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PRIMA BIOMED HAS ENROLLED THE FIRST PATIENT FOR THE CVac™ PHASE IIb TRIAL

Key points

- **First patient enrolled for US FDA Phase IIb clinical trial for CVac™ ovarian cancer therapy vaccine**
- **Randomised trial to be conducted with 60 patients across multiple global clinical sites**
- **Clinical assessments will be performed every 4 weeks and imaging via CT or MRI will be performed every 12 weeks**

Prima BioMed Ltd (ASX: PRR) today announced that it has commenced patient enrolment for its Phase IIb clinical trial for the CVac™ ovarian cancer therapy vaccine with the US Food and Drug Administration (FDA) with the first patient enrolled this week.

The study is being conducted with 60 patients across multiple global clinical sites, including key U.S. and Australian centers such as the Fred Hutchinson Cancer Center in Seattle and the Peter MacCallum Cancer Center in Melbourne. Prima estimates that recruitment will be completed by first quarter 2011.

The study design is a randomised and open label trial, comparing treatment with CVac™ to current best available supportive therapy.

The primary objectives of the study are to confirm the safety of CVac™ and compare disease progression- (PFS) between CVac™ and the control group. To assess PFS, clinical assessments will be performed every four weeks, and imaging with computed tomography (CT) or magnetic resonance imaging (MRI) will be performed every 12 weeks - until progression or withdrawal of the patient from trial. Initial safety data is expected by end of Q4 2011, after completion of the treatment phase. Initial PFS data is expected by end of Q4 2012, after all patients complete 2 years of observation.

With this current trial, Prima seeks to augment promising efficacy data generated by previous studies, including the phase IIa pilot study completed in 2007 on 28 patients.

Prima BioMed's Chief Medical Officer Dr Neil Frazer said: "CVac™ is an immunotherapy that utilizes the body's own immune system to fight cancer, with far fewer side effects than traditional oncology treatments. Unfortunately, even with advances in ovarian cancer therapy, a large percentage of women who are successfully treated initially will relapse. Currently, no therapy has demonstrated survival benefit for ovarian cancer patients in remission. We believe that CVac™ may offer significant therapeutic opportunity for women in remission, extending the time they remain cancer-free and improving their quality of life."

The global market for ovarian cancer therapeutics was valued at US\$2.1 billion in 2007, and is expected to be about US\$3.6 billion this year. Prima aims to develop CVac™ into the world's first commercially available ovarian cancer cell-based maintenance therapy.

Commenting on the commencement of patient recruitment, Prima BioMed Chief Executive Officer Martin Rogers said: "We are delighted to commence patient enrolment for our Phase IIb trial for CVac™. Setting a pharmaceutical grade manufactured product is one of goals in this study and to be able to assemble such a high calibre clinical group across multiple global sites represents a major step forward toward helping women who suffer from ovarian cancer and toward the commercialisation of CVac™.

Further details of the CVac™ phase IIb clinical trial are posted at clinicaltrials.gov and at www.primabiomed.com.au

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About CVac™ Ovarian Cancer Treatment

CVac™ is Prima BioMed's lead product. It is of key importance as there is a large unmet medical need for new treatments for ovarian cancer which has a very high morbidity rate. CVac™ is a maintenance therapy administered post-surgery and post-chemotherapy to delay relapse and control metastases.

There are currently no products available as maintenance based therapies for ovarian cancer and the global market for ovarian cancer therapeutics was valued at US\$2.1b in 2007 and is expected to total US\$3.6b this year.

Regulatory approval and commercialisation of CVac™ is the core focus for Prima.

About Prima BioMed

Prima BioMed is an ASX listed Australian health care company. The Company is focused on technologies in the fields of cancer immunotherapy and immunology. Prima's lead product is the CVac™ ovarian cancer therapy treatment. It has completed two successful clinical trials and is progressing toward eventual commercialisation in the United States, Australia, Europe, and globally.

The Company's broader, long term goal is to develop commercial cancer treatment technologies and programs for global markets.

Clinical Appendix

Study Title

A Randomized, Open-Label Phase IIb Trial of Maintenance Therapy with a MUC1 Dendritic Cell Vaccine (CVac™) for Epithelial Ovarian Cancer Patients in First or Second Remission

Study Design

This is a randomized, open-label, Phase IIb Trial to evaluate the safety and efficacy of CVac™ given as a single agent for epithelial ovarian cancer (EOC) patients who are in clinical complete remission (CR) following first or second-line chemotherapy.

A total of 60 subjects will be entered onto this study. The first six subjects who meet eligibility criteria will be treated with CVac™ in an open-label fashion to confirm the consistency of manufacturing of the vaccine and its safety when given to ovarian cancer subjects who are in first or second clinical CR. After the manufacturing characteristics of CVac™ are confirmed as consistent and the initial cohort has completed three injections of dendritic vaccine without treatment-related adverse events (AEs), enrollment into the randomized, controlled study will proceed.

An additional 54 subjects across six or more global clinical sites will be randomized to CVac™ or Standard of Care after having achieved a clinical CR (no clinical or radiologic evidence of disease following treatment for EOC, and cancer antigen 125 (CA-125), if previously elevated, has decreased by at least 50% and was maintained for a minimum of 28 days).

Clinical assessments will be performed every four weeks, and imaging with computed tomography (CT) or magnetic resonance imaging (MRI) will be performed every 12 weeks until progression or removal of the subject from study. Performance status and AEs will be assessed at each clinical assessment until disease progression.

Subjects are to be entered onto study within eight weeks after the last dose of chemotherapy which resulted in clinical complete remission. A total of 10 vaccine administrations will be given over 50 weeks. The vaccine will be administered intradermally in six to eight injection sites. Treatment with the vaccine will be discontinued if progression occurs prior to week 50.

Study Summary

The purpose of this study is to determine whether CVac™ is effective in the treatment of ovarian cancer patients who are in clinical complete remission following first or second-line chemotherapy.

Endpoints

PRIMARY OBJECTIVES:

- To confirm the safety of administering the CVac™ vaccine in this population.
- To determine the effects of the vaccine on progression-free survival (PFS).

SECONDARY OBJECTIVES:

- To determine overall survival (OS) for recurrent ovarian cancer patients who receive CVac™ after achieving remission in the first or second-line setting.
- Evaluation of host immunologic response to CVac™ administration.