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# Investor Update

DECEMBER 2017

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SOCIETY FOR IMMUNOTHERAPY OF CANCER (SITC) 2017 ANNUAL MEETING & BIO EUROPE 2017

BOARD OF DIRECTORS AND CLINICAL ADVISORY BOARD

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RUSSELL HOWARD

## Message from the Chair

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As your new Company Chairman, I would like to take this opportunity to welcome you to the first edition of our Investor Update (Vol. 22) as Immutep Limited.

It is a privilege to be taking over as Chairman at this exciting time in the Company's journey. I believe my extensive biotechnology industry and capital markets experience, both in Australia and the U.S., will be valuable as I look forward to leading the Company in advancing its innovative portfolio of oncology and autoimmune product candidates.

As a longstanding contributor to the biotechnology industry, there is no greater thrill than bringing novel and innovative treatments to market that prolong and improve patients' quality of life. There is a growing acknowledgment that immunotherapies will play a key role in the future treatment of cancer. The industry is investing heavily in this space, with combination treatments that may have synergistic mechanisms of action garnering the most attention. There are currently over 1,100 active oncology combination trials. As the global leader in LAG-3, Immutep has an enormous opportunity to capitalise on this movement.

I am very confident that we have the right product candidates, industry collaborations and team of professionals to build a highly successful global biotechnology company. I am extremely focused on ensuring we are able to advance our unique combination trials, build on our clinical partnerships, deliver sensible commercial pathways, and enhance shareholder value.

As our focus is now on LAG-3, which already has a close association with the name Immutep, the name change will assist in providing greater visibility for our Company both in the industry and global investment markets. Our CEO, Marc Voigt, and the team have worked tirelessly to build our Company's reputation and pipeline. I would like to thank all of the Immutep employees for their continued efforts.

Lastly, I would also like to acknowledge the excellent job former board members Lucy Turnbull and Albert Wong have done in guiding the Company over the past few years. Immutep is well positioned to take advantage of the multiple growth avenues ahead and I look forward to reporting on our continued progress.

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MARC VOIGT

## Message from the CEO

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I would like to take this opportunity to congratulate Russell Howard and Pete Meyers on their appointments as Chair and Deputy Chair of the board of directors, respectively. Both Russell and Pete have broad industry and commercial experience and a collective desire to bring innovation to the health care sector.

I would also like to thank Lucy and Albert for their guidance and counsel over the years, through what has been an important and successful transformation. I wish them both well in their future endeavours.

I am also very excited to deliver my first CEO message under the new Immutep name and logo. The Company has undergone significant change and this represents our successful transformation to a globally recognised leader in LAG-3.

As you may have noticed, we are now referring to our lead LAG-3 product candidate as Eftilagimod Alpha, or 'Efti' for short. This is the International Non-proprietary Name (INN) for LAG-3Ig or IMP321, which is regulated by the World Health Organisation. We will be referring to IMP321 as Efti in future communications.

We recently engaged with the U.S. FDA to discuss an Investigational New Drug Application (IND) for a regulatory pathway for the development of Efti in the United States. We intend to file an IND in the first half of calendar year 2018, which would provide the Company the opportunity to commence clinical studies and regulatory interactions in the U.S. in the future. This is an important component of our global commercialisation strategy for Efti.

### Intellectual Property

We continue to work with our pharma partners on their respective programs and in broadening our patent portfolio and global interest in LAG-3.

In November, we announced a new patent from the European Patent Office. Filed as a divisional

application, it follows the grant of the European parent patent, which was issued in 2013.

The claims of this new patent are geared toward the use of Immutep's lead candidate Efti in combination with a chemotherapeutic agent for the treatment of cancer.

According to the claims, Efti elicits a monocyte-mediated immune response and is administered before, with, or subsequent to administration of the chemotherapeutic agent. Importantly, these granted claims support the application of Efti in Immutep's AIPAC clinical trial in metastatic breast cancer in Europe.

