

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

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## **EFTILAGIMOD ALPHA (LAG-3Ig or IMP321) PRE-IND MEETING WITH THE FDA**

SYDNEY, AUSTRALIA - Prima BioMed Ltd (ASX: PRR; NASDAQ: PBMD) ("Prima") is pleased to announce that it held a Pre-Investigational New Drug Application (pre-IND) meeting with the U.S. Food and Drug Administration (FDA) in November to discuss the regulatory pathway for the development of Eftilagimod Alpha (LAG-3Ig or IMP 321) in the United States.

The FDA addressed Prima's questions related to preclinical, nonclinical, and clinical data and design of clinical trials of Eftilagimod Alpha in a chemo-immunotherapy setting and in an immuno-oncology combination trial. Prima intends to file an investigational new drug application (IND) in the first half of calendar year 2018. After having successfully started clinical development of Eftilagimod Alpha in Australia and Europe, an IND would provide Prima with the opportunity to commence clinical studies and regulatory interactions in the United States.

"The U.S. is the largest pharmaceutical market in the world, so the pre-IND meeting regarding Eftilagimod Alpha was an important milestone. Our meeting with the FDA was very productive and their guidance will be most valuable in assessing the appropriate U.S. clinical and regulatory strategies for Eftilagimod Alpha," said Marc Voigt, Prima's Chief Executive Officer.

### **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 Eftilagimod Alpha (LAG-3Ig or IMP321), based on the LAG-3 immune control mechanism which plays a vital role in the regulation of the T cell immune response. Eftilagimod Alpha is the International Nonproprietary Name (INN) for IMP321. Each INN is a unique name that is globally recognized to identify pharmaceutical substances or active pharmaceutical ingredients, and is regulated by the World Health Organisation (WHO).

Eftilagimod Alpha, which is a soluble LAG-3Ig fusion protein, is an APC activator boosting T cell responses. Eftilagimod Alpha 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 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 (PRR) and on the NASDAQ (PBMD) in the US. For further information please visit [www.primabiomed.com.au](http://www.primabiomed.com.au).

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