

02

# Investor Update

JUNE 2018

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MARC VOIGT

## Message from the CEO

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Welcome to the latest edition of Immutept's investor update. I am pleased to report that the team has made a great deal of progress since our last update in December 2017. We have a very active business development pipeline with multiple companies. One specific achievement brought to fruition is our entry into a clinical trial collaboration and supply agreement with Merck & Co. (known as MSD outside the US and Canada) for a new clinical trial combining its FDA-approved cancer drug pembrolizumab (Keytruda) with our lead product candidate efitilagimod alpha, or "efti" for short.

On the clinical development side, we reported very encouraging interim results from the first three cohorts of our TACTI-mel Phase I clinical trial, also combining Keytruda with efti. In addition, we have now reached the mid point for patient recruitment for our Phase IIb AIPAC (Active Immunotherapy PAClitaxel) clinical trial in breast cancer.

More broadly across the industry, the LAG-3 product development landscape has become busier in recent months. Overall, the LAG-3 landscape now has 30 clinical trials running, with products being evaluated in an estimated 6,700 patients globally. Within this busy landscape, we are pleased to say that Immutept remains the global leader in this exciting space, with four LAG-3 related product candidates in development in immuno-oncology and autoimmune diseases.

### IMMUTEP RINGS THE NASDAQ CLOSING BELL

On 1 June, members of the Immutept team met in New York with advisors and supporters to celebrate the Company's listing on NASDAQ by ringing the closing bell. This follows the Company's name change and change in Nasdaq ticker to IMMP.

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MARC VOIGT

## Message from the CEO

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*[Continued from p. 2]*

The NASDAQ bell ringing event was live streamed on Facebook and was broadcast in the U.S. on Fox, CNBC and other channels. If you missed the live stream and broadcast events, you can watch the video we created to mark the occasion, at [youtu.be/UzIQPrhaLT4](https://youtu.be/UzIQPrhaLT4)

The bell ringing ceremony was a moment to step back and take stock of all that the team has achieved. We are proud of our leadership position in the LAG-3 immunotherapy space, something which is increasingly being recognised by investors and other stakeholders.

Our lead product, efiti, has advanced to a Phase IIb clinical trial in breast cancer, a trial of significant size and potential, especially in Europe. In addition, we have committed partnerships in place with three of the world's largest pharmaceutical companies, Merck MSD, Novartis and GSK, plus our partner in China, Eddingpharm/EOC.

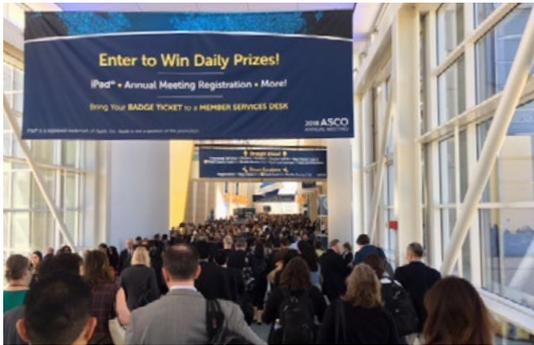
Along with our Australian Securities Exchange listing, our listing on NASDAQ has helped us achieve all this. We are very proud to be listed on NASDAQ and are grateful for the ongoing support we receive from all our shareholders.

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# LAG-3 FEATURED AT ASCO POSTER PRESENTATIONS

Immutep was pleased to see that LAG-3 was featured prominently at the recent American Society of Clinical Oncology (ASCO) Annual Meeting, in Chicago, Illinois which took place at the start of June. Our partner Novartis presented two posters, including the first ever data on LAG525 demonstrating encouraging results from its ongoing dose escalation study in combination with anti-PD1. These presentations were well received and attended at ASCO. Further details on these presentations can be accessed at [meetinglibrary.asco.org/record/159156/abstract](https://meetinglibrary.asco.org/record/159156/abstract) & [meetinglibrary.asco.org/record/165305/abstract](https://meetinglibrary.asco.org/record/165305/abstract)



Immutep presented two posters at ASCO which focused on the Company's Phase IIb AIPAC double blind placebo trial evaluating the efficacy of efi in patients with metastatic breast cancer.

