Harvard Clinical Research Institute Successfully Completes Randomization in the DAPT Study

The Associated Press

BOSTON--(BUSINESS WIRE)--Aug 7, 2012--The Harvard Clinical Research Institute (HCRI) announced today the successful completion of randomization in the DAPT Study, with the total number of patients randomized exceeding the upper goal set for the Study. The DAPT Study is a four-year clinical trial investigating the duration of dual antiplatelet therapy (DAPT, the combination of aspirin and a thienopyridine/antiplatelet medication to reduce the risk of blood clots) following drug-eluting stent implantations. The large-scale public health study is expected to bring clarity to the global medical community regarding the benefits of 12 versus 30 months of dual antiplatelet therapy in patients receiving drug-eluting stents to address coronary artery lesions. The American College of Cardiology/ American Heart Association currently recommend 12 months of dual antiplatelet therapy for patients undergoing percutaneous coronary intervention (PCI) following placement of a drug-eluting stent.

Laura Mauri, M.D., principal investigator of the DAPT Study, an interventional cardiologist at the Brigham and Women's Hospital and Harvard Medical School in Boston, MA and chief scientific officer of Harvard Clinical Research Institute, said: “The clinical community is awaiting a definite answer as to the appropriate duration of dual antiplatelet therapy that balances beneficial long-term outcomes while minimizing bleeding complications. The DAPT Study is uniquely designed to answer this question and to draw meaningful conclusions regarding specific risks and benefits, due to its large sample size, statistical power and focus on presenting data from real-world practice. We plan to announce final results from the Study in late 2014, which we expect will inform future practice guidelines on the duration of dual antiplatelet therapy following drug-eluting stent implantation.” Dean J. Kereiakes, M.D., co-principal investigator of the DAPT Study, medical director of The Christ Hospital Heart and Vascular Center and The Carl and Edyth Lindner Center for Research and Education at The Christ Hospital in Cincinnati, Ohio, added: “We are pleased to have successfully enrolled approximately 26,000 patients into the Study and into the participating manufacturers’ contributing studies, with approximately 12,000 total patients having been subsequently randomized. The large number of patients involved in the DAPT Study is a major strength of the trial and we are thankful to the over 450 sites throughout the United States, Canada, European Union, Australia and New Zealand that contributed to the Study.” The DAPT Study is being conducted through a public-private collaboration involving HCRI; four major stent manufacturers: Abbott (XIENCE V ®, XIENCE PRIME™), Boston Scientific Corporation (TAXUS ®, PROMUS ®), Cordis Corporation (CYPHER ®), Medtronic, Inc. (Endeavor ®); the manufacturers of thienopyridine/antiplatelet medications: Bristol-Myers Squibb Company/Sanofi Pharmaceuticals Partnership (Plavix ® (clopidogrel bisulfate)) and Eli Lilly and Company and Daiichi Sankyo Company, Limited (Effient/Efient ® (prasugrel)); and the U.S. Food and Drug Administration

(FDA). HCRI, which is responsible for the scientific management of the DAPT Study and the independent analysis of the resulting data, received funding support from each of the drug and device manufacturers.

DAPT Study Protocol The DAPT (dual antiplatelet therapy) Study is assessing the benefits of 12 versus 30 months of dual antiplatelet therapy for preventing stent thrombosis and major adverse cardiovascular and cerebrovascular events (MACCE) in subjects undergoing percutaneous coronary intervention (PCI) with drug-eluting stent placement for the treatment of coronary artery lesions. The trial is a four-year, prospective, randomized, double-blind trial evaluating subjects being treated with a drug-eluting stent (DES) or a bare metal stent (BMS) at over 450 centers worldwide. All subjects received 12 months of open-label thienopyridine/antiplatelet treatment in addition to aspirin. After 12 months, subjects who were free from all MACCE or major bleeding events were randomized 1:1 to either placebo or ongoing dual antiplatelet therapy for an additional 18 months followed by three months of observational follow-up. Both arms will continue aspirin therapy. The choice of stent type and thienopyridine drug was at the discretion of the patient and physician.

The co-primary endpoints for this trial are the incidence of the composite of all death, myocardial infarction (MI) and stroke (referred to as major adverse cerebral and cardiovascular events, or MACCE) between 12 and 33 months post-drug-eluting stent procedure and the incidence of stent thrombosis (ST) between 12 and 33 months post-stent procedure. The primary safety endpoint for this trial is incidence of major bleeding between 12 and 33 months post-drug-eluting stent procedure. The study will also include an adjusted comparison of patients treated with BMS compared with DES on varying durations of antiplatelet therapy.

More information about the DAPT Study is available at www.DAPTStudy.org [1] and the DAPT Study protocol and patient eligibility information are available on www.clinicaltrials.gov [2].

The Harvard Clinical Research Institute is a non-profit academic research organization with unparalleled access to resources in clinical research. The Institute advances the research of pharmaceutical, biological, and medical device products by developing collaborations between industry and academia. HCRI's partners include leading medical centers with worldwide recognition for high-quality medical care and state-of-the-art facilities. Its close affiliation with Harvard Medical School, Beth Israel Deaconess Medical Center and Partners HealthCare reinforces HCRI's commitment to engaging distinguished medical practitioners in thought-provoking, industry-sponsored research. The Institute's sponsors rely on its scientific objectivity to add unique value to the design of their studies, oversight of their research and analysis of their study data. As a leading provider of clinical trial services, HCRI plays an important role in assessing new products that improve the quality of peoples' lives.

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Links:
[1] http://www.DAPTStudy.org
[2] http://www.clinicaltrials.gov