# INVESTOR UPDATE







#### Marc Voigt, CEO

# Message from the CEO

#### **Business overview**

LAG-3 continues to capture the attention of the international pharmaceutical and investment communities. Immunotherapy is becoming a standard of care for many cancer

treatments – as evidenced at this year's European Society of Oncology (ESMO) 2017 Congress in Madrid, Spain, where LAG-3 was part of the discussion. Prima was represented by our Director of Clinical Development, Christian Mueller, who provides an update on ESMO later in this newsletter.

Operationally, our Australian Phase I clinical trial in metastatic melanoma, TACTI-mel, is progressing well and we are on track to complete recruitment for the third cohort (30 mg dosage) by the end of calendar year 2017. We will be presenting data from this trial at the World Immunotherapy Congress in Basel, Switzerland on October 31, 2017 and new data at the Society for Immunotherapy of Cancer (SITC) 2017 Annual Meeting, Maryland in the U.S. on November 10, 2017.

Similarly, recruitment for the randomised phase of our Phase IIb trial in metastatic breast cancer, AIPAC, is ongoing and we continue to open new clinical sites across Europe. We now have regulatory allowance in the Netherlands, Belgium, Hungary, Poland, the UK and Germany to recruit patients and have approval from the competent authority in France as well. Based on our current assumptions, the 226 patient trial should be fully enrolled towards the end of the first half of calendar year 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 year 2019. Meanwhile, final safety data from the 15 patient run in phase is anticipated before the end of this calendar year.

The INSIGHT clinical trial continues to make progress with first patients being treated, with Professor Al-Batran (Medical Director at the Institute of Clinical Cancer Research in Frankfurt) and his team studying our lead drug candidate IMP321 in what is the first ever investigation into whether a direct injection of IMP321 into the tumour can activate the antigen presenting cells located inside the tumour to boost the body's immune response. We believe the first data from this clinical trial could be expected in 2018.

Our lead candidate IMP321 also stands to be called "eftilagimod alpha" which is the International Nonproprietary Name (INN). The process of getting an INN is regulated by the World Health Organisation (WHO). Each INN is a unique name that is globally recognized and is public property. An INN name facilitates the identification of pharmaceutical substances or active pharmaceutical ingredients.

Financially we remain in good shape with our current cash reach extending to the end of calendar 2018, without taking into consideration any potential milestone payments from our existing partners (GSK, Novartis, Eddingpharm and Cytlimic). As at 30 September 2017 the Company's cash balance was approx. A\$17.0 million. This includes the A\$1.3 million in R&D tax refunds received from the French Government, the Novartis milestone payment, and the proceeds from the July U.S. capital raise (approximately A\$6.5 million).

#### **Intellectual Property**

We continue to work with our existing partners on their respective programs and in broadening our patent portfolio.

We recently secured a patent in Japan for our IMP731 antibody, which was licensed to GlaxoSmithKline (GSK) in December 2010. This provides protection for the antibody and also use of the antibody in the manufacture of a medicament for treating or preventing organ transplant rejection or treating an autoimmune disease.

We also announced the grant of a Japanese patent for the use of our lead product candidate IMP321 in the treatment of infectious diseases. This points to the broader potential of IMP321 as an immunostimulant and provides protection in Japan for a range of possible clinical indications beyond cancer.

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Our partner Novartis, which is developing the IMP701 antibody (referred to as LAG525 by Novartis) under license, was granted a Lebanese patent for LAG525, a humanised form of IMP701 currently being evaluated in a Phase I/II clinical trial together with PD1 inhibitor PDR001 for the treatment of cancer.

#### **Business Development**

As recently announced, Prima entered into a collaborative research project with Melbourne's Monash University to further explore the role of LAG-3 in immune responses. The government-funded Australian Research Council (ARC) awarded the collaboration A\$360,000, demonstrating the growing investment in, and support for prospective immunotherapeutic treatments for cancer and autoimmune disease. This is an exciting opportunity to collaborate with one of Australia's leading academic institutions over the next three years.

As the legitimacy of LAG-3 as a therapeutic target, either by modulating LAG-3 directly or its ligand (MHCII), continues to garner industry acknowledgement, so does our engagement with potential partners, which is becoming more intense. For example, in China we continue to support our partner Eddingpharm and its affiliate EOC Pharma in their efforts to progress Chinese regulatory and clinical pathways.

I would like to conclude by welcoming Grant Chamberlain as our newest Board member. In August Grant joined the Prima Board as a Non-Executive Director. Grant's extensive capital markets experience will be most valuable as we continue to pursue our strategy of creating shareholder value by leveraging Prima's position as a worldwide leader in the LAG-3 field.

I very much look forward to updating you on our ongoing progress in the months to come.



