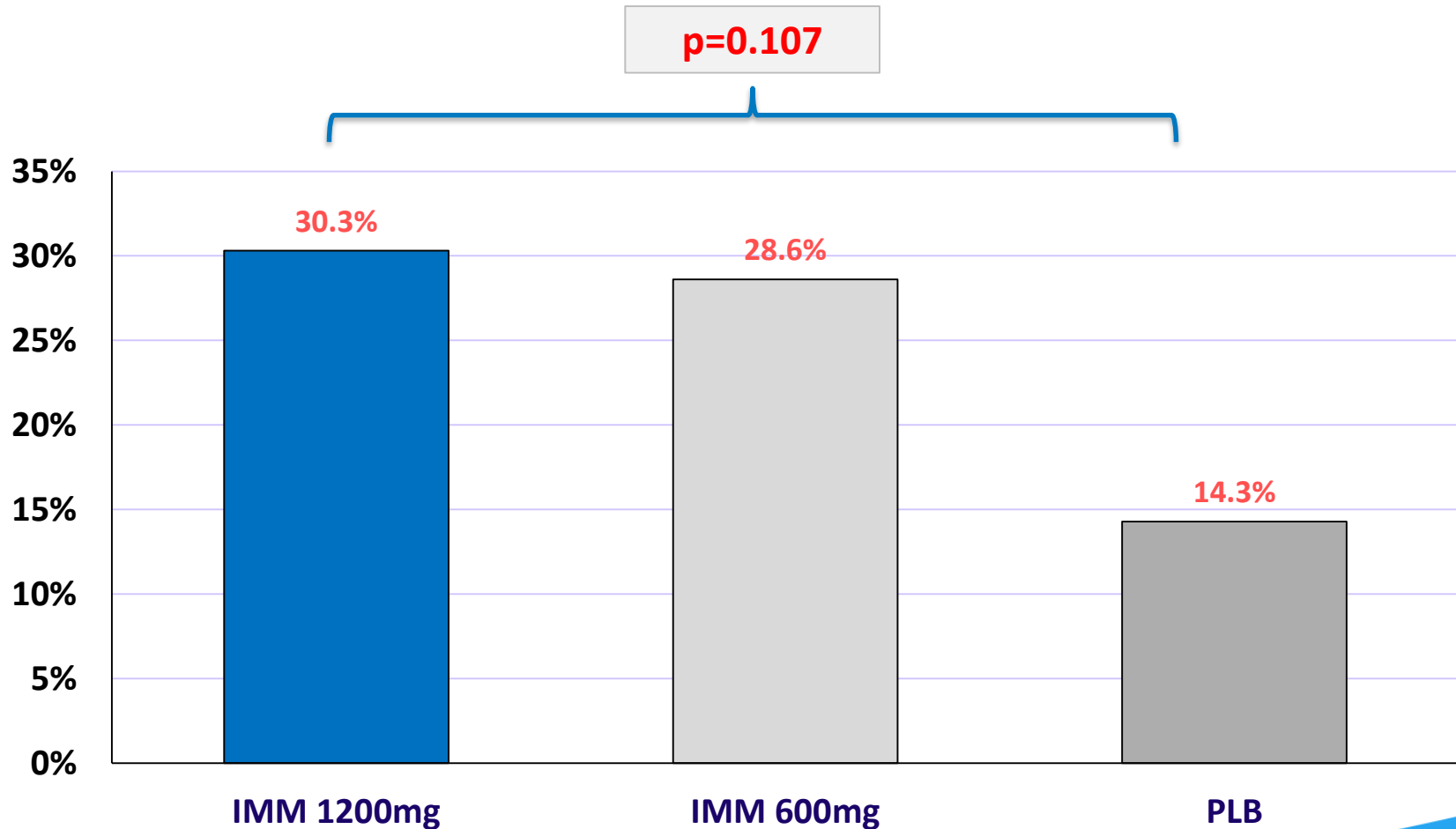
FIRST IN CLASS MoA LPS ANTAGONISM



- Obesity, Diet, Alcohol and liver disease
- Dysbiosis
- “leaky gut” (LPS)
- Endotoxemia
- LPS engages TLR4
- lipogenesis, inflammation, hepatocyte apoptosis and fibrosis

- Hyperglycemia drives intestinal barrier dysfunction and risk for enteric infection. Thaiss CA et al. Science, 2018
- Non-alcoholic fatty liver and the gut microbiota. Stavros B et al. Molecular Metabolism, 2016
- Age-Associated Microbial Dysbiosis Promotes Intestinal Permeability, Systemic Inflammation, and Macrophage Dysfunction. Thevaranjan N1, et al. Cell Host Microbe 2017.
- Hepatic TLR4 signaling in obese NAFLD. Sharifnia T, et al. Am J Physiol Gastrointest Liver Physiol 2015

