JenaValve Announces Certification of New **Transcatheter** Heart Valve Manufacturing Facility

Wholly-Owned Facility Fully Equipped to Develop, Test and Deliver Existing and Next-Generation Valve Technologies

Irvine, Calif.– November 11, 2015 – JenaValve Technology, Inc., a developer, manufacturer and marketer of next-generation transcatheter aortic valve replacement (TAVR) systems for the treatment of aortic valve disease, today announced it has received EN ISO 13485:2012 certification for its wholly-owned manufacturing facility in Leeds, United Kingdom.

”Attaining this certification is a testament to our internal heart valve expertise and continuous efforts to ensure that the quality of all generations of the JenaValve bioprosthesis consistently meet the needs of our customers and international regulatory requirements for manufacturing,” said Victoria Carr-Brendel, Ph.D., Chief Executive Officer of JenaValve. “Going forward, this facility will supply the valves needed to support our clinical trial programs and future commercial launches.”

The EN ISO 13485:2012 certification covers the design, development, manufacturing and distribution of JenaValve’s Transcatheter Heart Valves. The certification demonstrates that JenaValve has successfully implemented a quality management system that conforms to the worldwide standard for medical device and diagnostic manufacturing.

The ISO (International Organization for Standardization) is the world’s largest developer and publisher of International Standards. JenaValve’s EN ISO 13485:2012 + AC: 2012 certificate was awarded by the notified body, DEKRA.

Carr-Brendel continued, “This certification marks a significant milestone for JenaValve as we continue our transition to a vertically integrated company that is focused on meeting the needs of our physician customers, their patients and all requirements of global manufacturing regulations.”

About JenaValve
JenaValve Technology, with operating locations in Irvine, California, Leeds, England and Munich, Germany, develops, manufactures and markets transcatheter aortic valve replacement (TAVR) systems to treat patients suffering from aortic valve disease. The Company’s Transapical TAVR system, consisting of the JenaValve valve system plus Cathlete PLUS delivery system, has CE Mark approval for aortic valve stenosis and for the unique indication to treat

patients suffering from aortic valve insufficiency. JenaValve currently markets this product in Europe and other selected markets worldwide. JenaValve is backed by world class U.S., European and Asian investors, including Atlas Venture, Edmond de Rothschild Investment Partners, Gimv (a Euronext-listed investment company - ticker: GIMB), Legend Capital, NeoMed Management, Omega Funds, RMM, Sunstone Capital, Valiance and VI Partners. Additional information is available at www.jenavalve.com.

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