ventracor asx announcement

Major Milestone – 78.6% Success in BTT Trial

- Results from the US Bridge To Transplant (BTT) Clinical Trial shows success rate of 78.6% after 98 outcomes.
- 2nd Module of PMA Submission filed (over 8000 pages)
- Cumulative worldwide implants now 412
- First Half 2009 Revenue $12.8M

Sydney AUSTRALIA 29 January 2009: Ventracor Limited (ASX:VCR) reported today that the performance of the VentrAssist® Left Ventricular Assist Device (LVAD) in the US Bridge To Transplant (BTT) Trial showed a success rate of 78.6%. At the time of the interim analysis, the pre-specified performance goal is 75.5%, according to the strict criteria of the trial design. Ventracor's clinical trial partner, InCHOIR at Mt. Sinai School of Medicine in New York, is preparing the formal interim analysis for review by the DSMB. Enrolment in the BTT Trial is now almost complete with 138 patients enrolled of the 140 required.

The cardiology Principal Investigator of the BTT Trial, Dr. Andrew Boyle from the University of Minnesota in Minneapolis, said: "The enrolment rate in the VentrAssist Bridge to Transplant clinical trial has been brisk, which is a reflection of the favourable impression the community has towards the first centrifugal flow pump to reach clinical trials in the US." The surgeon Principal Investigator, Dr. Nader Moazami of Barnes Jewish Hospital at St. Louis University in St. Louis, Missouri, said: "It is very exciting to be part of the first trial of a 3rd generation LVAD in the U.S. This is yet another significant advance in mechanical circulatory support and expands the options available for treating patients with advanced heart failure."

There have been 57 patients enrolled in the EVERLAST Destination Therapy (DT) Trial. The recent change in the DT clinical trial of the Heartmate II Continued Access Protocol (CAP) has made it challenging to randomize patients to the first generation Heartmate XVE. The Company is working with the US FDA to modify the EVERLAST Protocol to no longer require randomization to the Heartmate XVE, which if approved is expected to encourage enrolment in the EVERLAST DT Trial.

In other news, the Company reported that the second module of the Pre-Market Approval Application has been filed with the US FDA. The Manufacturing Module is over 8000 pages of detailed technical explanations of the manufacturing processes used to make the VentrAssist LVAD.

The Company reported preliminary sales of $12.8M for the first half of FY2009.

The 400th patient was the first implant performed at the Freeman Hospital at Newcastle upon Tyne in the UK in early January. The VentrAssist LVAD has now been implanted in 412 patients in 45 hospitals in 10 countries worldwide, out of 57 hospitals trained. There are now 246 cumulative years of patient experience, and the longest duration implant is now 4.3 years. There is more clinical experience with the VentrAssist LVAD than with all other implantable third generation centrifugal pumps, combined.

About Ventracor

Ventracor is a global medical device company which produces an implantable blood pump, the VentrAssist® left ventricular assist device (LVAD), as therapy to improve the lives of heart failure patients and their families. Ventracor is dedicated to building partnerships with healthcare professionals to make the VentrAssist LVAD the standard-of-care worldwide.

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