



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

BROOMFIELD, CO – July 24, 2013 – [Colibri Heart Valve, LLC](#), a privately held medical device company, today announced that enrollment in the Company's first-in-human feasibility study is continuing, and early clinical results from the second implantation of the Colibri device confirm the positive clinical findings observed in its [first use](#). The Colibri transcatheter aortic valve implantation (TAVI) system (US Patent 8,361,144) is the world's first and only low profile, 14 French, pre-mounted, pre-crimped, and pre-packaged, ready-for-use [TAVI system](#). Colibri plans to provide updates on the first-in-human feasibility study at the upcoming London Valve Summit and TCT conferences in September and October respectively.

"The results seen to date from additional enrollment in our feasibility study support the excellent clinical results seen in the first patient to undergo the implantation procedure," stated [Joseph B. Horn](#), Colibri's president and chief executive officer. "While it is still early, the results demonstrate the system's ease of use and benefit of its low profile. Moreover, we have continued to see an effective orifice area of >2.0 and virtually no paravalvular leakage (PVL), which we believe may point to superior clinical outcomes. We look forward to continued enrollment in our study to confirm the potential benefits of the Colibri TAVI System."

"The low profile (14 French) of the Colibri TAVI System greatly improved the ease with which the mounted TAVI System is navigated through the vasculature (trackability) and positioning of the replacement heart valve in the native aortic valve plane compared to other TAVI systems," stated Dr. Pedro Ureña, one of the primary investigators of the Colibri clinical study and the director of the cardiovascular department at the Center of Advanced Medicine (CEDIMAT) in Santo Domingo, Dominican Republic. "The combination of these benefits and the convenience of receiving the Colibri TAVI system pre-packaged and ready-for-use are significant improvements that I look forward to confirming with additional enrollment in the study."

Colibri's first-in-human feasibility study is 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 TCT 2013 meeting this fall in San Francisco. 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 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, 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. 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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