XTENT Announces CUSTOM II Data Selected for Publication in EuroIntervention

MENLO PARK, Calif., Aug 26, 2008 /PRNewswire-FirstCall via COMTEX News Network/ -- XTENT, Inc. (Nasdaq: XTNT) today announced that the positive one-year follow-up data from the CUSTOM II trial was published in the most recent issue of the peer-reviewed journal, EuroIntervention. The lead author of the article was Dr. Pieter R. Stella, M.D., of University Medical Center Utrecht, Utrecht, The Netherlands on behalf of the CUSTOM II Investigators from 13 clinical sites across Europe.

The one-year CUSTOM II trial, a single-arm, 100-patient prospective study designed to evaluate the safety and efficacy of XTENT's Custom NX(R) drug-eluting stent (DES) system in patients with coronary artery disease, showed no new major adverse cardiac events (MACE) since the first analysis was performed at six months. The incidence of late stent thrombosis for patients treated with Custom NX in the study was zero percent.

CUSTOM II one-year follow-up results were first presented last year at Cardiovascular Research Foundation's (CRF) nineteenth annual Transcatheter Cardiovascular Therapeutics (TCT) meeting.

"This article marks our second publication of Custom NX data in this prestigious peer-reviewed journal this year," said Gregory D. Casciaro, XTENT's president and CEO. "We have been extremely pleased with the safety and efficacy Custom NX has demonstrated in the CUSTOM I, II and III trials, and appreciate the level of interest and support our technology continues to receive from the clinical community."

Results from the two-year follow-up of CUSTOM I, a 30-patient first-in-man study designed to evaluate the preliminary safety and feasibility of in-situ stent customization, were also published in EuroIntervention earlier this year. This study showed no new major adverse cardiac events (MACE) were reported since the one-year analysis, and the incidence of late stent thrombosis for patients treated with Custom NX was zero percent. The CUSTOM I article published in EuroIntervention was recognized by the journal's editorial board as one of the six best papers submitted to the journal during the previous winter, and Lutz Buellesfeld, M.D., of the HELIOS Heart Center in Siegburg, Germany, received an award in conjunction with the publication after presenting it at the annual EuroPCR meeting in May.

The CUSTOM II trial was designed to evaluate the safety and efficacy of Custom NX for the treatment of long and multiple lesions. Of the 100 patients enrolled, 69 patients were enrolled in the long-lesion arm, and 31 patients were enrolled in the two-lesion arm of the study. CUSTOM II enrolled one of the most difficult to treat patient populations ever studied in a DES trial. In the CUSTOM II patient population, the average vessel diameter was 2.57mm and the average lesion length was 28.7mm. Twenty-six percent of the study participants were diabetic. The percentage of patients with ACC/AHA lesion grade B2 or C was 65.1 percent. CUSTOM II's six-month clinical results have been sustained at one year. The target lesion revascularization rate remained constant at four percent, with no new MACE events, and no late stent thrombosis.

The EuroIntervention paper, titled "One year results of a new in-situ length-adjustable stent platform with a biodegradable Biolimus A9 eluting polymer: result of the CUSTOM-II trial," can be accessed at: http://www.europcronline.com/eurointervention/15th_issue/37/.

About the Custom NX(R) DES System

Custom NX is designed to enable a more personalized approach to the treatment of arterial disease based on each patient's individual lesion characteristics. The Custom NX system allows physicians to customize the length and diameter of the stent at the site of the lesion. The system features a proprietary modular stent design that consists of multiple 6mm cobalt chromium segments coated with Biolimus A9(R) and PLA, a biodegradable drug carrier. The Custom NX delivery system enables the stent length to be adjusted in 6mm increments and allows for the placement of up to 60mm of stent at one or more locations. The Custom NX DES System has not been approved for sale by any regulatory authority.

About XTENT

XTENT, Inc. is a medical device company focused on developing and commercializing innovative customizable drug eluting stent (DES) systems for the treatment of coronary artery disease (CAD). CAD is the most common form of cardiovascular disease and the number one cause of death in the United States and Europe. XTENT(R) Custom NX(R) DES Systems are designed to enable the treatment of single lesions, long lesions and multiple lesions of varying lengths and diameters, in one or more arteries with a single device. Note: XTENT(R) Custom NX(R) DES Systems have not been approved for sale by any regulatory authority.

Forward Looking Statements

This press release contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. Statements in this press release regarding XTENT's business that are not historical facts may be "forward-looking statements" that involve risks and uncertainties. Specifically, these statements include, but are not limited to those concerning: the performance of XTENT's DES Systems or the results of future clinical trials. Forward-looking statements are based on management's current, preliminary expectations, and are subject to risks and uncertainties that could cause actual results to differ from the results predicted and which are included in the "Risk Factors" section of XTENT's most recent quarterly report on Form 10-Q for the quarter ended June 30, 2008. This quarterly report was filed with the SEC on August 12, 2008, and is available on the company's investor relations website at http://www.xtentinc.com and on the SEC's website at http://www.sec.gov. Undue reliance should not be placed on forward-looking statements, which speak only as of the date they are made. XTENT undertakes no obligation to update publicly any forward-looking statements to reflect new information, events or circumstances after the date they were made, or to reflect the occurrence of unanticipated events.

SOURCE XTENT, Inc.

http://www.xtentinc.com