Enrollment Completed for Low-Risk Aortic and Mitral Patient Groups For On-X® Prosthetic Heart Valve Anticoagulation Clinical Study

The Associated Press

MINNEAPOLIS--(BUSINESS WIRE)--May 7, 2013--On-X ® Life Technologies, Inc. (On-X LTI) announced today that enrollment for the Low-Risk Aortic Valve and Mitral Valve Patient Groups has been completed. The Prospective Randomized On-X Valve Anticoagulation Trial (PROACT) was initiated with US FDA approval in 2006 and is being conducted at 36 centers throughout the United States and Canada. The purpose of the Low-Risk Patient Group of the PROACT trial is to determine if qualified recipients of the On-X aortic heart valve can be safely maintained with aspirin and clopidogrel (Plavix ®). The announcement was made today at the American Association for Thoracic Surgery (AATS) annual meeting.

The Low-Risk Patient Group of the PROACT trial is comprised of patients requiring aortic valve replacement who meet the low-risk criteria established by the study's protocol, which was reviewed and approved by the FDA under Investigational Device Exemption (IDE) rules. This is the only FDA-approved study using aspirin and clopidogrel as the anticoagulant for aortic valve patients receiving a mechanical valve. The Mitral Valve Patient Group follows patients taking reduced warfarin. The unique and innovative design and material features of the On-X valve, combined with the previously established clinical data for the valve, made conduction of the trial possible.

"The completion of enrollment for the low-risk aspirin and clopidogrel patient group is a very positive sign," said John Ely, Executive Vice President of Regulatory Affairs and Quality Assurance for On-X Life Technologies, Inc. and the primary coordinator of the PROACT trial. "It will allow us to more accurately project event rates and follow-up needs as we progress toward the study's completion. When the longer-term follow-up data are collected, analyzed and reviewed, we will be able to determine whether selected recipients of the On-X valve in the aortic position can be safely managed without warfarin anticoagulation. If that is the case, it will be an important breakthrough for prosthetic valve recipients." "I believe the completion of enrollment for the low risk ASA/clopidogrel group points to a day when we surgeons will be authorized to offer this option more widely," said Allen Henry Graeve, M.D., Site Investigator at Tacoma General Hospital in Tacoma, Washington. "I have two patients now on ASA/Plavix for six years and another two on it for five years. All are complication free and very happy to take two pills a day, not have their blood checked and be blessed with a permanent valve solution. One is very young and works abroad - he's so grateful to be free of complications and Coumadin®." "On-X LTI previously announced it submitted to the FDA a request to change the Instructions for Use for the On-X valve to include the opportunity to permit reduction in patient anticoagulation for all aortic patients," said Ely. "Similarly, our intent is to do this for the Low-Risk Patient Group once the data has sufficient

statistical significance, which will come with time. The completion of enrollment for this most important aspirin and Plavix group is a major milestone needed to achieve that objective." The On-X valve is the result of a breakthrough in medical grade carbon technology— On-X pure pyrolytic carbon. In addition to providing a more thromboresistant surface, the comparatively high strength of pure On-X carbon enabled On-X LTI to make significant valve design changes that resulted in a prosthesis that acts more like a natural valve in its treatment of blood. It is well documented that the On-X valve does not produce the turbulence and blood damage commonly produced by other mechanical heart valve prostheses and therefore significantly reduces the potential for life-threatening blood clots.

Until the completion and analysis of study data, On-X Life Technologies, Inc., continues to recommend standard anticoagulation therapy as presently prescribed by various professional societies for the On-X valve.

About On-X LTI
On-X ® Life Technologies (On-X LTI) develops heart valve replacements that significantly improve the quality of life of patients. Jack Bokros, Ph.D., and his associates founded On-X LTI in 1994 to further advance prosthetic heart valve technology by capitalizing on their new form of pyrolytic carbon. The company has FDA, CE and Japanese approval for sale of the On-X valve. On-X LTI also provides contract-manufacturing services utilizing its patented pyrolytic carbon to manufacturers of other medical products, including orthopedic joint and spine prostheses. Headquartered in Austin, Texas, On-X LTI is a privately held company. More information is located at www.onxlti.com.