### Business overview

Operationally, our Australian Phase I clinical trial in metastatic melanoma, TACTI-mel, is progressing well and we presented new data in a poster presentation at the Society for Immunotherapy of Cancer (SITC) 2017 Annual Meeting in the U.S. on November 10, 2017. The findings demonstrated anti-tumour activity when Efti is administered in combination with pembrolizumab.

The SITC poster presentation included data showing tumor reductions in 58% of advanced metastatic melanoma patients in the study, which is extremely encouraging for future clinical indications of Efti as well as combinatory trials.

The third cohort of TACTI-mel is now fully recruited and we expect results from all three cohorts in the first half of 2018. Similarly, recruitment for the randomised phase of our Phase IIb AIPAC trial in metastatic breast cancer is ongoing. In total, 29 out of 34 clinical sites have been activated with the outstanding site activations expected to occur in early calendar 2018.

*[Continued on p. 4]*

# Message from the CEO

[Continued from p. 3]

Based on our current assumptions, the 226 patient trial should be fully enrolled by mid calendar 2018. The primary Progression Free Survival (PFS) data readout of this portion of the study could be available as early as the first half of calendar 2019.

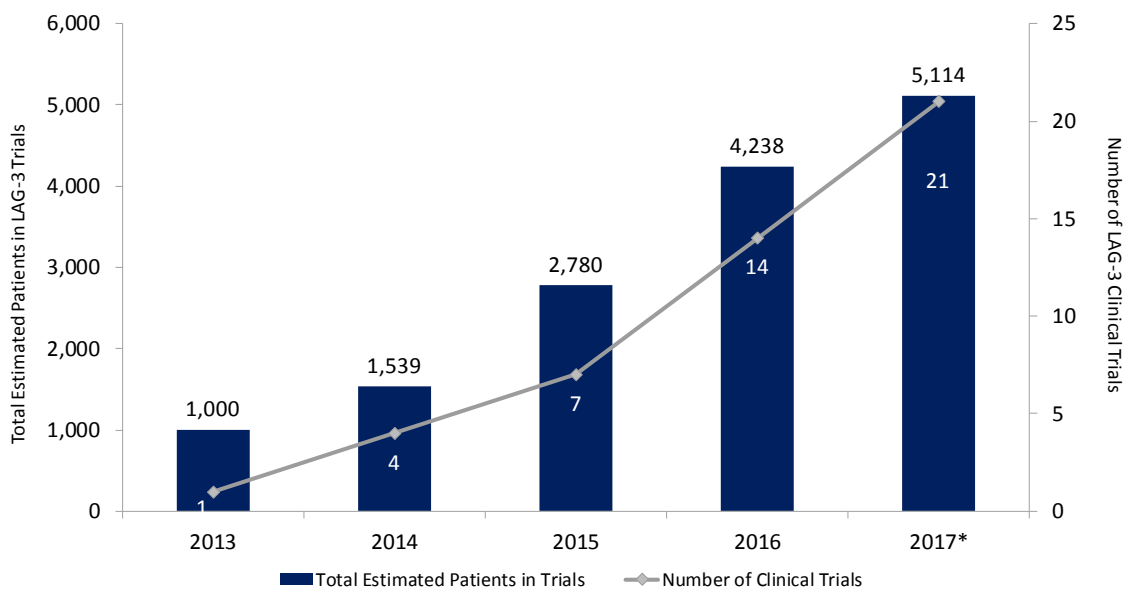
The investigator-led INSIGHT clinical trial, which is looking at Efti given as intra-tumoural or intraperitoneal injections, continues to make positive progress. Three patients have already been recruited in this clinical trial and we expect single case data throughout calendar 2018.

We will also keep you updated on relevant industry developments, including pertinent updates from our industry partners. Further to this, I would like to highlight that our partner Novartis again recently increased the number of patients in the Phase I/II trial of LAG525 (Single Agent and in Combination with PDR001 in Patients With Advanced Malignancies) by 99 patients to a total of 515 patients. In addition, Novartis are planning a completely new Phase II clinical trial aiming to recruit 160 patients. I believe that this is an encouraging sign for LAG525 (which we refer to as IMP701).

