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PRIMA BIOMED ANNOUNCES DATA FROM IMP321 AIPAC CLINICAL TRIAL IN BREAST CANCER

SYDNEY, AUSTRALIA - Prima BioMed Ltd (ASX: PRR; NASDAQ: PBMD) (“Prima” or the “Company”) today announced interim data from the AIPAC Phase IIb clinical trial for IMP321 in metastatic breast cancer (Active Immunotherapy PAClitaxel). The initial data confirms previous trial results showing IMP321 is safe and well tolerated.

In this Phase IIb study of IMP321 plus paclitaxel chemotherapy in patients with hormone receptor-positive metastatic breast cancer, data from all 15 patients in the safety run-in phase demonstrated that IMP321 is safe and well tolerated at both the 6mg and 30mg dosage levels. Immune monitoring data has also confirmed that IMP321, as an Antigen Presenting Cell (APC) activator, is working to generate the desired immune responses. The data demonstrated activation and an increased level of blood monocytes, dendritic cells and CD8 T-cells.

Prima’s Chief Medical Officer, Dr Frédéric Triebel, said: “Following the initial data released in June, we are now very pleased to confirm the safety, pharmacokinetics and pharmacodynamics of IMP321 across the initial patient cohorts at both dosage levels. This is another important step in de-risking our AIPAC trial as we look to commence the enlarged randomised and double-blind phase in the new year. We also look forward to providing further insights into efficacy of these safety run in patients by the middle of 2017.”

Subject to the confirmation of the dose escalation committee on the 30th December, Prima will now commence the randomised phase of the trial in January 2017. Patients will receive paclitaxel treatment plus placebo or paclitaxel in conjunction with IMP321.

About IMP321

IMP321 is a first-in-class Antigen Presenting Cell (APC) activator based on the immune checkpoint LAG-3. IMP321 represents one of the first proposed active immunotherapy drugs in which the patient’s own immune system is harnessed to respond to tumour antigenic debris created by chemotherapy. As an APC activator IMP321 boosts the network of dendritic cells in the body that can respond to tumour antigens for a better anti-tumour CD8 T cell response.

IMP321 has been shown in an open-label Phase I study¹, to be able to double the expected six-month response rate in HER-2 negative metastatic breast cancer patients receiving standard-of-care paclitaxel; from a 25% historic response rate², to 50% when combined with IMP321.

About Prima BioMed

Prima BioMed is a globally active biotechnology company that is striving to become a leader in the development of immunotherapeutic products for the treatment of cancer. 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](#)) and in a Phase I combination therapy trial in metastatic melanoma termed TACTI-mel (clinicaltrials.gov identifier [NCT 02676869](#)). A number of additional LAG-3 products including antibodies for immune response modulation in autoimmunity and cancer are being developed by large pharmaceutical partners.

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.

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¹ See Brignone et.al., J. Transl. Med. 2010, 8:71.

² Miller et. al., N. Engl. J. Med. 2007, 357: 2666-76.