SERUM ALANINE AMINO-TRANSFERASE (ALT) RATE OF SUBJECTS WITH $\geq 30\%$ DECREASE (n=94)*

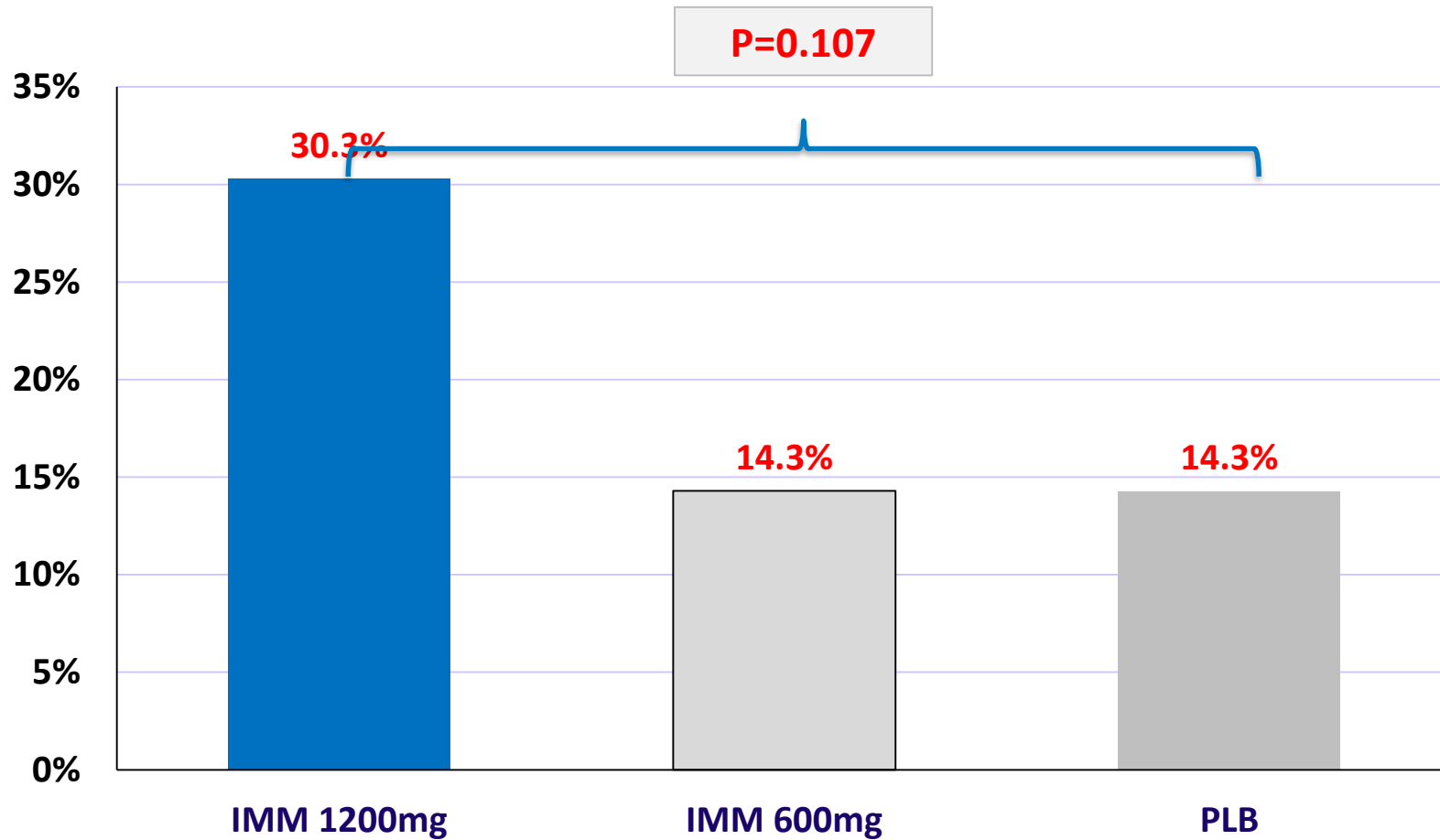


* outlier sites excluded (site recruiting <3 patients) – as commonly practiced in clinical trials