James Flinn

# MEET THE TEAM: JAMES FLINN

James is an Australian Patent Attorney with more than 18 years of professional experience in building and managing IP portfolios. He has worked in both private and corporate patent practice and prior to joining Prima worked for GlaxoSmithKline (GSK) for 7 years as Senior Patent Counsel, where he managed the global patent portfolio of GSK's dermatology business. James has also worked for two US-based pharmaceutical companies, a major Australian retailer, and a Melbourne based Patent Attorney firm.

James enjoys interacting with business stakeholders in the identification, capture, protection and commercialisation of IP, and seeing the value that can be created when IP is managed and exploited effectively. Since joining Prima, he has been most impressed by the business's ability to quickly capture opportunities and the access to senior management, which he sees as a real competitive advantage.

# 2017 EUROPEAN SOCIETY FOR MEDICAL ONCOLOGY (ESMO) REVIEW

Christian Mueller, Prima's Director of Clinical Development attended ESMO in early September and below shares his views on some of the key themes.

Firstly, consensus continues to build that immunotherapies will play a leading role in the treatment of cancer. Furthermore, the impressive results demonstrated by checkpoint inhibitors are driving interest in immunotherapy combinations that have synergistic methods of action.

PD-1 and PDL-1 antagonists will be the primary agent in this treatment paradigm, but the question remains: what will be administered in combination with a PD-(L)1 targeting therapeutic? Safety may be a key differentiator or driver in determining the winning combination strategies as side effects associated with some combinatory studies have prompted a clinical hold of two CTLA4 plus PD-1 programs by the FDA. Several CAR-T related trials have also demonstrated significant toxicity.

Secondly, the use of biomarkers will continue to grow in relevance as data has shown a difference in efficacy when tumors express high levels of the targeted molecule, even though this field is still very early. BMS presented additional data on relatlimab, the recently announced INN name for

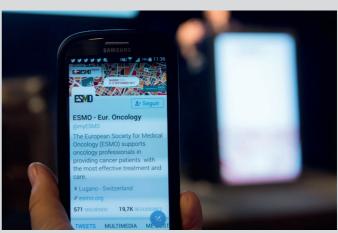
BMS 986016 (LAG-3 antagonist antibody) which is moving into late-stage development in combination with nivolumab and other agents.

BMS also referenced the utilization of a biomarker noting that patients with higher levels of LAG-3 expression had better responses than those with lower levels of LAG-3 expression. Regarding biomarkers, Fouad Namouni, BMS head of oncology, was quoted saying, "Biomarkers is a major investment field for us," and he continued "This is really the tip of the iceberg."

Prima views the positive relatlimab data BMS has been presenting as very encouraging as it helps validate LAG-3 as a meaningful therapeutic target.

Lastly, another important event that occurred earlier this year was the granting of accelerated approval by the U.S. FDA for pembrolizumab (Keytruda) in combination with pemetrexed and carboplatin (chemotherapy) for the treatment of patients with previously untreated metastatic non-squamous non-small cell lung cancer (NSCLC). This is relevant as this immunotherapy plus chemotherapy approach is the same one being employed by Prima in our AIPAC clinical trial.







## **Company Calendar**

October 31th, 2017	World Immunotherapy Congress, Basel, Switzerland. Frédéric Triebel is speaking about TACTI-mel, two ACTive immuno- therapies in melanoma: combination of an APC activator (IMP321 or LAG-3Ig) with Pembrolizumab at 5:50 PM.
November 08-12, 2017	SITC, Society for Immunotherapy of Cancer, National Harbor, MD, USA
17 November 2017	Annual General Meeting in November 2017, Sydney, Australia
November 14-16, 2017	ICI Europe - 3rd Annual Summit, Delivering Maximum Clinical Benefit Through Immune Checkpoint Modulation, Munich, Germany
March 19-23, 2018	3rd Annual Immuno-Oncology Summit Europe, Hilton London Canary Wharf, London, UK

# Follow Prima's progress

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

#### www.primabiomed.com.au

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

Prima 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**

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#### Facebook

www.facebook.com/PrimaBioMed

#### LinkedIn

www.linkedin.com/company/prima-biomed-ltd-

## Prima BioMed - Fast Facts

#### Listings

Australian Securities Exchange (ASX), NASDAQ

#### **Stock Codes**

ASX: PRR, NASDAQ: PBMD

#### **Issued Capital – Ordinary Shares**

2.36 billion (as of Oct 05, 2017)

#### **Market Capitalisation**

A\$61.4 million (US\$48 million) (as of Oct 05, 2017)

#### Issued ADR's

7.44 million (as of Sep 30, 2017)

#### Cash & Term Deposits

~ A\$17.0 million (US\$13.3 million) (as of Sep 30, 2017)

#### **Board of Directors**

Ms Lucy Turnbull, AO Non-executive Chairman

Mr Albert Wong Non-executive Deputy Chairman

Mr Marc Voigt Executive Director and

Chief Executive Officer

Dr Russell J Howard Non-executive Director

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

Ms Deanne Miller Chief Operating Officer,

General Counsel and Company Secretary

www.primabiomed.com.au