ABSTRACTS

1 HeartWare HVAD for the Treatment of Patients With Advanced Heart Failure Ineligible for Cardiac Transplantation: Results of the ENDURANCE Destination Therapy Trial

Purpose: Mechanically assisted circulation with the HeartMate II (HMII, Thoratec®) axial flow left ventricular assist device (LVAD) has been established as a viable option for the treatment of advanced heart failure in patients ineligible for heart transplantation. The HeartWare® centrifugal flow ventricular assist device system (HVAD) is currently approved for bridge to transplant in the US. The purpose of this study, which was sponsored by HeartWare®, was to compare the safety and effectiveness of the HVAD to HMII in patients with advanced heart failure ineligible for heart transplantation.

Methods: ENDURANCE was a prospective, multicenter evaluation of 450 patients with NYHA Class IIIB-IV symptoms randomized 2:1 to HVAD or HMII. Patients were adults with an ejection fraction ≤25% despite treatment with optimal medical therapy for ≥45 days or treatment with intravenous inotropes for ≥14 days or an intra-aortic balloon pump for ≥7 days. Exclusion criteria included significant end-organ dysfunction, recent myocardial infarction or stroke, coagulopathy, or an anticipated need for a right ventricular assist device. The primary endpoint was stroke free survival at two years defined as alive on the originally implanted device, transplanted or explanted for recovery without a disabling stroke (modified Rankin score >4). Treatment failure was defined as subject death, stroke with a residual modified Rankin score >4, or device malfunction or failure requiring exchange, explantation, or urgent transplantation within the first two years of support. ENDURANCE was designed and powered to demonstrate non-inferiority of the HVAD.

Results: Protocol-driven 24 month follow-up has recently been completed in 450 patients and the data is currently being locked and analyzed. Primary modified Rankin score >4. Treatment failure was defined as subject death, stroke with a residual modified Rankin score >4, or device malfunction or failure requiring exchange, explantation, or urgent transplantation within the first two years of support. ENDURANCE was designed and powered to demonstrate non-inferiority of the HVAD.

Conclusion: This large, randomized clinical trial of the HVAD as mechanical circulatory support for patients ineligible for heart transplantation represents the initial clinical experience supporting this patient population.

2 Long Term Support of Patients Receiving an LVAD for Advanced Heart Failure: A Subgroup Analysis of the Registry to Evaluate the HeartWare® Left Ventricular Assist System (The REVOLVE Registry)

Purpose: The REVOLVE Registry is an investigator-initiated registry established to collect post CE Mark clinical data on patients receiving the HeartWare® HVAD System in the European Union and Australia.

Methods: REVOLVE is a multi-center, prospective, single arm registry. Each patient is followed to device explant, transplantation or death. Data was collected on 254 commercial implants between February 2009 and March 2012 from nine centers in Europe (7) and Australia (2). We are now evaluating those patients who remained on support in order to summarize long term support and outcomes in this population. Summary statistics will be used to describe patient demographics, adverse events, length of support and outcomes.

Results: At the time of the initial analysis completed in November 2012, a total of 37 patients were on support for at least 2 years (range 730-1057 days), 26 of who were still alive on support. Another 126 patients who were supported for less than 2 years were still alive on support and could have potentially exceeded 2 years of support during this continued post hoc analysis period. Overall success at two years was 73%, while only 22% of patients were transplanted in the initial study period of February 2009 and November 2012 (see Figure).

Conclusion: Real world use of the HVAD Pump continues to support the excellent outcomes on the device, and due to the low rate of transplantation, successful long term support is observed in a significant cohort of patients receiving the device. Final data on the total patients who remained on support beyond 2 years will be available at the time of presentation.

3 A Multi-Institutional Outcome Analysis of Patients Undergoing Left Ventricular Assist Device Implantation Stratified By Sex and Race

Purpose: The REVOLVE Registry is an investigator-initiated registry established to collect post CE Mark clinical data on patients receiving the HeartWare® HVAD System in the European Union and Australia.

Methods: REVOLVE is a multi-center, prospective, single arm registry. Each patient is followed to device explant, transplantation or death. Data was collected on 254 commercial implants between February 2009 and March 2012 from nine centers in Europe (7) and Australia (2). We are now evaluating those patients who remained on support in order to summarize long term support and outcomes in this population. Summary statistics will be used to describe patient demographics, adverse events, length of support and outcomes.

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Conclusion: Real world use of the HVAD Pump continues to support the excellent outcomes on the device, and due to the low rate of transplantation, successful long term support is observed in a significant cohort of patients receiving the device. Final data on the total patients who remained on support beyond 2 years will be available at the time of presentation.

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