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## Abbott's XIENCE V(R) Superior to TAXUS(R) in Key Safety and Efficacy Measures in SPIRIT IV Trial

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San Francisco (ots/PRNewswire) - At One Year, XIENCE V Demonstrates:

- Statistical Superiority on Primary Endpoint of Target Lesion Failure, with a 38 Percent Reduction Compared to TAXUS
- 74 Percent Reduction in Stent Thrombosis (Blood Clots) Compared to TAXUS
- Low Event Rates across Multiple Subgroups of Complex Patients

Late-breaking data from the SPIRIT IV trial demonstrated that Abbott's market-leading XIENCE V(R) Everolimus Eluting Coronary Stent System achieved superiority in the key safety and efficacy measures of target lesion failure (TLF) and target lesion revascularization (TLR) compared to the TAXUS(R) Express2(TM) Paclitaxel-Eluting Coronary Stent System (TAXUS) at one year. With 3,690 patients, the SPIRIT IV trial is one of the largest randomized clinical trials between two drug eluting stents.

In the trial's primary endpoint, XIENCE V demonstrated a statistically significant 38 percent reduction in TLF compared to TAXUS (4.2 percent for XIENCE V vs. 6.8 percent for TAXUS, p-value = 0.001). TLF is defined as a composite measure of important efficacy and safety outcomes for patients and is defined as cardiac death, heart attack attributed to the target vessel (target vessel myocardial infarction), and ischemia-driven TLR (ID-TLR). The standard was established to harmonize the definition of major adverse cardiac events across various drug eluting stent trials. XIENCE V also demonstrated a statistically significant 46 percent reduction in TLR (repeat procedure) compared to TAXUS (2.5 percent for XIENCE V vs. 4.6 percent for TAXUS, p-value=0.001). TLR is one of the major secondary endpoints of the SPIRIT IV trial. The groundbreaking results were presented today by Gregg W. Stone, M.D., professor of medicine at Columbia University Medical Center, during the 2009 Transcatheter Cardiovascular Therapeutics (TCT) conference in San Francisco.

In addition to demonstrating superiority in the primary endpoint of TLF and major secondary endpoint of TLR, XIENCE V demonstrated an impressive low rate of stent thrombosis (blood clots) at one year. Per protocol definition, XIENCE V demonstrated an observed 80 percent reduction in stent thrombosis compared to TAXUS (0.17 percent for XIENCE V vs. 0.85 percent for TAXUS, p-value=0.004) at one year. Per Academic Research Consortium (ARC) definition of definite/probable stent thrombosis, XIENCE V demonstrated an observed 74 percent reduction in ARC definite/probable stent thrombosis at one year (0.29 percent for XIENCE V and 1.10 percent for TAXUS, p-value=0.004). The ARC definitions of stent thrombosis were developed to harmonize the definition of stent thrombosis across various drug eluting stent trials.

"SPIRIT IV represents one of the largest randomized trials of two drug eluting stents completed to date. Importantly, this study was performed without routine angiographic follow-up, which may result in a tendency to treat lesions which may not be causing symptoms, and potentially impact results," said Dr. Stone, who is also immediate past chairman of the Cardiovascular Research Foundation, New York; and principal investigator of the SPIRIT IV trial. "The SPIRIT IV results show that XIENCE V significantly reduces a patient's risk of experiencing a heart attack, the need for a repeat procedure or stent thrombosis."

### Event Rates in Complex Patients

The SPIRIT IV trial included multiple complex patient subgroups, including more than 1,100 patients with diabetes, who typically are sicker and have more challenging artery disease. In patients with diabetes, there was no difference in TLF between XIENCE V and TAXUS at one year (6.4 percent for XIENCE V vs. 6.9 percent for TAXUS, p-value=0.80). In patients without diabetes, XIENCE V demonstrated a 54 percent reduction in TLF compared to TAXUS at one year (3.1 percent for XIENCE V vs. 6.7 percent for TAXUS, p-value

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