The first poster discussed the results from the safety run-in phase of the AIPAC trial, results previously announced to the market. This poster was presented by Prof. Duhoux, Cliniques Universitaires Saint-Luc, Université Catholique de Louvain. Specifically, it reiterated that the overall response rate ("ORR") in patients to the combination of paclitaxel and efi was 47%, and that the disease control rate ("DCR") was 87%. It also noted that two of the responses to the combination therapy occurred relatively late in the treatment (after ~6 months) and that the safety run-in phase reported a very encouraging safety profile.

**Trial design**

**Safety results**

Safety parameter	Paclitaxel + efi (n=133)	Paclitaxel + placebo (n=133)	Overall (n=266)
Pro with any AE	6 (5.0%)	9 (7.0%)	15 (5.6%)
Pro with any SAE	5 (3.9%)	4 (3.2%)	9 (3.4%)
No of SAEs	30	6	36
No of SAEs rel. to efi	0	1	1
No of SAEs rel. to paclitaxel	1	0	1
Pro with any grade 3/4 AE	5 (3.9%)	7 (5.4%)	12 (4.6%)
Any grade 3/4 AE rel. to efi	0 (0%)	4 (3.2%)	4 (1.5%)
Any grade 3/4 AE rel. to paclitaxel	1 (0.8%)	3 (2.3%)	4 (1.5%)

**Efficacy results**

Response parameter	Paclitaxel + efi (n=133)
Complete Response (CR)	1 (0.8%)
Partial Response (PR)	7 (5.4%)
Stable Disease (SD)	6 (4.6%)
Progressive Disease (PD)	7 (5.4%)
Overall Response Rate (ORR)	7 (5.4%)
Disease Control Rate (DCR)	13 (10.0%)

**Pharmacodynamics**

**Conclusions**

- 30 mg efi is the RP1D in combination with weekly paclitaxel as a first-line chemotherapy treatment of MBC
- 6 and 30 mg efi are safe and well tolerated in combination with weekly paclitaxel
- Efi in combination with paclitaxel shows encouraging DCR (87%) and ORR of 47%
- Efi leads to sustainable (> 6 months) increase and activation of ABCs
- Efi leads to sustainable (> 6 months) increase in T cell numbers, together with an improved Th1 status

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# LAG-3 FEATURED AT ASCO POSTER PRESENTATIONS

[Continued from p. 5]

The second poster, presented by Dr. Dirix of GZA Hospitals Sint-Augustinus, Antwerp, Belgium, outlined the ongoing AIPAC trial, its design and primary end points. Both of Immutep's poster presentations were well attended and received by the scientific and medical community at ASCO.

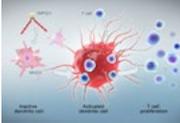
**AIPAC (Active Immunotherapy Paclitaxel): A randomized, double blind, placebo-controlled, multinational Phase Ib trial evaluating the efficacy of eftilagimod alpha (a soluble LAG-3 fusion protein) in combination with paclitaxel in hormone receptor positive metastatic breast cancer.**

**Dirix L<sup>1</sup>; Jager A<sup>2</sup>; Marmé F<sup>3</sup>; Brain E<sup>4</sup>; Armstrong A<sup>5</sup>; Nawrocki S<sup>6</sup>; Triebel F<sup>7</sup>**

<sup>1</sup>GZA Hospitals Sint-Augustinus, Antwerp, Belgium.  
<sup>2</sup>Erasmus MC Cancer Institute, Rotterdam, Netherlands  
<sup>3</sup>DFZ, Heidelberg, Germany  
<sup>4</sup>Hospit Curie Saint-Cloud & Paris, Paris, France  
<sup>5</sup>The Christie NHS Foundation Trust/Clinic, Medical Oncology Manchester, United Kingdom  
<sup>6</sup>Universitätsklinikum Centrum Klinische, Oncology Dept., Katowice, Poland  
<sup>7</sup>Research & Development, Immutep, Paris, France