SERUM ASPARTATE-AMINOTRANSFERASE AST RATE OF SUBJECTS WITH AST DECREASE* >30% (n=94)*



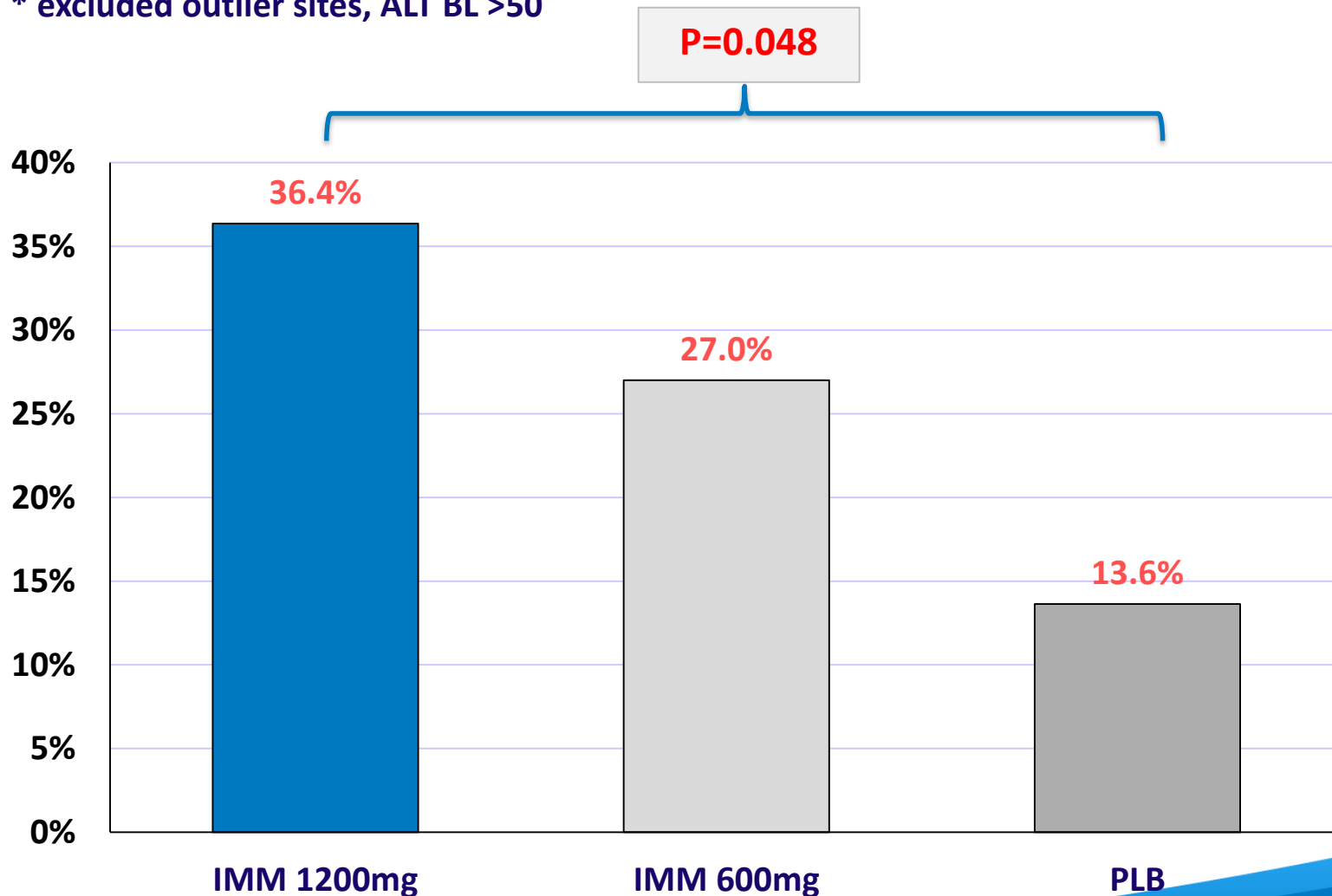
* excluded outlier sites



SERUM ALANINE AMINO-TRANSFERASE (ALT) RATE OF SUBJECTS WITH $\geq 30\%$ DECREASE*