Meanwhile our partner EOC Pharma, an oncology focused affiliate of Eddingpharm that holds the Chinese rights for Efti, continues to leverage the improved clinical and regulatory environment in China and successfully raised US\$32 million in capital from Chinese investors in November 2017. EOC plans to use these funds to commercialize its oncology portfolio, including Efti. This is part of a broader effort to increase access to novel therapies for patients.

We are very encouraged by increasing investment into development of products targeting LAG-3, the immune checkpoint discovered by our CSO, particularly from our licensing partners and look forward to updating you on further progress.

We believe that based on the current levels of investment by the industry (as illustrated in the chart below), LAG-3 is emerging as a very significant immune checkpoint. Six new clinical trials were started, or planned to start, in 2017 by other companies. This includes companies such as Boehringer Ingelheim, Tesaro, and MacroGenics entering the clinic for the first time with their LAG-3 product candidates, while BMS and Novartis commenced new clinical trials for their respective product candidates.



Sources: GlobalData, company websites, clinical trials.gov, and sec.gov  
 \* As of December 11, 2017

[Continued on p. 5]

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# Message from the CEO

[Continued from p. 4]

Notably, the CEO of BMS, Dr. Giovanni Caforio, stated during their last earnings call that he is really looking forward to the initiation of registration studies for their LAG-3 product candidate. Furthermore, Sanofi highlighted REGN3767, the product candidate they are developing with Regeneron, in their recent R&D presentation (December 13, 2017).

Even with the continued investment into LAG-3-related programs by other companies, Immutep remains the global leader in terms of the development of LAG-3 modulating therapeutics, as depicted in the LAG-3 Therapeutic Landscape Overview table below.

On behalf of Immutep Limited, I would like to wish all of our shareholders a happy and prosperous festive season and I look forward to updating you further on our progress in 2018.

### LAG-3 THERAPEUTIC LANDSCAPE OVERVIEW TABLE

Program	Company	Preclinical	Phase I	Phase I/ II	Phase II	Phase IIb	Total Estimated Patients
Eftilagimod Alpha	Immutep <sup>(1),(2)</sup>		● ●			●	244
LAG525	Novartis <sup>(3),(4)</sup>			●	●		675
Relatlimab	BMS <sup>(4)</sup>		● ● ●	● ● ●	● ● ● ●		3,319
REGN3767	Regeneron/ Sanofi		●				283
TSR-033	Tesaro		●				260
MK4280	Merck & Co. Inc.		●				240
MGD013	Macrogenics		●				131
BI 754111	B.I.		●				75
GSK2831781	GSK <sup>(3)</sup>		●				67
IMP761	Immutep	●					N/A
N/A	Agenus/ Incyte	●					N/A
N/A	Peregrine Pharma.	●					N/A
N/A	RXi Pharmaceuticals	●					N/A
N/A	F-star Bio/ Merck	●					N/A

Notes:

(1) Includes AIPAC, TACTI-mel, and INSIGHT clinical trial

(2) Total estimated patients does not include INSIGHT clinical trial

(3) Immutep partnered program

(4) As of December 11 2017, one clinical trial was still 'planned' and not open for enrollment

● Indicates product candidate that was developed by Immutep research & development

Sources: GlobalData, company websites, clinical trials.gov, and sec.gov  
As of December 11, 2017

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# SOCIETY FOR IMMUNOTHERAPY OF CANCER (SITC) 2017 ANNUAL MEETING & BIO EUROPE 2017

In November we attended two important conferences, presented new data from TACTI-mel and engaged in substantive interaction with several key industry players.

While SITC is a key conference in the field of immuno oncology, BioEurope is one of the largest international partnering & business development conferences.



