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Manufacturing Authorisation according §13 AMG for CVac™ Granted in Germany

Australian health care company Prima BioMed Ltd (ASX: PRR) (Prima) is pleased to announce that Prima's manufacturing partner for Europe, the Fraunhofer Institute for Cell Therapy and Immunology IZI, has received manufacturing authorization according §13 German Drug Act (AMG) to produce CVac™. This authorization is a key component of Prima's regulatory application to commence the planned CANVAS trial in Europe.

The authorization was provided after a successful Good Manufacturing Practices (GMP) inspection by Landesdirektion Leipzig, in consultation with the Paul-Ehrlich-Institut. The authorisation covers the complete CVac™ manufacturing for testing in clinical trials.

GMP inspection and subsequent manufacturing authorization is a prerequisite to production of any medicinal product intended for human administration in Europe. The process is governed by European Directives and the German Drug Act (AMG). The process includes checking whether all the stages of manufacture and quality controls are carried out in accordance with the basic principles of GMP. Such inspections assure that the facilities, equipment, personnel involved in production as well the process validation are suitable. Manufacturing authorization is only provided once a regulator is assured that manufacture and testing is carried out according to the latest standards prevailing in science and technology.

The Company placed a major emphasis on manufacturing quality in its Manufacturing Authorisation process.

Prima BioMed CEO Martin Rogers said: "We are delighted with the success of the GMP inspection, and the general quality of the development of our CVac™ product. We now look forward to applying for regulatory approval to conduct our CANVAS clinical trial in Europe and commence patient recruitment."

The head of the Department of Cell Engineering at the Fraunhofer IZI, Dr. Gerno Schmiedeknecht said: "We are pleased that our efforts to guarantee the highest quality of CVac™ production were confirmed by the authorities. This is a significant step for Prima BioMed's activities in Europe. We look forward to supporting the upcoming major clinical trial for CVac™."

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About CVac™ Ovarian Cancer Treatment

CVac™ is Prima BioMed's core product. It is a vaccine therapy treatment for ovarian cancer sufferers that is administered post-surgery and post-chemotherapy to delay the relapse and control the metastases of the cancer. There is a large un-met medical need for new treatments for ovarian cancer which has a very high morbidity rate, and there are currently no maintenance-based therapy products commercially available.

The Company has recently completed its Phase IIb trial for CVac™ with the US FDA and plans to commence CANVAS(**CAN**cer **VA**ccine **S**tudy) a multinational, multi-centre, randomised, double-blinded, placebo-controlled trial of CVac™ in Europe and the US this year. The Phase IIb and CANVAS trials aim to further confirm the ability of CVac™ to reduce the instance of relapse in ovarian cancer patients, control the metastases of the cancer and increase the life expectancy of patients.

Prima's ultimate goal is to commercialise CVac™ into the multi-billion dollar global pharmacy oncology market. The global market for ovarian cancer therapeutics was valued at US\$2.1b in 2007 and was estimated to have grown to US\$3.6b¹.

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 CVac™ ovarian cancer therapy treatment. It has completed two successful clinical trials and is progressing toward eventual commercialization 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.

About Fraunhofer Institute for Cell Therapy and Immunology

The Fraunhofer Institute for Cell Therapy and Immunology IZI is located in Leipzig, Germany. Its objective being to find solutions to specific problems at the interfaces between medicine, life sciences and engineering for partners active in medicine-related industries and businesses. The Institute's core competencies are to be found in regenerative medicine, or more precisely in cell-therapeutic methods of regenerating non-functioning tissue and organs through to the biological substitution with tissue cultivated *in vitro* (tissue engineering). The Institute works especially closely with hospital institutions, performing quality tests and clinical studies on their behalf. Additionally it also provides assistance in obtaining manufacturing licenses and certifications.

¹ Thomson Business Intelligence, *Ovarian Cancer Therapeutics Industry Analysis 2007*