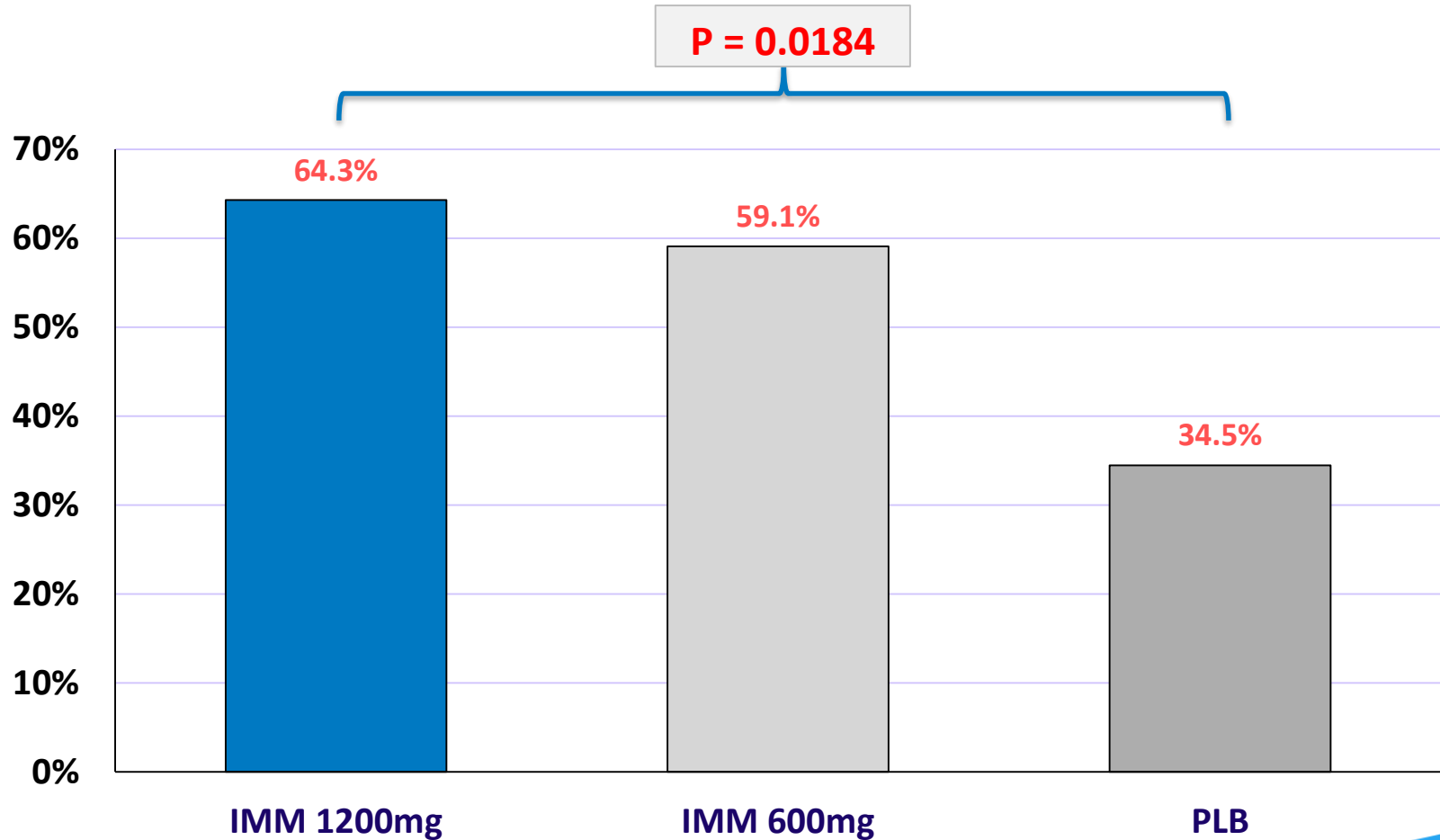
* excluded outlier sites, ALT BL >50



SERUM LIPOPOLYSACCHARIDES (LPS) RATE OF PATIENTS WITH $\geq 15\%$ DECREASE*



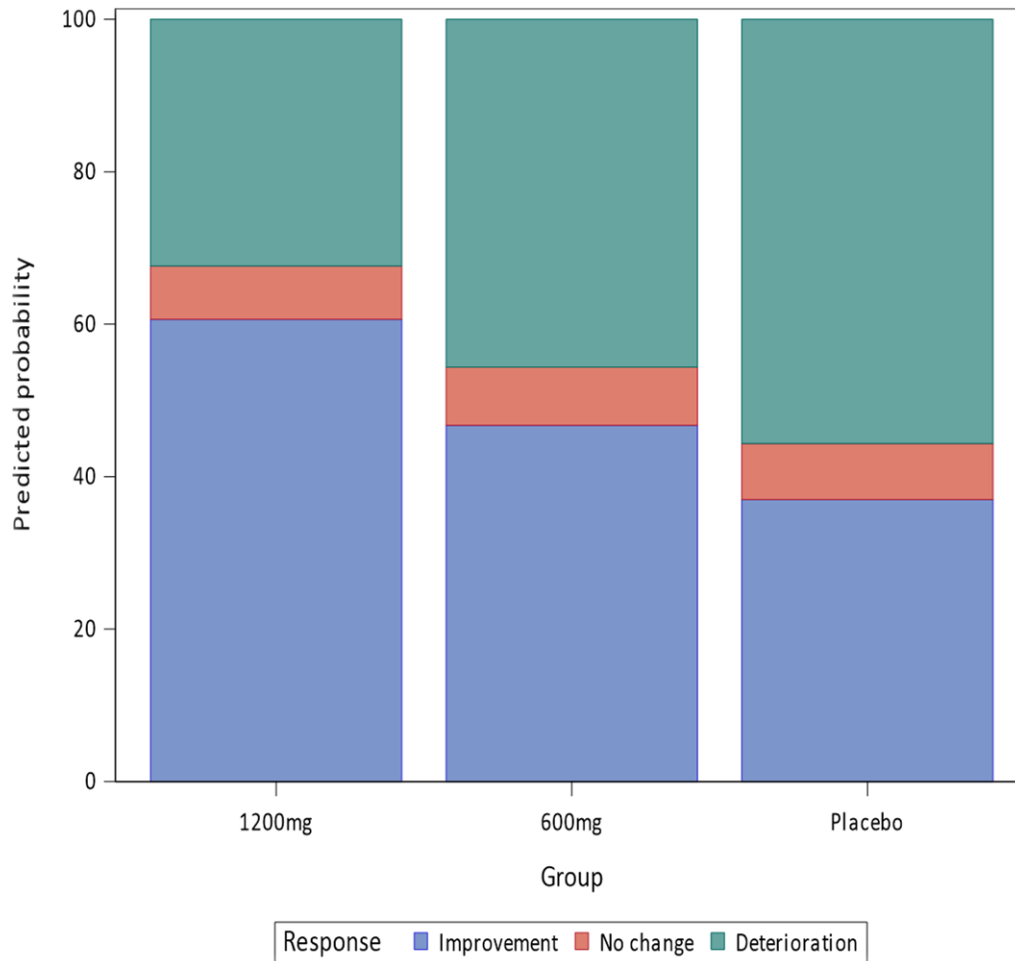
* Outlier sites excluded, Baseline LPS > 250