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**Pushing the accelerator and releasing the brake: testing the soluble LAG-3 protein (IMP321), an antigen presenting cell activator, together with pembrolizumab in unresectable or metastatic melanoma**

Victoria Atkinson<sup>1,2</sup>, Andrew Haydon<sup>1</sup>, Melissa Eastgate<sup>3</sup>, Amitesh Roy<sup>4</sup>, Adnan Khattak<sup>5</sup>, Christian Mueller<sup>6</sup>, Tina Dunkelmann<sup>7</sup>, Chrystelle Brignone<sup>8</sup>, Frederic Triebel<sup>9</sup>

**Trial Design**

- Phase 1, multi-cohort, open-label, dose escalation
- Recruitment of 18 patients at 6 sites in Australia
- Patients are on pembrolizumab monotherapy. After 3 cycles patients respond to pembrolizumab is unresponsive, in the case of suboptimal response (AE, iPR, iPR) and measurable disease patients are eligible for the study
- Beginning with cycle 1 of pembrolizumab, IMP321 infusions are administered every 2 weeks for a duration of 16 weeks (approximately 13 infusions)
- At weeks 1, 5, 9, or 13 IMP321 the first 3 patients will start treatment with week 10, after that time 4 patients complete the study observation period (24 hours after the 17<sup>th</sup> infusion). The remaining 9 patients can be enrolled in parallel
- Decision for dose escalation is done by the Data Safety Monitoring Board (DSMB). If more than 2 patients per cohort experience a dose-limiting toxic by D17, the dose will be considered at maximum tolerated dose

**Background**

LAG-3 (Lymphocyte-Associated Glycoprotein 75), a B7-1/B7-2 receptor, is a B7-1/B7-2 receptor that binds to B7-1/B7-2 and is expressed on activated T cells. LAG-3 is a B7-1/B7-2 receptor that binds to B7-1/B7-2 and is expressed on activated T cells. LAG-3 is a B7-1/B7-2 receptor that binds to B7-1/B7-2 and is expressed on activated T cells.

**Objectives**

To evaluate the safety, tolerability, and recommended Phase 2 dose of IMP321 when combined with anti-PD-1 treatment in patients with unresectable or metastatic melanoma

**Preliminary Safety Results**

18 patients received median 3.3 (range 1-13) IMP321 infusions and median of 1.7 (range 0-10) pembrolizumab infusions within the treatment period

\* No dose reductions were applied

\* No dose-limiting toxicities were observed

\* No treatment discontinuations due to AE

\* No dose-limiting toxicities in both cohorts

\* No noteworthy differences between the two dose groups (1 and 3 mg IMP321)

**Baseline Demographics and Efficacy Results**

**iPR assessments\***

**Systemic toxicities**

Median (range) grade	102 (98-105)	102 (98-105)
Diarrhea, n (%)	12 (10.1)	12 (10.1)
Colitis, n (%)	12 (10.1)	12 (10.1)
Abnormal LFTs, n (%)	12 (10.1)	12 (10.1)
Neutropenia, n (%)	12 (10.1)	12 (10.1)
Alanine aminotransferase (ALT) elevation, n (%)	12 (10.1)	12 (10.1)
Aspartate aminotransferase (AST) elevation, n (%)	12 (10.1)	12 (10.1)
Proteinuria, n (%)	12 (10.1)	12 (10.1)
Other SAEs, n (%)	12 (10.1)	12 (10.1)

**Response rate (ORR) in 102**

ORR, n (%)	102 (98-105)	102 (98-105)
ORR, n (%)	12 (10.1)	12 (10.1)
CR, n (%)	12 (10.1)	12 (10.1)
PR, n (%)	12 (10.1)	12 (10.1)
SD, n (%)	12 (10.1)	12 (10.1)
PD, n (%)	12 (10.1)	12 (10.1)
CR + PR, n (%)	12 (10.1)	12 (10.1)
CR + PR + SD, n (%)	12 (10.1)	12 (10.1)

