

ASX/Media Release (Code: ASX: PRR; NASDAQ: PBMD)

5 June 2017

## **LAG-3Ig (IMP321) DEMONSTRATES POSITIVE SAFETY AND EFFICACY QUALITIES IN BREAST CANCER CLINICAL TRIAL**

- **Breast cancer clinical trial demonstrates LAG-3Ig (IMP321) is safe and well tolerated**
- **Data shows IMP321 in combination with chemotherapy leads to a sustainable increase in antigen presenting cells (APC), CD8 T cells and an improved pre-dose Th1 status**
- **Encouraging activity with a disease control rate of 87%**

SYDNEY, AUSTRALIA - Prima BioMed Ltd (ASX: PRR; NASDAQ: PBMD) (“Prima” or the “Company”) has announced positive safety and efficacy data from the safety run-in stage of its clinical trial for IMP321 (LAG-3Ig) in metastatic breast cancer (MBC) at the American Society of Clinical Oncology (ASCO) 53<sup>rd</sup> annual meeting in Chicago, Illinois

AIPAC (Active Immunotherapy PAclitaxel) is Prima’s multicentre, Phase IIb, randomised, double-blind, placebo-controlled study in hormone receptor-positive MBC patients receiving IMP321 or placebo as adjunctive to first-line weekly chemotherapy, paclitaxel.

The safety run-in phase trialled the safety, immune-monitoring and activity of 15 patients. At both the 6mg and 30mg dose levels, IMP321 was shown to be safe and well tolerated. The higher 30mg dose demonstrated a stronger immune response, and was determined to be the recommended phase two dose (RPTD) for the ongoing randomised phase of 226 patients.

In addition, the safety run-in phase demonstrated that IMP321:

- in combination with paclitaxel shows an encouraging disease control rate (DCR) of 87%;
- leads to a sustainable (more than 6 month) increase and activation of antigen presenting cells (APCs), the primary Pharmacodynamic (PD) marker; and
- leads to a sustainable (more than 6 month) increase in CD8 T-cell and natural killer (NK) cell numbers, together with an improved pre-dose Th1 status, the secondary PD marker.

Prima’s Chief Medical Officer, Dr Frédéric Triebel, said: “This very positive data is a major milestone for our AIPAC trial. It further supports previous clinical data in metastatic breast cancer, which led to Prima designing and starting AIPAC along with Scientific Advice from the European Medicines Agency (EMA). The similar disease-free rate to that 30 patient trial, and stronger immune response from the higher 30mg dose further underpins the randomised phase for AIPAC currently underway.

The increase of APC numbers in the blood and their activation, which stimulate the body's immune response to fight cancer cells, has not previously been seen with other immune checkpoint inhibitors as IMP321 has a broader mode of activation, not restricted to T cells. Furthermore, the increased numbers of CD8 T cells and natural killer cells, and corresponding baseline Th1 status is a very positive indicator of the potential efficacy of IMP321 as these are known to be related to anti-tumour efficacy in patients."

The poster presentation, titled "Combination of paclitaxel and LAG-3Ig (IMP321), a novel MHC class II agonist, as a first-line chemoimmunotherapy in patients with metastatic breast carcinoma (MBC): Interim results from the run-in phase of a placebo controlled randomized phase II" was delivered by lead author, Dr Francois P. Duhoux from Université Catholique de Louvain, Cliniques universitaires Saint-Luc, Brussels, Belgium on Sunday, 4<sup>th</sup> June.

The full poster presentation can be found on the Prima BioMed website at [www.primabiomed.com.au](http://www.primabiomed.com.au). Details of the AIPC study are posted on [www.clinicaltrials.gov](http://www.clinicaltrials.gov) (clinicaltrials.gov identifier [NCT 02614833](https://clinicaltrials.gov/ct2/show/study/NCT02614833)).

#### **About Prima BioMed**

Prima BioMed is a globally active biotechnology company that is a leader in the development of immunotherapeutic products. Prima BioMed is dedicated to leveraging its technology and expertise to bring innovative treatment options to market for patients and to maximise value to shareholders.

Prima's current lead product is IMP321, based on the LAG-3 immune control mechanism which plays a vital role in the regulation of the T cell immune response. IMP321, which is a soluble LAG-3Ig fusion protein, is an APC activator boosting T cell responses. IMP321 is currently in a Phase II clinical trial as a chemoimmunotherapy for metastatic breast cancer termed AIPAC (clinicaltrials.gov identifier [NCT 02614833](https://clinicaltrials.gov/ct2/show/study/NCT02614833)) and in a Phase I combination therapy trial in metastatic melanoma termed TACTI-mel (clinicaltrials.gov identifier [NCT 02676869](https://clinicaltrials.gov/ct2/show/study/NCT02676869)). A number of additional LAG-3 products including antibodies for immune response modulation in autoimmunity and cancer are being developed by Prima's pharmaceutical partners. Prima is also developing an agonist of LAG-3 (IMP761) for autoimmune disease.

Prima BioMed is listed on the Australian Securities Exchange and on the NASDAQ in the US. For further information please visit [www.primabiomed.com.au](http://www.primabiomed.com.au).

#### **For further information please contact:**

##### **U.S. Investors:**

Matthew Beck, The Trout Group LLC  
+1 (646) 378-2933; [mbeck@troutgroup.com](mailto:mbeck@troutgroup.com)

##### **Australian Investors/Media:**

Matthew Gregorowski, Citadel-MAGNUS  
+61 2 8234 0105; [mgregorowski@citadelmagnus.com](mailto:mgregorowski@citadelmagnus.com)