SERUM LPS

OVERALL RESPONSE TO TREATMENT

TERTILE ANALYSIS



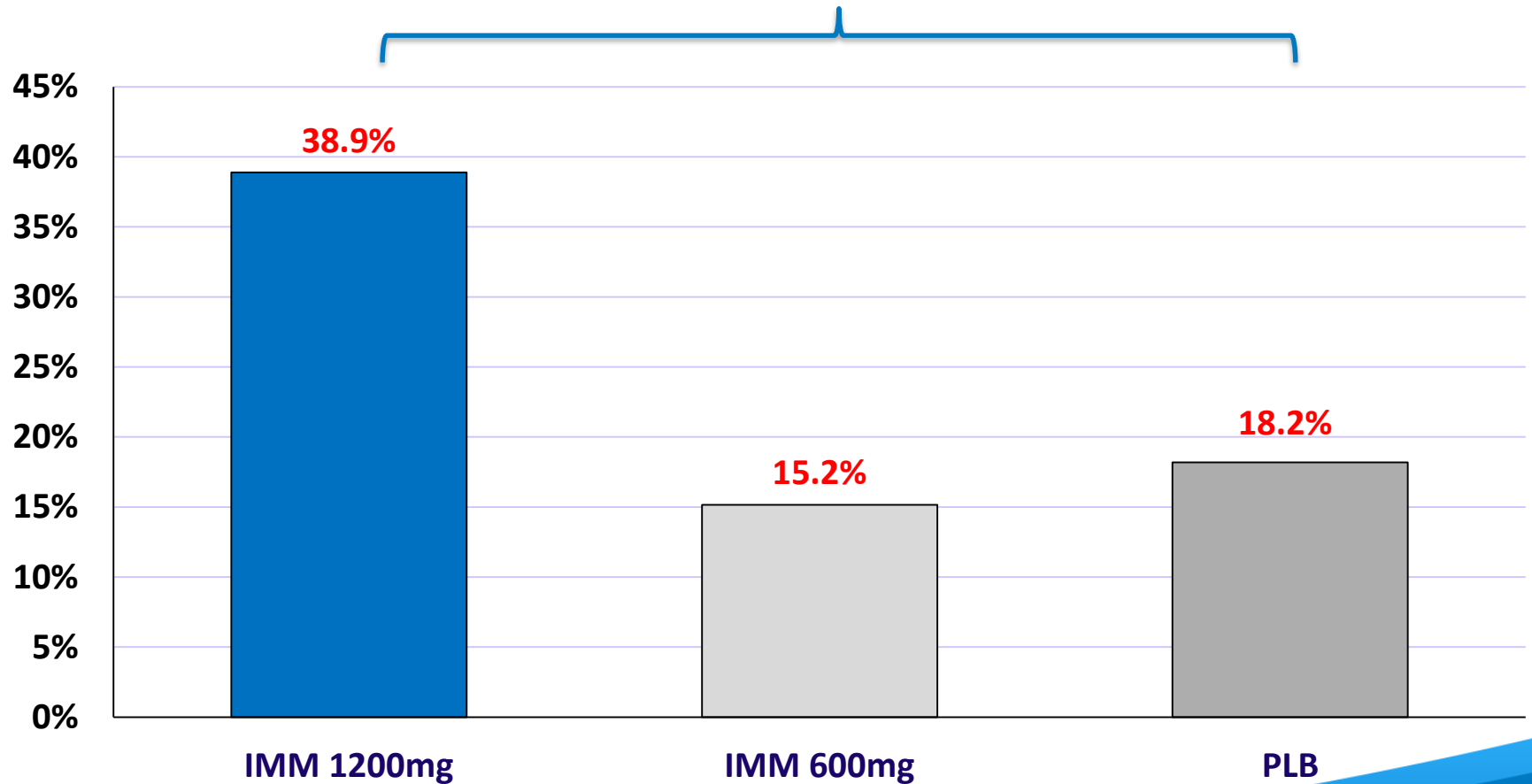
- Analysis aimed at looking at the entire population
- Shows an overall beneficial effect across all patients
- Minimizes risk of cut-off selection bias
- $p=0.0715$ (1200mg vs. PLB)

SERUM CYTOKERATINE-18 (CK-18) RATE OF PATIENTS WITH $\geq 15\%$ DECREASE (n=94)*



* excluded outliers sites

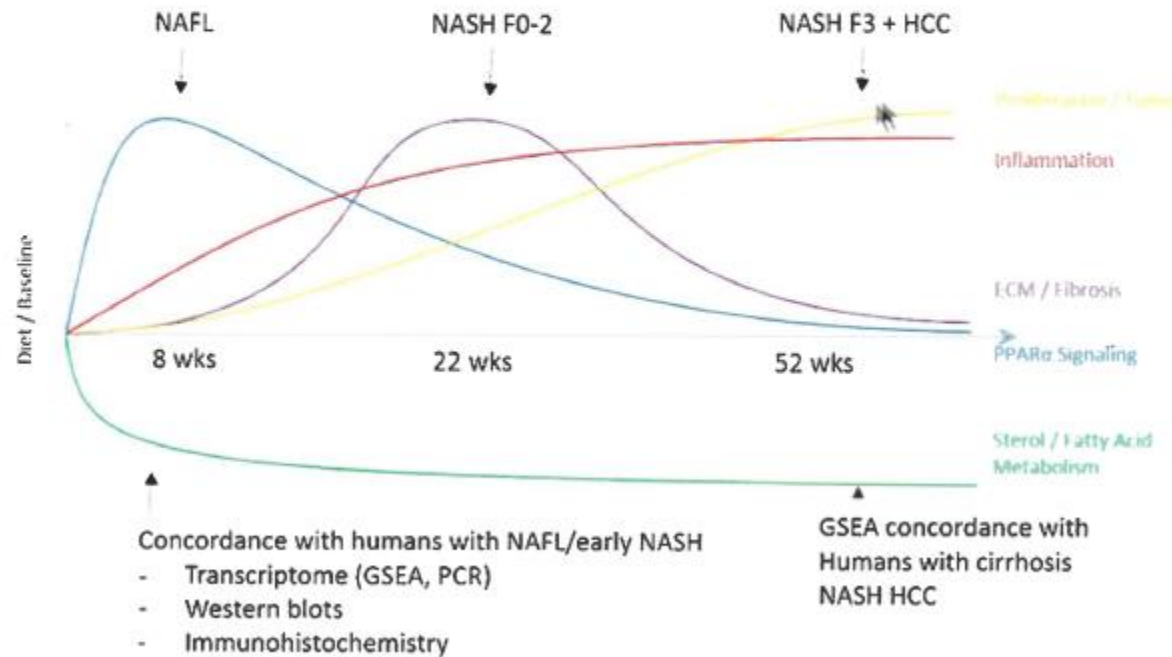
P = 0.0494



Disease Biology Provides Targets For Therapeutics



Tracking the molecular evolution of NASH provides a comprehensive list of potential targets for therapy