**Background**



Eftilagimod alpha (efti, previously IMP321) is a recombinant LAG-3 fusion protein that binds to MHC class II and mediates antigen-presenting cell (APC) activation followed by CD8 T-cell activation. The activation of the dendritic cell network with efti injected s.c. the day after chemotherapy at a time when these APC are loaded with tumor antigens may lead to stronger anti-tumor CD8 T cell responses. This is approached in the present AIPAC trial (Active Immunotherapy Paclitaxel) in hormone receptor-positive stage IV metastatic breast carcinoma patients receiving eftilagimod alpha or placebo as adjunctive to weekly paclitaxel as a first-line chemotherapy. The safety run-in stage (stage 1) is completed, whereas the randomized part (stage 2) is actively recruiting.

For more information, please visit [immutep.com/investors](http://immutep.com/investors) [media/presentations.html](http://media/presentations.html) or use the following:



Copies of this poster obtained through Quick Response (QR) Code are for personal use only and may not be reproduced without permission from ASCO® and the author of this poster.

The AIPAC trial protocol has been released on 28 August 2015. The trial identifiers are IMP321-0113 (sponsor code), 2015-00254-03 (EUROCT) and NCT02614833 (ClinicalTrials.gov). Corresponding author: Frederic Triebel, frederic.triebel@immutep.com

**Objectives (randomisation stage)**

- To determine the efficacy of efti combined with weekly paclitaxel versus weekly paclitaxel plus placebo in hormone receptor positive metastatic breast cancer patients
- To characterise the anti-tumour activity of efti, safety, tolerability, immunogenic properties, quality of life, immune responses and biomarker of efti + paclitaxel versus placebo.

**Trial design**

A multicentre, placebo-controlled, double blind, 1:1 randomised Phase Ib clinical trial in 2 stages:

- Safety run-in stage (n=15)\*:** open-label, determining recommended Phase 2 dose of efti in combination with paclitaxel for randomized phase
- Randomisation stage (n=226):** placebo-controlled, double-blind, treatment: efti + paclitaxel vs. paclitaxel + placebo

**Treatment design**

The treatment consists of a chemo-immunotherapy phase followed by a maintenance phase:

- chemo-immunotherapy phase:** 6 cycles of 4 weeks with weekly paclitaxel (80 mg/m<sup>2</sup>, corticoid premedication allowed) at Days 1, 8 and 15 + either efti or placebo, on Days 2 and 16 of each 4-week cycle.
- maintenance phase:** responding or stable patients will receive afterwards study agent (efti or placebo) every 4 weeks for additional 12 injections



**Study duration**

- Study start: First patient first visit (stage 1) by January 2016
- Start of the randomisation stage: first patient first visit (stage) by January 2017
- Estimated last patient first visit: H2 2018
- Estimated study end: 36 months after last patient first visit (stage 2)

**Involved countries**

- The AIPAC trial was submitted and approved in 7 countries:
  - Belgium
  - The Netherlands
  - France
  - Hungary
  - Poland
  - United Kingdom
  - Germany
- Number of sites: 34



\*Please note, the safety run-in stage is completed and is not part of this poster. Details and results are shown on poster #131 (abstract 1050).

**Main Exclusion criteria**

Patients are to be excluded from the study at the time of screening for any of the following reasons:

- Prior chemotherapy for metastatic breast adenocarcinoma
- Disease-free interval of less than twelve months from the last dose of adjuvant chemotherapy
- Candidate for treatment with trastuzumab (or other Her2/neu targeted agents)
- Systemic chemotherapy, endocrine therapy, or any other investigational agent within 4 weeks prior to first dose of study treatment and until completion of study treatment
- Known cerebral or leptomeningeal metastases
- Active acute or chronic infection
- Active autoimmune disease requiring immunosuppressive therapy
- Known HIV positivity, history of Hepatitis B or C exposure, currently controlled by antiviral therapy
- Any condition requiring continuous systemic treatment with either corticosteroids (>10 mg daily prednisone equivalents) or other immunosuppressive medications within 4 weeks prior to first dose of study treatment. Inhaled or topical steroids and physiological replacement doses of up to 10 mg daily prednisone equivalent are permitted in the absence of active autoimmune disease

