Berlin Heart’s EXCOR® Pediatric Ventricular Assist Device (VAD) Receives FDA Approval

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THE WOODLANDS, Tex., and BERLIN, 19 December, 2011—The Berlin Heart Group announced today that the FDA has granted “Humanitarian Device Exemption” (HDE) approval of the Berlin Heart EXCOR® Pediatric Ventricular Assist Device (VAD).

The Berlin Heart EXCOR® Pediatric VAD is a mechanical cardiac support system for critically ill pediatric patients suffering from severe heart failure. The system is designed to support pediatric patients of all age groups, from newborns to teenagers, and is intended to bridge patients awaiting heart transplantation from days up to several months, until a donor heart becomes available. The Berlin Heart EXCOR® Pediatric VAD, which has previously been approved for use in Europe and Canada, is now the only Ventricular Assist Device that is designed specifically for the pediatric population to be approved in the United States.

The National Principal Investigator for the Berlin Heart EXCOR® Pediatric VAD study, Charles D. Fraser, Jr., M.D., Surgeon-In-Chief and Head of the Division of Congenital Heart Surgery at Texas Children’s Hospital and Professor of Surgery and Pediatrics, Baylor College of Medicine in Houston, Texas, said, “On behalf of the many investigators, coordinators, and administrative personnel involved in the study, I am extremely gratified by the news that the Excor Pediatric VAD has achieved an HDE approval by the FDA. This is a landmark event for children suffering from terminal heart failure. The medical community is now able to offer this lifesaving device to support desperate children who would not otherwise survive while awaiting a heart transplant. This ushers in a new era for children with heart disease. The study involved an incredible effort from 15 centers across North America with extensive experience in pediatric heart failure and transplantation and should serve as a model for future collaborative device investigations involving children, industry, medicine, and the FDA.”

Stefan Thamassett, Chairman of the Board of Berlin Heart, said “This milestone marks the closure of a long process, and we are very happy that we were able to reach this for the Berlin Heart Group. Our special thanks goes to all of the participating clinics and their doctors as well as our countless patients and their relatives; and of course we would like to thank our employees, because without their tireless commitment we would not have been able to reach this goal. We are looking forward to a new and exciting chapter in the history of Berlin Heart.”

Bob Kroslowitz, President and CEO of Berlin Heart’s North American operations, added: “Being granted HDE approval is an outstanding achievement for the whole Berlin Heart team. The FDA worked effectively with Berlin Heart to refine the design of the clinical trial with the potential for a meaningful study with useful conclusions. With the approval, we are now able to more readily offer this important lifesaving technology to this most important patient population. We are grateful and need to especially thank our study sites, our investigators and most importantly, the families of the children that participated in the study. Additionally, without the support of my colleagues in Berlin and the Berlin Heart team in the US, especially Mary Beth Kepler, Vice President of Regulatory Affairs, the approval could have never been achieved.”
The EXCOR® Pediatric VAD clinical study, which enrolled the first patient in November 2007, is the first prospective clinical trial ever conducted to investigate the safety and benefit of a Ventricular Assist Device in the pediatric population. Full enrolment of the trial took approximately 33 months. The following US centers participated in the IDE study: Arkansas Children’s Hospital (AR), Boston Children’s Hospital (MA), Children’s Healthcare of Atlanta (GA), Children’s Hospital of Wisconsin (WI), The Children’s Hospital of Denver (CO), Lucille Packard Children’s Hospital at Stanford (CA), Mott Children’s Hospital (MI), Mount Sinai Hospital (NY), Pittsburgh Children’s Hospital (PA), Riley Children’s Hospital (IN), Seattle Children’s Hospital (WA), St. Louis Children’s Hospital (MO), Texas Children’s Hospital (TX), Children’s Hospital at the University of Alabama at Birmingham (AL), and the University of Minnesota at Fairview (MN).

About Berlin Heart
Berlin Heart GmbH is the only company worldwide that develops, produces, and distributes implantable and external ventricular assist devices (VADs) for patients of every age and body size. The company offers pumps, cannulas, and external components for internal and external use to stabilize cardiac activity in acutely ill patients. Its products are market leaders in their respective segments in Germany and in Europe. The company also manufactures the implantable left ventricular assist device INCOR®, which has been designed for long-term application in adult patients. The longest the device has supported a patient to date is more than five years and ongoing. INCOR is not FDA-approved, but widely used in Europe. Berlin Heart Inc., the company’s US subsidiary, was founded in 2005 to support the North American centers. Further product information is available from the company website: [www.berlinheart.com](http://www.berlinheart.com).

Contact:

**Berlin Heart GmbH**
Kerstin Unkel  
Marketing & PR  
Wiesenweg 10  
12247 Berlin  
unkel@berlinheart.de

**Berlin Heart Inc.**
Robert Kroslowitz  
200 Valleywood  
Suite A500  
The Woodlands, TX 77380  
kroslowitz@berlinheart.com