SUMMARY



- IMM-124E targets inflammation a major disease driver
- Inflammation drives disease progression from NAFLD to NASH to NASH fibrosis to NASH **Hepatocellular carcinoma and NASH Cirrhosis**
- Our Medical Advisory Board was particularly interested in further evaluating the compound in NASH cirrhosis
- Huge potential to treating patients exhibiting endotoxemia and elevated gut permeability e.g. cirrhotics either NASH or of any cause (evaluating on de-/compensated near compensation)
- *“The potential clinical applications for this drug candidate are numerous and very exciting indeed” – Immuron MAB*

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



Two Ongoing NIH funded Phase 2 Programs: 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: 133 patients with biopsy proven NASH
- **Timing: topline results reported 1Q 2018**

ASH

- NIH funded; sponsored by University of Virginia
- 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)
- Fully recruited: 56 patients
- Endpoint: ALT
- Timing: topline results in 2019

Pediatric NAFLD

- NIH funded; sponsored by Emory University
- Lead Principal Investigator: Miriam Vos;
- Current enrollment: 19/40 patients
- Endpoint: ALT; 3 months treatment
- Timing: topline results in 1Q 2019

IMM-529

Neutralizing *Clostridium difficile*, while Sparing the
Microbiome

IMM-529 in *Clostridium difficile* Infection (CDI)



- **Biologic with unique triple mechanism of action**
 - Targets and neutralizes the toxin B, the spores and the vegetative cells
- **Potential to redefine the standard-of-care (SOC) therapy for CDI**
 - **Stops virulence, without impacting the microbiome**
 - Compelling data in all three phases of the disease including (1) prevention of primary disease, (2) treatment of primary disease and (3) prevention of recurrence
 - Orally administrated, safe
- **>70% survival rate in CDI mice treated with IMM-529 vs. <7% survival rate in control groups**
- **Potential orphan disease designation; Potential breakthrough / fast track designations**
- **Market exclusivity** (biologics; High barriers to generic biosimilar entry)

IMM-529 for the Treatment of CDI



Market Opportunity

- Therapeutic market is expected to grow from US\$356.3 million in 2014 to over \$1.5 billion by 2024 – CAGR 15%
- Nearly 30,000 patients die each year from *C. difficile* infections (US)
- Potential orphan disease (7 years market exclusivity and premium pricing)

Unmet Need

- Vancomycin and metronidazole are the current standard of care, accounting for 80% of patient share (US)
- However, therapies are plagued by significant CDI recurrences (1st relapse: 25%; 2nd: 40%; 3rd: 50%) underscoring need for new treatments
- There is also growing resistance to vancomycin treatment

IMM-529 Positioning

- Highly differentiated – Neutralizes *C. difficile* but does not impact microbiome
- Only asset that targets not only toxin B but also the spores and the vegetative cells responsible for recurrence
- Can be used in combination with standard of care
- Targets many isolates

Triple Action MOA

Neutralizing *C. difficile*; Sparing the Microbiome



Spores – Infectious Particles

IMM-529 antibodies bind to multiple epitopes on surface antigens on spores and prevent adheres to host cells and limit germination.

Heat, ethanol and UV resistant. Survive gastric acid, adhere to cells in the colon and germinate.

Vegetative Cells

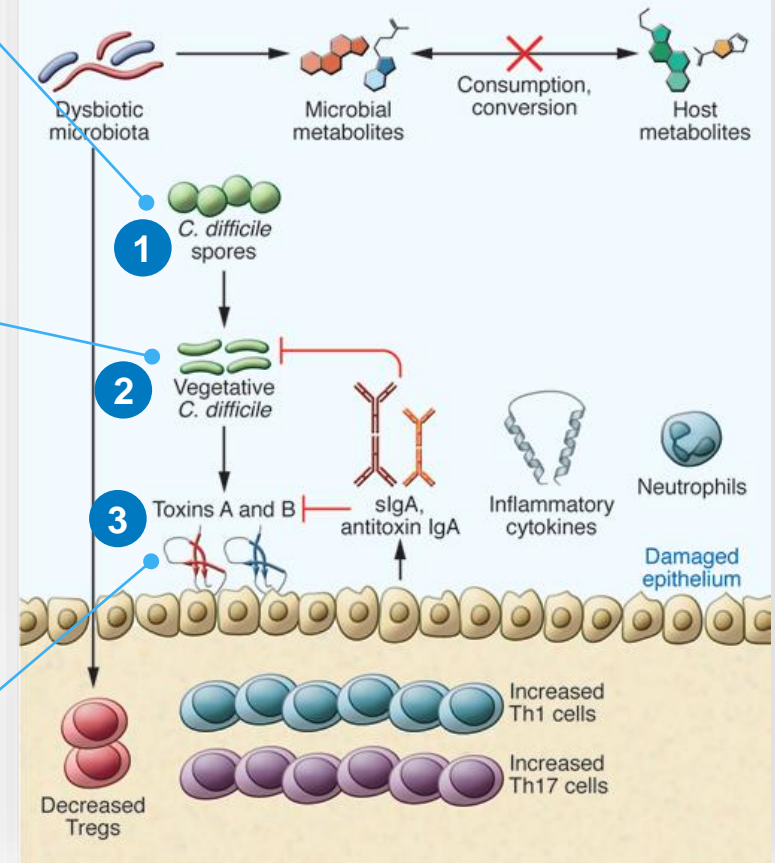
IMM-529 antibodies bind to multiple epitopes on the surface layer proteins (SLP) on vegetative cells and limit colonization.