**Main Inclusion criteria**

- Able to give written informed consent and to comply with the protocol
- Stage IV oestrogen receptor positive and/or progesterone receptor positive breast adenocarcinoma, histologically proven
- Female of age 18 years or above
- Patients who are indicated to received first line chemotherapy with weekly paclitaxel
- Effective contraception or postmenopausal or permanently sterilized or otherwise be incapable of pregnancy
- ECOG performance status 0-1
- Expected survival longer than three months
- Resolution of toxicity of prior therapy to grade < 2 (except for alopecia and transaminases in case of liver metastases)
- Evidence of measurable disease as defined by RECIST version 1.1
- Adequate laboratory criteria

**Statistical analysis (randomisation stage)**

- N = 226 patients
- Minimum of 152 PFS events

**Endpoints:**

- Progression-free survival and overall survival
- Assessment of adverse events according to National Cancer Institute common terminology criteria for adverse events and other safety parameter
- Time to next treatment, objective response rate according to RECIST 1.1, time to and duration of response and duration of stable disease
- Plasma concentration time profile of efti and derived PK parameters
- Development of anti-drug (efti) antibodies
- Assessment of TH1 biomarker of interest as pharmacodynamics markers in the same subset of patients monitored for blood cell phenotype
- Determination of autoantibodies
- Assessment of serum tumour markers

APC...antigen-presenting cell  
ECOG...Eastern Cooperative Oncology Group  
efti...Eftilagimod alpha  
MHC...Major Histocompatibility Complex  
PFS...Progression-free survival

A third poster presentation relating to efti was presented by our partner, IKF from Frankfurt, Germany, and outlined the clinical trial design of INSIGHT, an open-labeled Phase I clinical trial to evaluate the feasibility and safety of intra-tumoral, intra-peritoneal, and subcutaneous injections with efti for advanced stage solid tumors. INSIGHT is an ongoing investigator sponsored trial. The INSIGHT poster is available at the following link

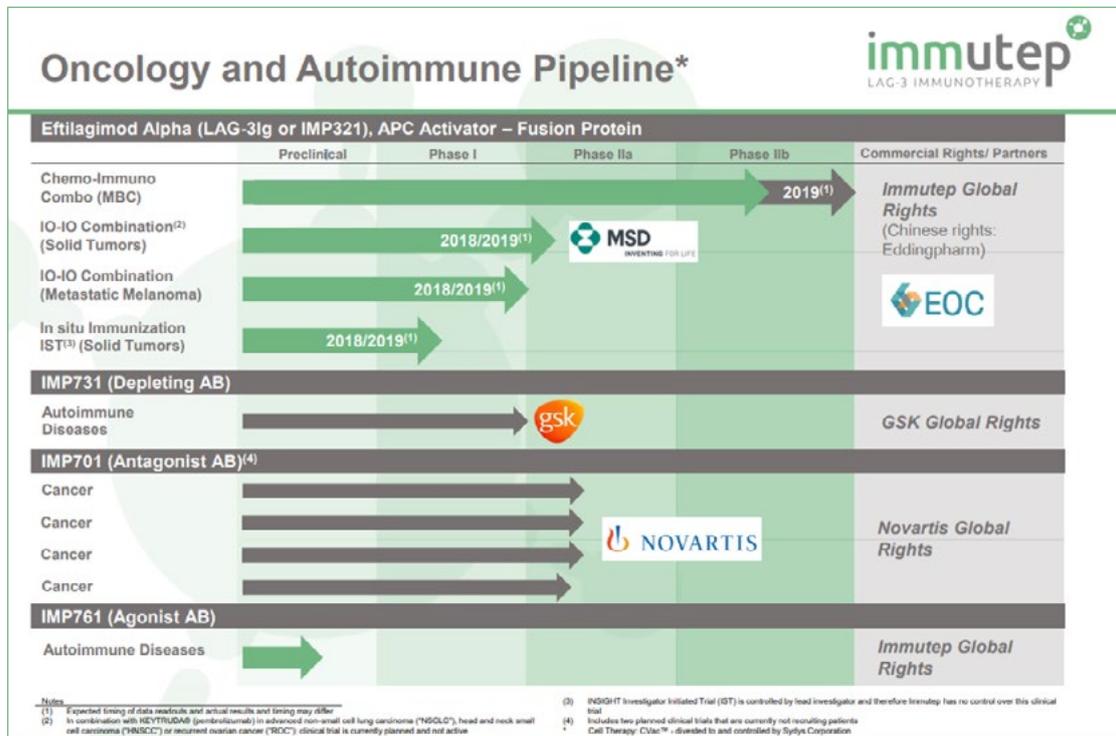
[immutep.com/files/content/investor/presentation/2018/INSIGHT%20Trial%20ASCO%20Poster.pdf](http://immutep.com/files/content/investor/presentation/2018/INSIGHT%20Trial%20ASCO%20Poster.pdf)



