

ASX/Media Release
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PRIMA BIOMED SUBMITS CVAC™ IND APPLICATION WITH US FDA

- **Investigational New Drug (IND) application major commercialisation milestone for CVac™**

Australian health care company Prima BioMed (Prima) (ASX: PRR) is pleased to announce that it has submitted its Investigational New Drug (IND) application with the US Food and Drug Administration (FDA) to evaluate the Company's core product, the **CVac™** ovarian cancer therapy vaccine.

The submission of the IND with US FDA is one of the major milestones to be achieved in the commercialisation process for **CVac™**, and represents one of the critical requirements of the product's development cycle. The granting of Investigational New Drug status is a pre-requisite for all new drug human clinical trial required for FDA approval for commercialisation.

The filing of the IND represents the culmination of years of scientific and pre-clinical validation of the technology and commitment from Prima and its world class medical advisory team. The IND submission is being managed by former US FDA Deputy Director of Cell and Gene Therapy Dr. Joyce Frey-Vasconcells, currently Executive Director, PharmaNet Consulting, and the Company looks forward to delivering the outcomes of the IND to the market as soon they become available.

Prima BioMed Chairman said: "The submission of our IND application for **CVac™** with the US FDA is a major step forward in the development timeline for this product and strengthens the potential for the **CVac™** cancer vaccine immunotherapy to provide a positive solution for ovarian cancer sufferers."

"We look forward to working closely with the FDA to continue to advance the development of what we hope will be the first commercially available active cancer vaccine immunotherapy product for women with ovarian cancer in the world," Mr Gokyildirim said.

The Company continues to make rapid progress towards commercialising **CVac™** into the global multi-billion oncology pharmacy market. **CVac™** is an ovarian cancer therapy vaccine treatment which is administered post-surgery and post-chemotherapy to delay relapse and control metastases. There is a large un-met medical need for new treatments for ovarian cancer which has a very high morbidity rate, and at present there are no maintenance-based therapy products commercially available.

Prima is making excellent progress in preparation for **CVac™**'s US FDA Phase IIb/III Pivotal Trial, which the Company plans to commence in the near future. The protocol design for the selection of patients to participate in the Trial has been undertaken and completed, by world leading Gynaecological Oncologist Dr Heidi Gray at the prestigious Fred Hutchinson Cancer Centre in Seattle in the USA. The Centre will also host the US section of the Pivotal Trial.

ENDS

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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 vaccine therapy treatment. It has completed two successful clinical trials and is in the final stages of US FDA approval and eventual commercialisation.

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