Fimbriae and other surface layer proteins (SLP) contribute to bacterial colonization. Fimbriae are used to adhere to other bacteria and to host cells and is one of the primary mechanisms of virulence

Toxin B

IMM-529 antibodies bind to multiple epitopes effectively neutralize toxin B, inhibiting toxin mediated epithelial cell apoptosis and limit toxin translocation into the systemic circulation and inflammatory cascades.

Toxin B is essential for virulence. Toxin B disrupt the cytoskeleton and tight junctions of intestinal epithelial cells.

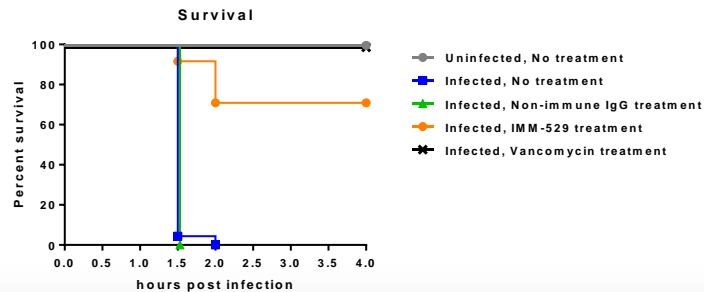


Results of Pre-Clinical Studies

Hutton et al; Scientific Reports June 2017 | 7: 3665 | DOI:10.1038/s41598-017-03982-5



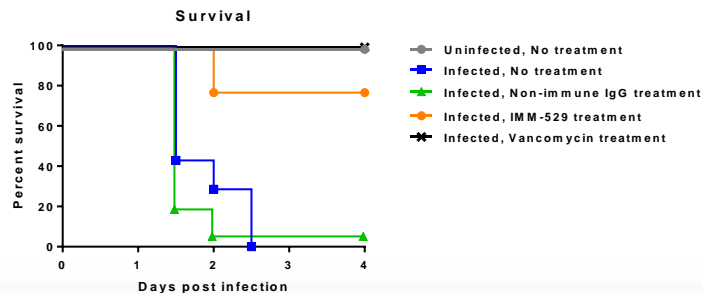
Prevention Studies



Demonstrated ~70% survival rate without use of antibiotics vs. 0% for control group ($P < 0.0001$)

All studies statistically significant

Treatment Studies

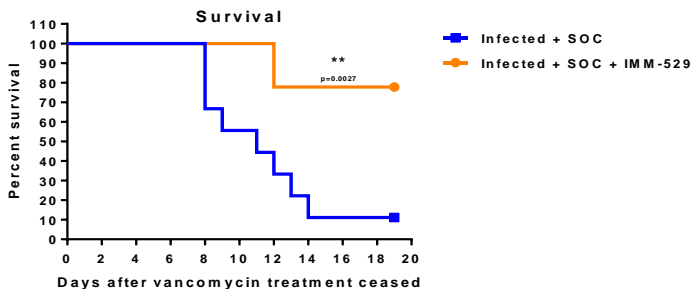


Demonstrated ~80% survival rate without use of antibiotics vs. <7% in control group ($P < 0.0001$)

Potentially only therapeutic (approved or in development) that can treat all phases of the disease:

1. Prophylaxis
2. Treatment
3. Recurrence

Relapse Studies



Demonstrated ~20% relapse rate vs. ~80% relapse rate in control group ($P < 0.0027$)

Phase 1/2 Study Design









Phase 1/2 Study in CDI Initiated 4Q 2017

- **Phase 1/2, randomized, double blind, placebo-controlled clinical study of IMM-529 for the treatment of CDI**
- **60 subjects** to be enrolled up to 3 weeks of definitive diagnosis of CDI (at least 20 subjects to be enrolled within the first 72 hours)
- **Subjects randomized to IMM-529 or placebo in a 2:1 ratio**
- **Treatment duration:** 28 days on top of SOC (vancomycin / metronidazole)
- **Follow-up:** 3 months overall
- **Primary objective:** To evaluate the safety and tolerability of IMM-529 together with standard of care (SOC) in patients with CDI
- **Secondary objective:** To evaluate the effectiveness of IMM-529 together with SOC to treat patients with CDI

NASH and *C. difficile* Comps Indicate Potential for Substantial Growth



Company	Ticker	Program	Development Stage	Market Cap*
Program in NASH				
 Intercept	ICPT	Obeticholic acid	Phase 3	US\$2.9B
 GENFIT TOWARDS BETTER MEDICINE	GNFT	Elafibranor	Phase 3	US\$1.1B
 Conatus Pharmaceuticals	CNAT	ENCORE-LF	Phase 2	US\$195M
Program in <i>C. Difficile</i>				
 SERES THERAPEUTICS™	MCRB	SER-109; SER-262	Phase 2	US\$423M
 summit	SMMT	SMT19969	Phase 1	US\$143M
 assembly biosciences	ASMB	ABI-M101	Preclinical	US\$419M