# OPERATIONAL PROGRESS

Due to recent operational and partner progress, Immutep is pleased to have expanded its clinical development pipeline considerably, with the addition of our TACTI-002 Phase II trial as well as two new Phase IIa trials from our partner, Novartis.

An enlarged version of the below product pipeline chart can be found in the Corporate Presentation slide deck at [immutep.com/files/content/investor/presentation/2018/20180517%20Immutep%20May%20Corporate%20Presentation%20updated.pdf](http://immutep.com/files/content/investor/presentation/2018/20180517%20Immutep%20May%20Corporate%20Presentation%20updated.pdf)



## Encouraging TACTI-mel interim results

Our TACTI-mel Phase I clinical trial in Australia is evaluating the combination of efti and Keytruda in unresectable or metastatic melanoma patients. We were delighted to see that the combination treatment is delivering long lasting and durable responses in a subset of patients. We previously announced an Overall Response Rate ("ORR") of 61% (11/18 patients) based on an analysis of measuring tumour size from the beginning of treatment with Keytruda (cycle 1) and including the response rate to the combination therapy as well as 33% (6/18) when measured from the start of treatment with the combination of efti and Keytruda (cycle 5).

This trial was recently extended to encompass a fourth cohort of patients that will start the combination treatment at cycle 1 at the 30 mg dose. Three patients in this fourth cohort have now received their first dose and recruitment is expected to be complete in the next couple of months.

We expect updated data from TACTI-mel to be reported at the Society for Immunotherapy of Cancer (SITC) Annual Meeting which will take place in November 2018.

[Continued on p. 7]

# OPERATIONAL PROGRESS

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*[Continued from p. 6]*

## **AIPAC trial now 50% recruited**

Immutep's AIPAC trial is progressing well. We are pleased to have reached the mid point in patient recruitment in June, meaning that we have enrolled and commenced dosing of 113 patients across 30 clinical sites situated in Belgium, the Netherlands, Poland, Hungary, United Kingdom, France and Germany.

AIPAC is our Phase IIb clinical trial evaluating efti in combination with paclitaxel in metastatic breast cancer. Following positive safety data, Immutep has now moved into the randomised phase of trial.

During the past year CDK4/6 inhibitors (e.g. Ibrance from Pfizer) have been approved for the treatment of metastatic breast cancer to reinforce hormonal therapy given for 6-12 months in most patients before the first-line chemotherapy setting. While the first line chemotherapy setting is unchanged for these patients, the approval impacted the rate of recruitment for our AIPAC study, as patients now have an additional treatment option before receiving chemotherapy and becoming eligible to participate in the AIPAC trial. As a one-time practice changing event it resulted in a temporary slowdown in the rate of recruitment for AIPAC, however this has now accelerated again especially as all European sites are now actively recruiting.

