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Gap Analysis Report Received for preIND meeting with US FDA

Path to preIND meeting with US FDA for ovarian cancer treatment on track

Executive Summary

- Lead product **CVac™**, a treatment for ovarian cancer, Gap Analysis Report Received; an important step in securing a preIND meeting with the US Food and Drug Administration
- **CVac™** has potential to fill void in large un-met medical need for new treatments for ovarian cancer which has a very high morbidity rate
- Global market for ovarian cancer therapeutics was US\$2.1bn in 2007 and is expected to grow to US\$3.6bn by 2010
- US FDA grants Special Protocol Assessment for Phase III for Dendreon, A US company developing similar technology for prostate cancer
- Significant US Patent granted for Prima subsidiary, antibody development company, Oncomab
- Leading cancer/oncology and immunology expert Professor Ian Frazer engaged as a scientific advisor to the Company

Australian cancer treatment development company Prima Biomed ("Prima", "the Company") (ASX: PRR) is pleased to provide the following update on advances in its cancer treatment technologies and programs.

Gap Analysis Report of CVac™ Received

CVac™ is a treatment for ovarian cancer and is Prima's lead product, The Company has received the requisite Gap Analysis of **CVac™**, which is an important step toward securing a preIND meeting with the US Food and Drug Administration Investigational New Drug Application (FDA IND).

Prima views **CVac™** as being of key importance as there is a large un-met medical need for new treatments for ovarian cancer which has a very high morbidity rate. The insidious nature of

the disease generally results in late diagnosis of the disease, and of the 70% of patients diagnosed with stage III or IV disease the five year survival rate is only 10-20%.

The **CVac™** product is being developed as a maintenance therapy that is most likely to be 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 **CVac™** has the competitive advantage of its product features, the therapeutic approach and the high barriers to entry generated by intellectual property and licensing agreements.

The global market for ovarian cancer therapeutics has shown consistent growth and in 2007 was valued at US\$2.1 billion and this is expected to total US\$3.6 billion by 2010. Regulatory approval over the next 6-9 months of **CVac™** is of considerable importance and the core focus for Prima.

The Gap Analysis was undertaken by the global drug development company, PharmaNet Inc ("Pharmanet").

Pharmanet provided Prima with experienced scientists, senior management and its successful approach to enabling relationships with the appropriate US regulators. The Pharmanet Oncology team has experience in all stages of development up to and including the registration process, as well as expertise in therapeutic modes including chemotherapy, radiotherapy, biologics, and medical devices.

CVac™ is also potentially useful in the treatment of several other solid tumours including lung, breast, colon, renal and prostate cancer, as it targets a tumour protein, mucin-1, which all these tumours express at relatively high levels.

Plan for submission to US FDA for a pre-IND meeting is being formulated with Pharmanet.

US FDA and Dendreon - Large step forward for Dendreon and for Prima

Last week US company Dendreon received was granted Special Protocol Assessment by the US FDA for its prostate cancer treatment Dendreon is a US company listed on the NASDAQ with a market capitalization in excess of \$500M, which specialises in the discovery, development and commercialisation of therapeutic treatments to fight cancer.

Dendreon uses a technology similar to Prima, but for applications with prostate cancer not ovarian cancer, and as such Prima views the Dendreon US FDA approval as a significant step forward for its own ovarian cancer treatment.

The Special Protocol Assessment granted by the US FDA for Dendreon accelerates the timing of the final results and a pathway to commercialisation for the treatment of prostate cancer patients.

US Patent granted for Oncomab

In January, a very significant and attractive patent was granted for Prima's subsidiary, Oncomab Pty Ltd ("Oncomab"). Oncomab is an antibody development company and The United States Patent and Trademark Office granted and issued US Patent Number 7,318,924 to Oncomab.

The patent describes the use of therapeutic antibodies that target the tumour antigen, cripto-1, in the treatment of cancer. The patent specifically claims:

A method of treating cancer in a patient whose cancer cells over-express Cripto-1 by administering a therapeutically effective amount of a monoclonal antibody that binds a Cripto-1 and inhibits growth or spread of the cancer cells either by:

- a) Inducing apoptosis as a result of the binding of the antibody to the Cripto-1 on cancer cells; or*
- b) Inducing cell death by delivery to cancer cells of a cytotoxic compound conjugated to the monoclonal antibody*

The patent also claims chimeric and human antibodies as well as antibody fragments. A Patent Term Adjustment has also been issued, extending the patent term by an additional 467 days from 26 March 2022, thus providing patent protection through until 6 July 2023.

Prima is in confidential discussions with a number of international pharmaceutical and biotechnology companies regarding the sale or sublicensing of Oncomab.

Professor Ian Frazer advising Prima Biomed

Prima is also pleased to announce that it has engaged leading cancer/oncology and immunology expert Professor Ian Frazer as a scientific advisor to the Company.

Prof. Frazer has a wealth of experience in cancer/oncology and immunology. He is best known for his work on the development of the world's first cervical cancer vaccine, which works by protecting women from Human papillomavirus.

The US FDA approved cervical cancer vaccine (**Gardasil™**) in 2006 and it is now currently available worldwide, manufactured by Merck & Co and distributed in Australia by CSL Ltd. Prof. Frazer has undertaken a body of work to transform the treatment of cancer to benefit patients and transform lives. Prof Ian Frazer is the president of the Cancer Council, was named Australian of the Year 2006 and recipient of the Florey Medal named in honour of Australian Nobel laureate Howard Florey.

Prima welcomes the experienced guidance and strength of advice that Prof. Frazer will provide.

Corporate Development

Prima will update the market as further information becomes available, and it is the consistent commitment of the board and management to take every opportunity to generate and maximize wealth for the company and its investors.

The company intends principally to do this via the pursuit of a US FDA IND for **CVac™** and successful partnering of the future clinical trials.

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About Prima Biomed Ltd

Prima Biomed (ASX: PRR) is a biotechnology company based in Sydney, Australia. The Company is focused on technologies in the fields of immunology and cancer immunotherapy. Prima is focused on developing a dendritic-cell based immunotherapy targeting mucin-1 tumour expressed antigen. Prima's lead product, CVac™ has completed Phase IIa clinical development in Ovarian Cancer and is working to a path of US FDA IND approval.

For further information, visit www.primabiomed.com.au

This release may contain forward-looking statements. Various factors could cause actual results to differ materially from those projected in forward-looking statements, including those predicting the timing and results of clinical trials, interpretation and implications of such results, availability or adequacy of financing, the sales and marketing of commercial products or the efficacy of products. Although the Company believes that the forward - looking statements contained herein are reasonable, it can give no assurance that the Company's expectations are correct. All forward - looking statements are expressly qualified in their entirety by this cautionary statement.

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