ventracor

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23 December 2004

Securities and Exchange Commission
Division of Corporate Finance
Office of International Corporation Finance
450 Fifth Street, NW
WASHINGTON DC 20549
USA

Dear Ladies and Gentleman

Re: Ventracor Limited
File # 82-4630

Ventracor Limited (the "Company") is furnishing herewith information pursuant to Rule 12g3-2(b)(1)(i) of the Securities Exchange Act of 1934, as amended (the "Exchange Act").

The attached documents are being furnished with the understanding that they will not be deemed "filed" with the Securities and Exchange Commission or otherwise subject to the liabilities of Section 18 of the Exchange Act, and that neither this letter nor the furnishing of such documents shall constitute an admission for any purpose that the Company is subject to the Exchange Act.

If you have any questions or comments please call the undersigned at (61) 02 9406 3100.

Very truly yours

per K Callaghan

Andrew Geddes
Corporate Communications

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ventracor

asx announcement

Application to Begin US Clinical Trials of Ventracor's 'Artificial Heart'

Sydney, 23 December 2004: Ventracor Limited (VCR:ASX) today shipped its investigational device exemption (IDE) application for lodgement with the US Food and Drug Administration (FDA) requesting permission to start a bridge-to-transplant trial in the USA in 2005.

Ventracor Limited Chief Executive Officer, Colin Sutton PhD, said: "Ventracor has submitted its IDE submission on schedule and delivered on its promise to meet this important milestone in the international commercialisation of the VentrAssist™.

"Submission of our IDE application is a major achievement involving thousands of hours of work by our engineering, regulatory, quality and clinical staff.

"The submission totalled 10,476 bound pages of reports, clinical data and validation work.

"This achievement moves us another significant step closer to sales of our Australian-developed heart assist technology in North America.

"The US market is crucial to our business model of realising our vision of becoming the world's pre-eminent supplier of cardiac assist systems for people suffering end-stage heart failure.

"Following approval, Ventracor expects to start enrolling patients in its US bridge-to-transplant (BTT) human clinical trial by the middle of 2005," Dr Sutton said.

The US bridge-to-transplant trial will be conducted at leading hospitals across the USA by the Columbia University Medical Center's International Center for Health Outcomes and Innovation Research (InCHOIR) in New York.

"The start of our clinical trial next year in the USA will be a defining moment for the company and the submission of our IDE marks a major step towards this realisation.

"Throughout this important process, our primary goal will be to ensure the market is kept progressively informed on a timely basis " Dr Sutton said.

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Outline of steps to market for active implantable medical devices in the USA

- Implantable medical devices require a Pre-Market Approval (PMA) by the US Food and Drug Administration (FDA) prior to marketing within the USA.
- To obtain all relevant clinical data to support a PMA application, an investigational device exemption (IDE) is required from the FDA.
- An IDE allows an unapproved device to be implanted under controlled conditions for the purpose of gathering safety and effectiveness data.
- Ventracor's US clinical trial program will be run by the Columbia University Medical Center International Center for Health Outcomes and Innovation Research (InCHOIR) in New York.
- Once clinical data has been gathered establishing the safety and effectiveness of the VentrAssist™, Ventracor will submit a PMA for approval to sell the device as a bridge-to-transplant.
- The PMA process involves a review of device-related information, including clinical trial data and auditing of quality systems for compliance of the design process and manufacturing within the provisions of Code 21 of the US Code of Federal Regulations, Part 820 – *Good Manufacturing Practice (GMP) for Medical Devices.*
- The company will require a separate IDE and clinical trial to establish the use of the VentrAssist™ LVAS as an alternative to heart transplant.

About Ventracor

Ventracor (ASX:VCR) is an international medical technology company that has developed a life-saving heart pump, the VentrAssist™ left ventricular assist system (LVAS), for patients in cardiac failure. The company is focused on commercialising the VentrAssist™ and bringing it to global markets in record time. Ventracor is confident of obtaining a significant share of the massive LVAS market, which independent analysts expect to be valued at between $US7.5 billion and $US12 billion per year.

For further information, please contact:

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