**Patient Case A1 (Pembrolizumab + 1 mg IMP321)**

**Conclusion:**

- Combination of IMP321 (1 and 3 mg) and pembrolizumab in unresectable melanoma patients is safe and well tolerated
- Antitumor activity (tumor reduction) was observed in 7/12 patients (58%) in this study prior to study of these patients either had a suboptimal response to or had disease progression when treated with pembrolizumab monotherapy
- Data presented support the hypothesis that combining an APC activator (IMP321) with a checkpoint inhibitor (pembrolizumab) results in a therapeutic synergy and a potential clinical benefit over checkpoint inhibitor monotherapy
- Data presented support the hypothesis that combining an APC activator (IMP321) with a checkpoint inhibitor (pembrolizumab) results in a therapeutic synergy and a potential clinical benefit over checkpoint inhibitor monotherapy
- The study cohort (102 mg) of this cohort is ongoing
- Data presented support further investigation of IMP321 in combination with PD-1/PD-L1 checkpoint inhibitors in different cancer types

Pushing the accelerator and releasing the brake: testing the soluble LAG-3 protein (IMP321), an antigen presenting cell activator, together with pembrolizumab in unresectable or metastatic melanoma.

Poster Number P259

Authors: Victoria Atkinson, Andrew Haydon, Melissa Eastgate, Amitesh Roy, Adnan Khattak, Christian Mueller, Tina Dunkelmann, Chrystelle Brignone, Frederic Triebel

Click here to see detailed Poster:

[PDF](#)



IMMUTEP

## Board of Directors

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Members of the Immutep Board of Directors are listed below.



RUSSELL HOWARD, PHD

**Non-Executive Chairman**

Dr. Russell Howard joined the Board in 2013 and is a highly regarded Australian scientist, executive and entrepreneur with nine patents and over 150 scientific publications to his name. He is currently Chairman of cleantech company Oakbio, Inc., Executive Chairman of NeuClone Pty Ltd and Head of Commercial Strategy, Genomics at Genome.One.

PETE MEYERS

**Non-Executive Director & Deputy Chairman**

Pete Meyers joined the Board in early 2014. He has had an extensive career in healthcare both in senior industry roles and as an investment banker. He is currently the Chief Financial Officer of Nasdaq-listed Eagle Pharmaceuticals, Inc. and Chairman and President of The Thomas M. Brennan Memorial Foundation.



MARC VOIGT

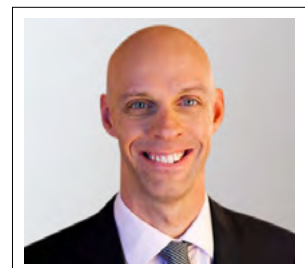
**Executive Director & Chief Executive Officer**

Marc Voigt joined the Company as Chief Financial Officer and Chief Business Officer in 2012 and was appointed CEO and Executive Director in 2014. He has extensive experience in the investment and biotechnology sector having worked as an investment manager for Allianz Insurance biotech venture fund, and has held the positions of CFO/CBO at Revotar Biopharmaceuticals AG and Medical Enzymes AG.

GRANT CHAMBERLAIN

**Non-Executive Director**

Grant Chamberlain joined the Board in August 2017 and practices as a corporate adviser and entrepreneur. With more than 20 years' experience in investment banking and transaction work, he was Head of Mergers & Acquisitions and Financial Sponsors Australia at Bank of America Merrill Lynch until June 2017 and also held senior positions at Nomura Australia and Deutsche Bank. Grant recently joined OneVentures as a Principal in November 2017.



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## Clinical Advisory Board

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Members of the Immutep Clinical Advisory Board are listed below.

**Professor Martine J. Piccart**, professor of oncology at the Université Libre de Bruxelles (ULB) and Head of the medicine department at the Institute Jules Bordet, in Brussels, Belgium.

**Doctor Luc Dirix**, Head of Medical Oncology at the Oncology Center at AZ Sint-Augustinus Hospital in Antwerp, Belgium.

**Professor David Cameron**, the Clinical Director and Chair of Oncology at The University of Edinburgh Cancer Research Centre in the UK.

