

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

22 December 2015

PRIMA BIOMED INITIATES PHASE IIB STUDY IN METASTATIC BREAST CANCER

- Institutional Review Board approval now obtained at four clinical sites in Belgium and three sites in the Netherlands
- First clinical site initiated in Belgium, University Hospital Saint-Luc in Brussels
- First patient expected to be dosed in early 2016

SYDNEY, AUSTRALIA - Prima BioMed Ltd (ASX: PRR; NASDAQ: PBMD), a leading immuno-oncology company, is pleased to announce the initiation of the first trial site for AIPAC, the Phase IIb 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 metastatic breast cancer. Prima announced on 27 October 2015 that Belgium had become the first jurisdiction to clear the AIPAC clinical trial application by the competent regulatory authority. Now, four sites within Belgium and three sites within the Netherlands have been approved by their Institutional Review Boards. The University Hospital Saint-Luc in Brussels will be the first AIPAC trial site ready for patient enrolment. The first patient is expected to be dosed in early 2016.

AIPAC, which has received Scientific Advice from the European Medicines Agency, is expected to recruit patients across 30 sites in 6 European countries once all approvals have been obtained. Work with the relevant pharmaceutical regulators and site administrators will continue for the remainder of 2015 and into 2016 to progress the study to its full recruitment capacity.

Prima's CSO & CMO, Dr. Frédéric Triebel, welcomed the news from Brussels. 'In a previous clinical trial, my colleagues and I were able to show that IMP321, acting as an Antigen Presenting Cell activator, generated about a doubling in response rate to paclitaxel in metastatic breast cancer over historic controls. It is gratifying to see the clinic at Saint-Luc collaborate with us to bring this potentially revolutionary new drug to market and thereby benefit patients for whom current treatment options are limited.'

Dr Duhoux of the King Albert II Cancer Institute (University Hospital Saint-Luc) commented. 'Favourable patient outcomes have been a hallmark of recent clinical research in the immuno-oncology field. While clinical success is not guaranteed for any investigational-stage compound, as an academic hospital, we at Saint Luc have sought to be at the forefront of new developments in the field and are therefore pleased to be associated with IMP321 and this carefully designed study'.

About AIPAC

Title of Study	AIPAC (Active Immunotherapy PAClitaxel): A multicentre, Phase IIb, randomised, double blind, placebo-controlled study in hormone receptor-positive metastatic breast carcinoma patients receiving IMP321 (LAG-3Ig fusion protein) or placebo as adjunctive to a standard chemotherapy treatment regimen of paclitaxel
Objectives	<p>Primary Objective</p> <ul style="list-style-type: none"> To determine the efficacy (as assessed by Progression-Free Survival [PFS]) in hormone receptor-positive metastatic breast cancer patients treated with IMP321 or placebo as adjunctive to a standard chemotherapy of paclitaxel <p>Secondary Objectives</p> <ul style="list-style-type: none"> To determine the safety and tolerability in hormone receptor-positive metastatic breast cancer patients treated with IMP321 or placebo as adjunctive to a standard chemotherapy of paclitaxel To assess the overall survival (OS), time to next treatment (TTNT), objective response rate (ORR), time to and duration of response and duration of stable disease in patients treated with IMP321 or placebo as adjunctive to a standard chemotherapy of paclitaxel To characterise the pharmacokinetic (PK) properties of IMP321 in this setting (safety run-in stage only) To assess the quality of life (QOL) related to IMP321 treatment compared to placebo <p>Exploratory Objectives</p> <ul style="list-style-type: none"> To evaluate the immune response, including monocyte number and activation, and CD8 T cell number and activation, in relation to treatment with IMP321 compared to placebo in a subset of 60 patients To identify biomarkers (as determined in archival tumour tissue) that correlate with clinical outcome and treatment response
Study Design	<p>This is a multicentre, placebo-controlled, double-blind, 1:1 randomised Phase IIb study in female hormone receptor-positive metastatic breast cancer patients. The study comprises two stages. In the open-label, safety run-in stage, the Recommended Phase 2 Dose (RPTD) of IMP321 in combination with paclitaxel will be confirmed. In the placebo-controlled, double-blind randomisation stage, paclitaxel + IMP321 at the RPTD will be compared to paclitaxel + placebo</p>
Planned Sample Size	<p>Approximately 211 patients</p>
Study Population	Key Inclusion Criteria

	<ul style="list-style-type: none"> • Stage IV oestrogen receptor positive and/or progesterone receptor positive breast adenocarcinoma, histologically proven by biopsy of the primary tumour and/or a metastasis • Patients who are indicated to received first line chemotherapy with weekly paclitaxel • Evidence of measurable disease as defined by RECIST version 1.1 <p>Key Exclusion Criteria</p> <ul style="list-style-type: none"> • 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)
ClinicalTrials.gov Identifier	NCT02614833

As advised in July 2015, AIPAC’s expected duration based on forecast recruitment times and patient follow up, is around three years. Details of the AIPAC study will be posted at www.clinicaltrials.gov under clinical trial identifier NCT02614833.

About University Hospital Saint-Luc

University Hospital Saint-Luc and partners are committed to providing patients with top-quality, dependable, easily accessible care with the most advanced technology. The group is a reference point for not only Belgium but the rest of the world as regards certain complex disorders. They continually produce excellent results in their work as a teaching hospital center with the principal activities of research, innovation, and teaching shared by The Université catholique de Louvain (UCL).

About Prima BioMed

Prima BioMed is a globally active biotechnology company positioned 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 for cancer chemo-immunotherapy and in other combinations which has completed early Phase II trials. 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 Stock Exchange and on the NASDAQ in the US. For further information please visit www.primabiomed.com.au.

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