MedicalXpress

The Lancet publishes first clinical trial data of a fully bioabsorbable drug-eluting stent

March 14 2008

Data published today in *The Lancet* from ABSORB, the world's first clinical trial of a fully bioabsorbable drug eluting stent for the treatment of coronary artery disease, demonstrated no stent thrombosis, no clinically driven target lesion revascularizations (re-treatment of a diseased lesion), and a low (3.3 percent) rate of major adverse cardiac events (MACE) in 30 patients out to one year.

These one year results for Abbott's bioabsorbable everolimus eluting stent were consistent with performance demonstrated by the system at 6 months, as previously reported in October 2007. Abbott's prospective, non-randomized, ABSORB clinical trial is designed to evaluate the overall safety and performance of a fully bioabsorbable everolimus eluting stent out to 5 years.

"Abbott's bioabsorbable everolimus eluting stent has demonstrated excellent clinical safety out to one year in patients with coronary artery disease," said Patrick W. Serruys, M.D., Ph.D., Professor of Interventional Cardiology at the Thoraxcentre, Erasmus University Hospital, Rotterdam, and co-principal investigator in the ABSORB study. "The positive results from this clinical trial form a strong basis for the development of additional bioabsorbable stent platforms with the potential to eliminate some of the restrictions posed by metallic stents in areas such as vessel imaging and vessel remodeling."

At 6 months, the overall MACE rate in the ABSORB trial was 3.3 percent (one patient, n=30) and late loss, a measure of reduction in

vessel lumen diameter after stenting, was 0.44 mm. At one year, the overall MACE rate in the ABSORB trial was consistent with results at 6 months (one patient, 3.3 percent, n=30; 3.4 percent adjusted for one patient who withdrew from follow-up, known to be event free at 1 year, n=29). MACE is a composite measure of cardiac death, heart attack and re-treatment of a diseased lesion (ischemia-driven target lesion revascularization) in the ABSORB trial. Abbott's bioabsorbable everolimus eluting stent also demonstrated 100 percent procedural success and 94 percent device success in the ABSORB trial.

"Patients and physicians like the idea of a stent that does its job and is then absorbed away," said John A. Ormiston, M.B., Ch.B., cardiologist at Auckland City Hospital, in Auckland, New Zealand and principal investigator in the ABSORB trial. "Abbott's bioabsorbable stent has the potential to hold an artery open long enough for healing to occur, and we would expect an artery that is healed to function as it did before it became diseased."

Abbott is the only company with a fully bioabsorbable drug eluting coronary stent in clinical trials. Abbott’s bioabsorbable everolimus eluting coronary stent is made of polylactic acid, a proven biocompatible material that is commonly used in medical implants such as dissolvable sutures. As with a metallic stent, Abbott’s bioabsorbable stent is designed to restore blood flow in clogged coronary arteries, and to provide mechanical support until the blood vessel heals. Unlike a metallic stent, however, a bioabsorbable stent is designed to be slowly metabolized by the body and completely absorbed over time.

"Abbott's bioabsorbable drug eluting stent system is a great example of scientific innovation leading to a breakthrough treatment for heart disease that has the potential to improve patients' lives," said John M. Capek, Ph.D., executive vice president of medical devices, Abbott. "We look forward to continuing to evaluate the safety and effectiveness of

our bioabsorbable stent platform in additional patients in the coming months."

Source: Abbott Laboratories