**Doctor Samson Fung** of Fung Consulting in Germany provides strategic and operational assistance to pharmaceutical and biotech companies including Novartis and Bristol-Myers-Squibb. Dr. Fung is the CEO & Managing Director of Volvox Therapeutics.

**Professor Salah-Eddin Al-Batran**, Medical Director at the Institute of Clinical Cancer Research in Frankfurt, Germany.

Read more on Immutep's Advisory Board [here](#).

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## COMPANY CALENDER

# What's next

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January 8th 2018

36th Annual J.P. Morgan Health Care Investor Conference, San Francisco, California, USA

[more](#)

March 19th 2018 - March 23rd 2018

3rd Annual Immuno-Oncology Summit Europe, Hilton London Canary Wharf, London, UK

Frédéric Triebel speaks on the subject:

“LAG-3: Identification & Validation of the Next Generation Checkpoint Pathway”

[more](#)

May 16th 2018 - May 18th 2018

13th annual Advanced Therapy and Regenerative Medicine Congress 2018, 16 – 18 May, London, UK

Frédéric Triebel speaks on the subject:

“LAG-3: the next immune checkpoint after CTLA-4 and PD-1/PDL-1?”

[more](#)

May 24th 2018 - May 25th 2018

3rd Annual Advances in Immuno-Oncology Congress, 24 - 25 May 2018, London, UK

Frédéric Triebel speaks on the subject:

“Two ACTIVE Immunotherapies in melanoma (TACTI-mel): results of a phase I trial with metastatic melanoma patients treated with a soluble LAG-3 receptor (LAG-3Ig or efitlagimod alpha) as an antigen presenting (APC) activator combined with pembrolizumab.”

[more](#)

June 1st 2018 - June 5th 2018

2018 ASCO Annual Meeting, McCormick Place, Chicago, IL, USA

[more](#)

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IMMUTEP

## Fast Facts

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### Listings

Australian Securities Exchange (ASX), NASDAQ

### Stock Codes

ASX: IMM, NASDAQ: IMMP

### Issued Capital – Ordinary Shares

2.36 billion (as of Dec 14, 2017)

### Market Capitalisation

A\$56.4 million (US\$43.2 million)  
(as of Dec 14, 2017)

### Issued ADR's

~7.2 million (as of Dec 14, 2017)

### Cash & Term Deposits

~ A\$15.0 million (as of Dec 8, 2017)

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## Board of Directors

### Russell J Howard, PhD

Non-executive Chairman

### Mr Marc Voigt

Executive Director and Chief Executive Officer

### Mr Pete A Meyers

Non-executive Director

### Grant Chamberlain

Non-executive Director

## Senior Management

### Prof Dr Frédéric Triebel

Chief Medical Officer and Chief Scientific Officer

### Deanne Miller

Chief Operating Officer, General Counsel and  
Company Secretary

[www.immutep.com](http://www.immutep.com)

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## FOLLOW IMMUTEP'S PROGRESS

Immutep is dedicated to maintaining consistent and clear communications with our investors. In addition to our quarterly newsletter, we encourage our shareholders to continue following Immutep's progress in a number of ways:

### [www.immutep.com](http://www.immutep.com)

The company website is a treasure trove for those in search of details about our company, our management team, and archived information. We encourage everyone to check it out regularly.

### [www.clinicaltrials.gov](http://www.clinicaltrials.gov)

Immutep registers all of our clinical trials, and the details of enrolling doctors, on the ClinicalTrials.gov website, a service of the United States National Institutes of Health. This register is the largest such repository of clinical trial information around the world.

Our ClinicalTrials.gov ID for our trials are as follows:

- TACTI-mel trial is NCT02676869
- AIPAC trial is NCT02614833

### **Twitter**

<https://twitter.com/Immutep>

### **Facebook**

<https://www.facebook.com/Immutep/>

### **LinkedIn**

<https://www.linkedin.com/company/857541/>

