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**PRIMA BIOMED RECEIVES POSITIVE SCIENTIFIC ADVICE FROM THE EUROPEAN MEDICINES AGENCY FOR ITS LEAD PRODUCT, IMP321**

**The EMA has now confirmed in writing its endorsement of the development program of IMP321 in metastatic breast cancer.**

SYDNEY, AUSTRALIA - Prima BioMed Ltd (ASX: PRR; NASDAQ: PBMD) ("Prima" or the "Company"), a leading immuno-oncology company, is pleased to announce that it has received positive Scientific Advice from the European Medicines Agency ("EMA" or the "Agency") on the development path for its lead product, IMP321 in metastatic breast cancer.

The EMA, located in London, is the agency responsible for the scientific evaluation of medicines developed by pharmaceutical companies for use in the European Union. After dialogue between Prima and the EMA, the Agency has now confirmed in writing its endorsement of the development program of IMP321 in metastatic breast cancer.

Encouragingly, the planned Phase IIb study, to be called AIPAC (Active Immunotherapy PAClitaxel) is considered well designed by the Agency. AIPAC is now expected to initiate in Europe during the 4th quarter of 2015. While the EMA never endorses any statement on the likelihood of future regulatory decisions, the Agency's communication has suggested that the achievement of certain clinical endpoints may lead to Marketing Authorization in the EU based on this one pivotal study.

After a smaller safety run-in phase that will extend into 2016 and will yield valuable safety, pharmacokinetic and pharmacodynamic data, AIPAC will proceed to recruit around 200 patients with HER-2 negative metastatic breast cancer, randomising them 1:1 to either standard-of-care paclitaxel plus placebo or paclitaxel plus IMP321.The trial will have Progression-Free Survival as its Primary Endpoint, with response rates according to the RECIST criteria and Overall Survival among the secondary endpoints. The study has been powered to show a four-month PFS advantage for the treatment group[1]. Allowing time for patient recruitment and follow-up, AIPAC's expected duration is around three years.

Prima's Chief Scientific and Medical Officer, Professor Frédéric Triebel, stated, "The EMA's Scientific Advice represents a significant step forward in terms of IMP321 clinical development in Europe. We now have the opportunity to introduce active immunotherapy to metastatic breast cancer patients, a promising novel strategy that we believe has the potential to fulfil an

[1] In HER2-negative metastatic breast cancer PFS can be as low as 6 months - see Miller et. al., N Engl J Med. 2007 Dec 27; 357(26):2666-76.

unmet medical need." Dr. Triebel added, "We wish to thank the EMA's Scientific Advice Working Party for their input and guidance."

**About Scientific Advice**

Scientific Advice is a procedure offered by the EMA to pharmaceutical industry participants for clarification of questions arising during development of medicinal products. Scientific Advice is prospective in nature and it focuses on development strategies rather than pre-evaluation of data to support a Marketing Authorisation Application (MAA). Scientific Advice is legally non-binding and is based on the current scientific knowledge which may be subject to future changes. Nevertheless, the advice provided is taken into consideration during MAA and any deviations from the advice given need to be well justified.

**About AIPAC (Active Immunotherapy PAClitaxel)**

AIPAC is the acronym for Prima's planned multicenter, Phase IIb, randomized, double blind, placebo-controlled clinical trial in HER-2 negative metastatic breast cancer patients receiving IMP321 or placebo as adjunctive to the standard-of-care chemotherapy drug paclitaxel. In a Phase IIa trial, IMP321 was able to increase the response rate (as per the RECIST criteria) at six months in these patients from the 25% expected of paclitaxel[2] to 50% for IMP321 plus paclitaxel[3]. The primary purpose of the AIPAC trial is to determine the clinical benefit of IMP321 in terms of Progression-Free Survival in this patient population (power 80%). Details of the AIPC study will be posted on www.clinicaltrials.gov in due course.

**About IMP321 and cancer immunotherapy**

IMP321 is a cancer immunotherapy agent currently in mid-stage clinical development with Prima BioMed, where it is the company's lead compound. Immunotherapy is a process whereby a disease such as cancer is treated either by activating or suppressing components of the immune system to generate a response. LAG-3, or Lymphocyte Activation Gene 3, is able to stimulate and in other cases inhibit an immune response, through involvement in a number of immune pathways. IMP321 is a soluble LAG-3Ig fusion protein which works by binding to MHC class II molecules on APCs such as dendritic cells to activate them. The APCs are important for showing cancer antigens to T cells and activating them to destroy cancer cells. IMP321 is a first-in-class APC activator.

**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.

[2] See Gray et. al., J Clin Oncol. 2009 Oct 20; 27(30): 4966–4972.
[3] See Brignone et.al., J Transl Med. 2010 Jul 23;8:71.

Prima's original product, called CVac, is an *ex vivo* dendritic cell priming therapy that in May 2015 yielded favourable Phase II data in second remission ovarian cancer patients. Prima is currently seeking partners for further development of this therapy. 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 soluble LAG-3, is a T cell immunostimulatory factor for cancer chemoimmunotherapy 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, on the NASDAQ in the US. For further information please visit www.primabiomed.com.au.

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