*As of May 4, 2017

Capital Profile Immuron Limited (ASX:IMC NASDAQ:IMRN)



Current Top 10 Shareholders

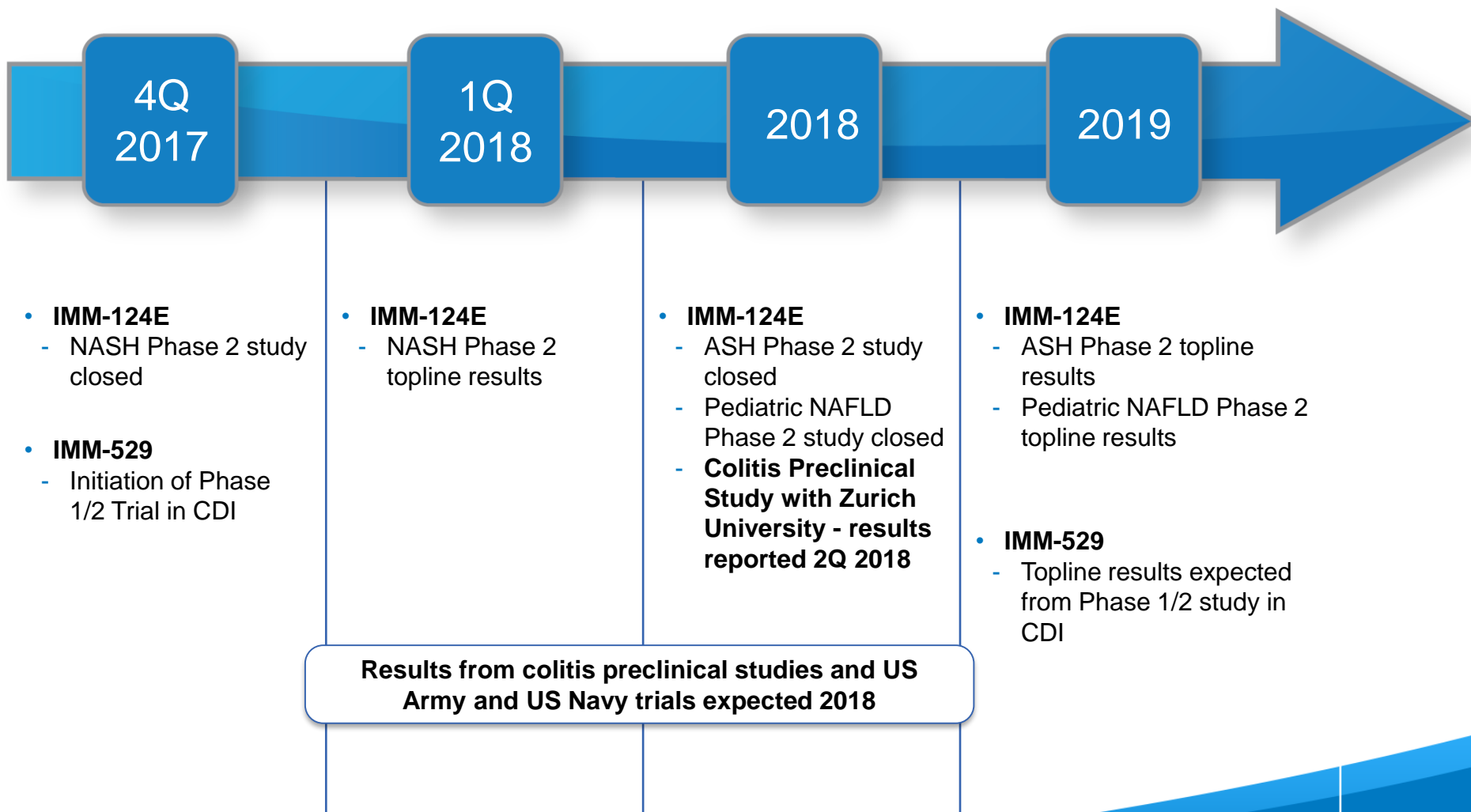
Rank	Holder Name	Current Qty	%
1	HSBC CUSTODY NOM AUST LTD (ADR Program)	13,764,344	9.64%
2	CITICORP NOMINEES PTY LIMITED	12,715,858	8.91%
3	* GRANDLODGE PTY LTD	9,556,682	6.69%
4	AUTHENTICS AUSTRALIA PTY LTD	8,624,999	6.04%
5	* MR PETER ANASTASIOU	2,907,236	2.04%
6	INVERAREY PL	2,731,632	1.91%
7	INSYNC INVESTMENTS PTY LTD	2,500,000	1.75%
8	MR WILLIAM DAVID FRANK BIRD	2,500,000	1.75%
9	ADVANCE CLINICAL SYSTEMS	2,296,874	1.61%
10	* MR STEPHEN ANASTASIOU	2,035,371	1.43%
TOTAL TOP 20 SHAREHOLDERS		59,632,996	41.77%
BALANCE OF SHARES		83,145,210	58.23%
TOTAL SHARE ON ISSUE		142,778,206	100.00%

* Denotes a Director Related Entity

Current Company Market Capitalization

AUD\$49.25M ≈ USD\$36.13M (21st August 2018)

Key Milestones Expected to Drive Value



Thank You