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PRIMA BIOMED ANNOUNCES FIRST SAFETY, PHARMACOKINETICS AND IMMUNO-MONITORING DATA FROM PHASE IIB CLINICAL TRIAL OF IMP321

SYDNEY, AUSTRALIA - Prima BioMed Ltd (ASX: PRR; NASDAQ: PBMD), a leading immuno-oncology company, is pleased to announce initial safety data from the first cohort of patients in its Phase IIb AIPAC chemo-immunotherapy clinical study of Prima's lead compound, IMP321.

AIPAC (Active Immunotherapy PAClitaxel) is a multi-national, randomised, double-blind, placebo-controlled study of IMP321-plus-paclitaxel in hormone receptor-positive metastatic breast cancer. The trial is currently being conducted out of Belgium, The Netherlands and now also Hungary, with further European sites to be initiated in the future.

The first six patients have received 6 mg doses of IMP321 in combination with paclitaxel. This dose has proved to be safe and well tolerated with no drug related serious adverse events. The data also demonstrated activation of blood monocytes/dendritic cells and CD8 T cells.

Prima's Chief Medical Officer, Dr Frederic Triebel, said: "The data from this initial open-label run-in cohort of six patients confirms the safety, pharmacokinetics and pharmacodynamics of IMP321 and we are encouraged to have met our anticipated timelines for recruitment. We will now start enrolling nine additional patients in the second cohort with 30 mg of IMP321, with the results of both cohorts to be presented and compared in the fourth quarter of 2016. Then the randomisation phase with the recommended phase IIb dose will begin enrolling approximately 196 patients."

Prima's CEO, Marc Voigt, commented: "We are pleased to have confirmed previous results at the 6 mg dose in metastatic breast cancer. We believe that the interim results obtained at 6 mg significantly de-risk the remainder of the trial as the previous phase I/IIa trials provided very encouraging results with that dose level."

The primary purpose of the AIPAC trial is to determine the clinical benefit of IMP321 in terms of Progression-Free Survival as the primary clinical endpoint. Details of the AIPAC study are available at NCT 02614833.

About IMP321

IMP321, a first-in-class Antigen Presenting Cell (APC) activator based on the immune checkpoint LAG-3, 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 study[1], 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 rate[2] (RECIST criteria), 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 IIb clinical trial as a chemo-immunotherapy 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). 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.

For further information please contact:

Prima BioMed Ltd:

Australia Investor/Media:
Mr Matthew Gregorowski, Citadel-MAGNUS
+61 (2) 8234 0100; mgregorowski@citadelmagnus.com

U.S. Investors:

[1] See Brignone et.al., J. Transl. Med. 2010, 8:71.
[1] Miller et. al., N. Engl. J. Med. 2007, 357: 2666-76.

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