International Society for Heart & Lung Transplantation
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Multicenter ENDURANCE Trial of Patients with Advanced Heart Failure Presented at ISHLT Meeting

NICE, FR (April, 16, 2015) – Yesterday, results of the ENDURANCE destination therapy clinical trail were presented at the 35th Annual International Society for Heart and Lung Transplantation Meeting and Scientific Sessions, by Francis D. Pagani, M.D., Ph.D., University of Michigan, a co-principal investigator for ENDURANCE. Results showed no significant difference in overall patient survival, confirming non-inferiority was established for the HeartWare® assist device compared with the control device for destination therapy in patients with end-stage heart failure.

ENDURANCE is the largest trial to date for the long-term use of a left ventricular assist device (LVAD). The purpose of the study was to assess the effectiveness and safety of the HeartWare® centrifugal flow ventricular assist device system (HVAD) against any other LVAD approved for use by the U.S. FDA for destination therapy. Results showed no significant difference between HVAD and the control with regard to the primary endpoint of stroke-free survival at two years.

Dr. Pagani reported that 55.0% of the investigational device patients attained the primary endpoint of the trial, which is stroke-free survival (Modified Rankin Score ≥4) at two years, defined as alive on the originally-implanted device, transplanted or explanted due to patient recovery. In comparison, 57.4% of patients in the control arm achieved the primary endpoint of the study. Based on these results for the primary endpoint of the ENDURANCE study, non-inferiority of the investigational device was established (p=0.0060).

"This trial is very important, as it shows that patients on MCS destination therapy have an excellent long-term survival and that the H-VAD system can be used in a similar way as the VAD in the control group," said Andreas Zuckermann, MD, ISHLT 2015 Scientific Program Committee Chair.

ENDURANCE, a multicenter study with nearly 450 patients at 48 U.S. hospitals began in 2010. Patients selected for the study had end-stage heart failure, did not respond to standard medical management and were ineligible for cardiac transplantation. Primary endpoint data was presented during Thursday's Opening Plenary Session at the ISHLT meeting in Nice, France.

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The International Society for Heart and Lung Transplantation (ISHLT) is a not-for-profit professional organization with more than 2,700 members from over 45 countries dedicated to improving the care of patients with advanced heart or lung disease through transplantation, mechanical support and innovative therapies via research, education and advocacy. For more information, visit www.ishlt.org.

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