

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

15 May 2014

# CVAC DEMONSTRATES IMPROVEMENT IN PROGRESSION FREE SURVIVAL IN SECOND REMISSION OVARIAN CANCER

- Final PFS data from CAN-003 trial of CVac indicate stronger trends toward improvement in second remission ovarian cancer patients than previous top-line data
- Validates objectives of recently launched 210-patient, phase 2, CAN-004-B trial
- Dr. Heidi Gray to deliver oral presentation (Abstract #5504) at ASCO Annual Meeting

SYDNEY, AUSTRALIA - Prima BioMed Ltd (ASX: PRR; NASDAQ: PBMD) ("Prima") is pleased to announce that CVac demonstrated a clinically meaningful improvement in progression-free survival ("PFS") over standard of care in second remission ovarian cancer patients in the CAN-003 protocol. Final PFS analysis from CAN-003 indicates even stronger trends toward improved clinical outcomes for CVac treated patients than top-line data announced in September 2013 had suggested. The strong efficacy signal supports further investigation in Prima's CAN-004-B phase 2 trial of 210 ovarian cancer patients with relapsed platinum-sensitive disease who enter second remission. The U.S. Food and Drug Administration recently granted Fast Track designation for CVac in this indication.

In second remission patients (n=20) from CAN-003, median PFS for CVac was estimated to be greater than 12.91 months, compared to median PFS of 4.94 months for the control group (hazard ratio=0.32; p=0.04). Consistent with conclusions drawn from the previous top-line data analysis, PFS was not improved for CVac patients in first remission (hazard ratio=1.18; p=0.69).

Matthew Lehman, Prima's CEO said: "The CAN-003 PFS data strongly supports our continued development of CVac in second remission ovarian cancer patients and validates the goals of our 210-patient, phase 2, CAN-004-B trial for which we recently commenced enrolment. We are thrilled to be developing a cutting edge immunotherapy that has the potential to significantly help patients with ovarian cancer."

As previously announced, the final CAN-003 PFS data has been accepted for oral presentation by Dr. Heidi Gray, the trial's lead investigator, at the American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago on 31 May 2014 at 2:27pm local time. ASCO Abstract #5504 entitled "Progression-free survival in ovarian cancer patients in second remission is improved with mucin 1-autologous dendritic cell therapy" is now publically available at http://abstracts.asco.org/.

<sup>&</sup>lt;sup>1</sup> Hazard ratios were estimated using a Cox proportional hazards model. P-values were calculated using the logrank test (2-sided).

Overall survival (OS) data is not yet mature enough for analysis. Dr. Gray will, however, provide an update on the status of overall survival data during her oral presentation at ASCO. It is projected that OS data will mature for statistical analysis in approximately the fourth quarter of 2014.

After the oral presentation at the ASCO meeting, Dr. Heidi Gray and Dr. Brad Monk, chair of Prima's clinical advisory board, will hold a teleconference to discuss the presentation and take questions from the public. The timing of this teleconference will be advised.

#### About the CAN-003 clinical trial

CAN-003 is a 63-patient phase 2 study evaluating the effects of CVac, as compared to an observational standard of care arm (OSC), in epithelial ovarian cancer patients in complete remission after first or second line treatment. In accordance with the protocol design, the first seven patients on the trial were all assigned to receive CVac in order to test the comparability of product manufacturing in a new facility.

The subsequent 56 patients were randomized 1:1 to either the CVac group or observational standard of care (OSC) and included in the intent-to-treat analysis. 36 patients were in first remission (19 patients were assigned to CVac and 17 to OSC) and 20 patients were in second remission (10 patients were each assigned to CVac or OSC). Final PFS data was analysed after thorough quality control reviews of investigator-evaluated progression and appropriate censoring of data from patients who had not progressed during the study.

The primary objectives of the trial are to determine the safety of CVac administration and to determine CVac's effect on progression-free survival. Secondary objectives of the trial are to determine CVac's effect of overall survival and to evaluate host immunologic responses to CVac.

#### **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

## For further information please contact:

#### **USA Investor/Media:**

Adam Holdsworth, ProActive Capital +1 (646) 862 4607; adamh@proactivecapital.com

### Australia Investor/Media:

Mr Matthew Gregorowski, Citadel Communications

+61 (0) 422 534 755; mgregorowski@citadelpr.com.au

# **Europe Investor/Media:**

Mr. Axel Mühlhaus, edicto GmbH +49 (0) 69 905505-52; amuehlhaus@edicto.de