Possible changes in patient characteristics at the start of chemotherapy should not have an impact on the robustness of the AIPAC trial due to the double-blind randomization design. From a commercial perspective, the number of patients entering the first line chemotherapy setting should remain the same. We project that the required 226 patients will be recruited into AIPAC by the end of calendar year 2018. Our first Progression Free Survival data is expected to be reported in calendar year 2019.

## **TACTI-002 IND application preparation**

Preparations for our newly announced TACTI-002 Phase II clinical trial are progressing well. The team has been working on the trial protocol and preparing the investigational new drug (IND) application, for submission to the U.S. FDA.

Up to 120 patients will be recruited for the trial which will take place across approximately 15 study centres in the U.S., Europe and Australia. The trial will evaluate the combination of efti with MSD's Keytruda in patients with two different types of cancers, head and neck squamous cell carcinoma and non-small cell lung cancer.

Patients participating in the trial will be given the combination treatment from day 1 of cycle 1, mirroring the study design of the fourth cohort of our TACTI-mel trial.

We expect to be reporting the first data from the trial in 2019.

## **INSIGHT patient recruitment progress**

As mentioned, INSIGHT is an investigator sponsored trial by Immutep's partner, IKF in Frankfurt, Germany.

IKF has advised Immutep that patient recruitment to the trial is progressing, with 10 patients now participating in the study. We expect our partner to report interim data later in calendar year 2018. As detailed above, IKF also presented a poster at ASCO in Chicago last week.

## **Pre-clinical development of IMP761**

Our pre-clinical product candidate IMP761 has also advanced, completing a pre-clinical study in autoimmune disease. We look forward to reporting data from the study later in the calendar year.



## PARTNERING UPDATE

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Partnering continues to form an integral part of our clinical development strategy. We are pleased to currently have ongoing partnerships in place with GSK, Novartis and Eddingpharm (EOC), along with our collaboration with Merck & Co.

### **Eddingpharm/EOC commissions batches of efti from WuXi Biologics**

Immutep is pleased to advise that its Chinese partner EOC Pharma, an oncology focused affiliate of Eddingpharm, has commissioned the manufacture of Good Manufacturing Practice (GMP) batches of efti from our manufacturing partner in China, WuXi Biologics.

The GMP batches are to be used for EOC Pharma's clinical development program for efti. Following the granting of EOC Pharma's Investigational New Drug (IND) application in China in late December 2017, EOC is preparing to commence a Phase I, open-label, single center, non-randomised, dose-escalation study to evaluate the safety, tolerability and pharmacokinetic profile of efti in combination with chemotherapy treatment, paclitaxel, in HR+ metastatic breast cancer patients.

EOC Pharma anticipates that the first patient will be dosed in the Phase 1 clinical trial in July 2018, with patient recruitment expected to be complete by Q1 of year 2019.

By way of background, Immutep and Eddingpharm entered into a licensing agreement in 2013 whereby Immutep granted Eddingpharm exclusive development rights for efti in China, including Hong Kong, Macau, and Taiwan. The license was later transferred from Eddingpharm to EOC Pharma upon the consent of Immutep.

### **GSK completes Phase 1 clinical study**

GSK, which holds the exclusive worldwide rights to IMP731 for autoimmune diseases, completed its Phase I clinical study in psoriasis in March 2018. GSK's investigational product, GSK2831781, is derived from Immutep's IMP731 antibody and aims to kill the few activated LAG-3+T cells that are auto-reactive in autoimmune diseases, leading to long term disease control without generalised immune suppression. We expect that GSK will provide an update on the trial outcome later this year.

*[Continued on p. 9]*

# PARTNERING UPDATE

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*[Continued from p. 8]*

## **Novartis doubles number of LAG525 clinical trials**

Continuing its development of LAG525, our partner Novartis expanded its clinical development program for this product candidate in April 2018. Building on its two Phase IIa clinical trials, it now plans to begin another two Phase IIa clinical trials in June/July 2018 in triple-negative breast cancer (126 patients) and metastatic melanoma (160 patients). Altogether, these four clinical trials will see LAG525 evaluated in close to 1,000 patients.

