Colibri Heart Valve Receives ISO 13485 and EN ISO 13485 Certification

BROOMFIELD, CO – March 3, 2017 – Colibri Heart Valve LLC, a privately held emerging medical device company focused on structural heart applications, announced today that it has received certification from DEKRA Certification B.V. that the company complies with the European requirements of ISO 13485 and EN ISO 13485 for a comprehensive quality management system for the design and manufacture of the company's pre-packaged, ready-for-use, transcatheter aortic heart valve implantation (TAVI) system.

"The addition of ISO 13485 and EN ISO 13485 certification is an important milestone for the company and demonstrates Colibri's commitment to quality and ensures the company will be compliant with quality standards," said William Jackson, Colibri's vice president of regulatory, clinical, and compliance. "Obtaining ISO 13485 and EN ISO 13485 certification is a major milestone necessary for Colibri to ultimately obtain CE certification which will allow Colibri to sell its TAVI product(s) in 32 member countries along with additional countries that recognize CE certification."

"Obtaining ISO certification positions the company to advance our clinical program in support of commercializing Colibri's next-generation proprietary, glutaraldehyde-free, pre-packaged ready-for-use, TAVI system," said Joseph B. Horn, Colibri's president and chief executive officer. "The Colibri TAVI System is designed to address the expanding patient populations including those in the emerging markets which the company is preparing to pursue globally through our Chinese joint venture, Venibri Medtech."

A crimped and loaded heart valve on a delivery catheter which is pre-packaged and ready-for-use, provides significant time, cost and safety benefits associated with a transcatheter heart valve replacement procedure. The Colibri TAVI System is ideally suited for expanding the use of this treatment modality into emerging world markets. The superior design features of the Colibri TAVI System positions the product to address the variations in patient aortic valve structures, such as bicuspid valves, and also prosthetic valve mismatch as the indications for expanded use. With the addition of ISO 13485 and EN ISO 13485 certification, Colibri will be able to initiate clinical studies to advance its pre-mounted, pre-packaged, sterilized dry heart valve technology in the coming months.

For more information on the Colibri TAVI System's differentiated design features and technology pipeline please visit the Colibri Heart Valve website at www.colibrihv.com.

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." The TAVI procedure 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 15 years of research and development into transcatheter valve technology. Colibri's unique tissue processing method produces extremely strong, durable, and biocompatible tissue. The proprietary method 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 and will be available in multiple sizes.

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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