



## **Colibri Heart Valve, LLC Announces Successful Clinical Use of the First Ready-to-Use Transcatheter Aortic Heart Valve System**

BROOMFIELD, CO – December 5, 2012 – [Colibri Heart Valve](#), LLC today announced that it has successfully completed the first clinical use of the Company's proprietary transcatheter aortic heart valve. The Colibri transcatheter aortic valve implantation (TAVI) system is the world's first and only low profile, 14 French pre-mounted, pre-crimped, and pre-packaged, ready-for-use, TAVI system. These advantages are designed to reduce delivery profile along with a reduction in preparation and insertion time which are not available in any other device, either currently available or in known development.

"The successful first-in-patient implantation of this breakthrough TAVI system is a significant and exciting milestone for our company," stated [Joseph B. Horn](#), Colibri's president and chief executive officer. "While there have been many advancements in TAVI technology in recent years, we believe the advantages offered to physicians and hospitals by the Colibri TAVI system have the potential to measurably simplify and reduce pre-procedure preparation time and therefore overall cost. In addition, we believe the low profile 14 French introducer used in our system has the potential to be used in patients not currently considered TAVI candidates due to the relatively small diameter of their femoral arteries, thereby increasing the number of TAVI femoral patients who may benefit from this procedure."

Dr. Pedro Ureña, the director of the Cardiovascular Department at the Center of advanced medicine (CEDIMAT) in Santo Domingo, Dominican Republic, performed a procedure last week on a female patient with extensive calcification of her aortic valve. Dr. Ureña was observed by Colibri's scientific founders, Drs. R. David Fish and David Paniagua. Commenting on his first-hand experience with Colibri's TAVI system, he noted, "I was very impressed with the ease and speed with which my team and I were able to implant the Colibri valve. The time from removing the valve from its sterile package to valve deployment was much shorter than with other TAVI systems. The fact that the valve arrived ready to use, crimped and mounted on the delivery catheter greatly reduced our preparation time, an important convenience when performing a procedure as complex as a TAVI procedure. The relatively short pre-procedure requirement also reduced the time the patient was under anesthesia, an important factor for high risk patients, and allowed my staff to devote more time to patient care."

This patient was treated as part of Colibri's first-in-human feasibility study, an international prospective, multicenter, non-randomized, investigational study to assess the safety, technical feasibility, and deployment characteristics of the 24mm Colibri aortic heart valve and delivery system. Enrollment in the ongoing clinical study of the

Colibri TAVI system in up to 10 patients is taking place at multiple trial sites outside the U.S. and is expected to yield 30-day follow-up data by the end of the first quarter of 2013. To be eligible for the study, individuals must have severe symptomatic aortic valve stenosis and be very high risk for open-heart valve replacement surgery. Study participants will be monitored at 30 days and one year following implantation.

**About Colibri Heart Valve, LLC and the 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, pre-crimped, 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. The Company’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](http://www.colibrihv.com).

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