As many of you may know, LAG525 is an anti-LAG-3 monoclonal antibody that blocks LAG-3-mediated immune down-regulation and is derived from Immutep's IMP701 antibody. Novartis holds the exclusive worldwide rights from Immutep to market LAG525 once approved. Immutep is entitled to milestone payments as development progresses and royalties from the marketed product.

Novartis recently highlighted its focus on "smart combinations" for cancer. As part of this program, it has selected LAG525, licensed from Immutep, as one of two immunotherapies that have shown early clinical activity in some cancers in combination studies, and that warrant further clinical investigation. You can read the full article from Novartis on smart combinations here - [bit.ly/2LZbG3q](https://bit.ly/2LZbG3q)

## **CYTLIMIC**

Earlier in the year, our partner CYTLIMIC commenced its Phase I study for adjuvant immunotherapy at Yamaguchi University Graduate School of Medicine. The study is the second that tests CYTLIMIC's cancer peptide vaccine in combination with Immutep's efti.

Yamaguchi University Professor Dr. Shoichi Hazama anticipates that the second study of its innovative peptide vaccine CYT001 in combination with efti will yield deeper insights into its activity in tumors and the vaccine effects in suppressing recurrence of hepatocarcinoma. In this sense, the YCP02 study is both scientifically and clinically very important.

In April, CYTLIMIC announced the registration of a Japanese patent directed to the combination adjuvant containing its peptide vaccine CYT001. The adjuvant contains efti and a TLR3 agonist, which act synergistically to boost the effect of the peptide antigen in the vaccine.



## FINANCING UPDATE

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In addition to the operational progress, the Company was also able to successfully conclude an equity raise corner-stoned by two major Australian institutional investors, Australian Ethical Investment and Platinum Asset Management. The raise was also supported by our former Chairman Lucy Turnbull, AO and Ridgeback Capital. In addition, we would like to thank our shareholders for their support in the share purchase plan which closed in mid-April 2018. The total proceeds from this raise were A\$13.16m leading to a cash reach well into the 4th quarter of calendar year 2019.



## OUTLOOK

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The second half of 2018 will be busy again with data from TACTI-mel and INSIGHT as well as potential updates from our partners. Also, we will see the start of TACTI-002 and possibly also a Phase I clinical trial in China sponsored by EOC Pharma.

We also hope for progress in terms of the general LAG-3 landscape and will remain to be very active in terms of business development.

We thank our shareholders, partners and of course physicians and patients and their families for all the support and interest in the past months.



COMPANY CALENDER

## What's next

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### August 2018

Appendix 4E & 2018 Full Year Statutory Accounts

### October 2018

ESMO Congress, Munich, Germany - 19 Oct - 23 Oct 2018

### November 2018

33rd Annual Meeting SITC 2018; Starts: Nov 7, 2018 - Nov 11, 2018; Walter E. Washington Convention Center, 801 Mt Vernon PI NW, Washington, D.C., DC 20001

### November 2018

Annual General Meeting



IMMUTEP

## Fact Facts

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### Listings

Australian Securities Exchange (ASX), NASDAQ

### Stock Codes

ASX: IMM, NASDAQ: IMMP

### Issued Capital – Ordinary Shares

3.03 billion (as of Jun 14, 2018)

### Market Capitalisation

A\$105.9 million (US\$80.0 million)  
(as of Jun 14, 2018)

### Issued ADR's

~7.2 million (as of May 31, 2018)

### Cash & Term Deposits

~ A\$20.0 million (as of Mar 31, 2018) not including A\$6.31M from SPP received in April 2018

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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

[immunetep.com](http://immunetep.com)

## 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:

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

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

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### [LinkedIn](https://linkedin.com/company/857541/)

[linkedin.com/company/857541/](https://linkedin.com/company/857541/)