



Colibri Heart Valve Announces Clinical Update in the Company's Feasibility Study of the First Ready-to-Use Transcatheter Heart Valve System

BROOMFIELD, CO – February 3, 2014 – [Colibri Heart Valve, LLC](#), a privately held emerging medical device company, has shared findings from long-term follow-up of patients enrolled in the Company's [first-in-human study](#) of its proprietary 24mm transcatheter aortic valve implantation (TAVI) system. The five patients enrolled in the study continue to demonstrate successful outcomes with zero-to-trace paravalvular leak (PVL) and a high retrained effective orifice area (EOA) of greater than 2.0 cm² up to one year post implantation.

“We believe these patient outcomes are directly related to the [design features](#) of the Colibri TAVI valve, which uses a proprietary leaflet design that optimizes opening and closing valve behavior while being delivered through a low profile 14Fr catheter,” stated [Joseph B. Horn](#), Colibri's president and chief executive officer. “The large EOA and minimal PVL, combined with the convenience of a pre-mounted and pre-packaged, ready-for-use TAVI system will be important and sustained differentiators in the TAVI marketplace. As cost constraints become ever more important in the worldwide health care markets, the ability to manufacture a cost-effective product while maintaining clinical outcomes will be of critical importance. The company that can deliver these benefits for hospitals and patients will be successful even in established markets. Colibri's streamlined production methods will allow us to bring a very cost-effective TAVI product to market. Moreover, we are confident that our broad patent portfolio will be effective in protecting Colibri's pre-packaged, pre-mounted, dry valve technology across all heart valve applications.”

Dr. Pedro Ureña, primary investigator of the Colibri clinical study and director of the cardiovascular department at the Center of Advanced Medicine (CEDIMAT) in Santo Domingo, Dominican Republic, added, “The five patients who participated in Colibri's first-in-human study all continue to do well and the valve has performed better than we expected. The large EOA achieved following implantation (≥ 2.0 cm²), no femoral complications or stroke, and no need for pacemaker implantation, suggests that Colibri's valve design may have superior patient benefits over current transcatheter heart valves, based on observed clinical results.”

About the Colibri Heart Valve and the Ready-to-Use Colibri TAVI System

Colibri Heart Valve, LLC is a privately held medical device company based in Broomfield, CO that researches and develops novel heart valve technologies. Colibri has developed a pre-mounted and pre-packaged, ready-for-use transcatheter aortic valve implantation (TAVI) device called the “[Colibri TAVI System](#).” TAVI is an important treatment option for heart valve replacement due to its minimally invasive nature, clinical efficacy, extensive patient experience, and reduced procedural costs. Colibri's advanced technology is a culmination of over 10 years of research and development by Colibri's founders, Dr. David Paniagua and Dr. R. David Fish into the tissue, valve design, frame, and delivery catheter. Colibri's unique tissue processing method produces extremely strong, durable, and biocompatible tissue. The proprietary tissue enables loading, crimping, and packaging of the Colibri

valve at manufacture, making in-procedure valve rinsing and loading at time of use unnecessary. The “Colibri TAVI System” is designed to be shipped ready-for-use.

Colibri’s corporate headquarters and pre-commercialization facilities are located in Broomfield, Colorado with R&D located in Houston, Texas. For more information, visit: www.colibrihv.com.

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