ventracor

asx announcement

Regulatory and Marketing Progress Update

FDA Changes to Accelerate Patient Recruitment

Key points

- US feasibility study patient recruitment to accelerate
- CE Mark approval still anticipated in 1st quarter of 2007
- VentrAssist to be launched in Europe in September
- Clinical performance of VentrAssist exceeds expectations.

SYDNEY, Australia 3 July 2006: Ventracor Limited (ASX:VCR) incoming Chief Executive Officer Peter Crosby today said Ventracor had received approval from the US Food & Drug Administration (FDA) to immediately change the protocol for its US feasibility study to help complete recruitment.

Six people have been implanted in the 10-patient study to date. The new changes will now allow patients to be discharged to a non-acute care setting under the hospital's control, whereas previously the FDA had required all patients to stay in hospital until heart transplantation.

"The FDA's approval of discharge to a non-acute care setting makes participation in Ventracor's trial more attractive to potential patients and should be a catalyst for recruitment," Mr Crosby said.

He added clinical data from patients in Europe and Australia support the safety of sending patients home with the VentrAssist. The Company is continuing to pursue FDA approval to allow patients to be discharged home.

He said a new application had been submitted to the FDA last Friday (30 June) using this data to request patients to be discharged home after a suitable time in the intermediate care facility.

"It is important to note there have been 60 VentrAssist LVADs implanted, which is more than all other third generation centrifugal pumps from all competitor companies combined.

"This is an outstanding achievement and reflects the success of the strategic approach we have taken to our global clinical trial program," Mr Crosby said.

CE Mark approval on track

"A preliminary analysis of the CE Mark Trial data shows the clinical performance of the VentrAssist exceeds our expectations and strengthens our competitive position," Mr Crosby said.

"By mid July, the trial for European approval will be completed, and we will be able to finalise the clinical data submission as part of a three-step process."

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The submission process for CE Mark involved submission of a design dossier which was submitted end of May, a Quality System Audit scheduled for the end of July and results of the Clinical Trials.

He confirmed the company still expects to achieve CE Mark approval and first commercial sales in Europe by the first quarter of 2007.

VentrAssist Market Launch in September

"In anticipation of the CE Mark Approval, we are launching the VentrAssist in Europe at the European Association of Cardiothoracic Surgery (EACTS) meeting in September," Mr Crosby said.

"Scientific papers reporting the clinical performance of the VentrAssist will be presented at the EACTS meeting and also at the meeting of the Heart Failure Society of America (HFSA) in Seattle in September this year.

"We have a great product, world class manufacturing capability, distribution in key markets and strong collaborative teams in place in Europe, the US and Australia.

We intend to secure a major leadership position in the global LVAD market," Mr Crosby said.

About Ventracor
Ventracor is a global medical device company which has developed a blood pump, the VentrAssist left ventricular assist device (LVAD) for patients in heart failure. Ventracor plans to bring the VentrAssist to the global market.

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