

## XIENCE® V Drug Eluting Stent from Abbott Outperforms Market-Leading Stent in Reducing Major Adverse Cardiac Events at Two Years

Long-term data presented for the first time today from the SPIRIT III trial, Abbott's U.S. pivotal trial studying the XIENCE® V Everolimus Eluting Coronary Stent System, demonstrated that XIENCE V continues to deliver clinically superior benefits for patients compared to the TAXUS® paclitaxel-eluting coronary stent system. In this trial of more than 1,000 patients, XIENCE V demonstrated a 45 percent reduction in the risk of major adverse cardiac events (MACE) and a 32 percent reduction in the risk of target vessel failure (cardiac events related to the treated vessel) at two years as compared to TAXUS. The SPIRIT III two-year results were presented by Gregg W. Stone, M.D., principal investigator of the SPIRIT III trial, during the late-breaking clinical trials session at EuroPCR 2008.

"Not only did XIENCE V clearly differentiate itself from the TAXUS stent in the first year after treatment, it has now demonstrated even more positive effects at two years in the SPIRIT III trial," said Dr. Stone, Columbia University Medical Center and chairman, Cardiovascular Research Foundation, New York. "As measured by clinically significant reductions in target vessel failure and MACE, XIENCE V demonstrated an even greater improvement in patient outcomes compared to TAXUS at two years than at one year, driven by numerically lower rates of heart attacks and lower observed rates of re-intervention of the target lesion. We also saw encouraging trends for lower observed rates of late and very late stent thrombosis in XIENCE V-treated patients, especially in those who discontinued dual antiplatelet therapy."

The SPIRIT III trial of 1,002 patients, which is the basis for the pre-market application of XIENCE V to the U.S. Food and Drug Administration (FDA), demonstrated the following key results for XIENCE V at two years:

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- A 45 percent reduction in the risk of major adverse cardiac events (MACE) compared to TAXUS (7.3 percent for XIENCE V vs. 12.8 percent for TAXUS, p-value=0.004)\*. MACE is an important composite clinical measure of safety and efficacy outcomes for patients, defined as cardiac death, heart attack (MI), or ischemia-driven target lesion revascularization (TLR driven by lack of blood supply).

- A 32 percent reduction in the risk of Target Vessel Failure (TVF, cardiac events related to the treated vessel) compared to TAXUS (10.7 percent for XIENCE V vs. 15.4 percent for TAXUS, p-value=0.04)\*. TVF is a composite clinical measure of safety and efficacy outcomes defined as cardiac death, heart attack (myocardial infarction or MI) or target vessel revascularization (TVR).

- A 40 percent reduction in the risk of ischemia-driven target lesion revascularization (ID-TLR) as compared to TAXUS (4.6 percent for XIENCE V vs. 7.5 percent for TAXUS, p-value=0.07)\*.

- Low rates of stent thrombosis between one and two years, defined as very late stent thrombosis, per Academic Research Consortium (ARC) definition of definite/probable stent thrombosis (0.3 percent for XIENCE V and 1.0 percent for TAXUS) and per the SPIRIT III protocol (0.2 percent for XIENCE V and 1.0 percent for TAXUS). The ARC definitions of stent thrombosis were developed to

eliminate variability in the definitions across various drug eluting stent trials.

"From these results, it is clear that XIENCE V can deliver sustained benefits to patients over the long term," said John M. Capek, Ph.D., executive vice president, Medical Products, Abbott. "We continue to be pleased with the way XIENCE V is performing, with outstanding results that are consistent with what we have seen throughout the SPIRIT III trial."

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