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PRIMA BIOMED'S CVAC™ GRANTED FAST TRACK DESIGNATION BY FDA

SYDNEY, AUSTRALIA - Prima BioMed Ltd (ASX: PRR; NASDAQ: PBMD) ("Prima") is pleased to announce today that the United States Food and Drug Administration ("FDA") granted **Fast Track Designation** to the CVac clinical development program at Prima. This program is intended to improve overall survival in patients with relapsed platinum-sensitive epithelial ovarian cancer who enter a second complete remission. Prima will work closely with the FDA in accelerating its development program for CVac to potentially bring this treatment option to patients in the U.S.

Matthew Lehman, Prima's CEO said: "This designation is an important milestone for Prima. The FDA decision is in recognition of the serious nature of ovarian cancer and the clear unmet medical need to develop new treatments for relapsed platinum-sensitive ovarian cancer in remission. Building from our CAN-003 trial data, which indicated an improvement in progression-free survival in this patient population, we look forward to accelerating our recently commenced CAN-004-B trial to establish overall survival advantages of CVac as soon as possible."

Established under the FDA Modernization Act of 1997, Fast Track is a process designed to facilitate the development, and expedite the review of drugs to treat serious conditions and fill an unmet medical need. The purpose is to get important new drugs to the patient earlier. Fast Track designation is reserved for therapies that attempt to treat diseases where no other therapy is available or where the Fast Track therapy shows some advantages over available therapy.

Fast Track designation confers some or all of the following benefits: more frequent meetings with FDA to discuss the drug's development plan and ensure collection of appropriate data needed to support drug approval, more frequent written correspondence from FDA about such things as the design of the proposed clinical trials and use of biomarkers, eligibility for *Accelerated Approval* and *Priority Review*, if relevant criteria are met, and *Rolling Review*, which means that a drug company can submit completed sections of its Biological License Application (BLA) or New Drug Application (NDA) for review by FDA, rather than waiting until every section of the application is completed before the entire application can be reviewed.

This Fast Track status granted by the FDA for CVac comes in addition to the **"Orphan Drug Designation"** previously granted by the FDA in September 2010. Orphan Drug Designation is intended to provide incentives to encourage companies to pursue cures and treatments for

rare diseases by providing major benefits during the product commercialisation process. Key incentives include the exclusive rights to the cure or treatment for a specific condition for 7 years post the approval to commercially market CVac and waiving of FDA fees.

CVac has an additional designation to facilitate its delivery to patients. In June 2010 CVac was granted "**Orphan Medicinal Product Designation"** by the European Medicines Agency (EMA). This designation also provides major benefits during product commercialisation. Key incentives include the exclusive rights to the cure or treatment for a specific condition for 10 years post the approval to commercially market CVac and the provision of tax reductions.

About Prima BioMed

Prima BioMed is a globally active leader in the development of personalized immunocellular therapeutic products for the treatment of cancer. Prima is dedicated to leveraging its technology and expertise to bring innovative treatment options to market for patients and to maximize value to shareholders. Prima's lead product is CVac™, an autologous dendritic cell-based product currently in clinical trials. www.primabiomed.com.au

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