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HARVARD CLINICAL RESEARCH INSTITUTE EXPANDS DAPT STUDY INTO EUROPE

- First European Patients Enrolled into Four-year, Public Health Study to Investigate the Duration of Dual Antiplatelet Therapy Following Drug-eluting Stent Procedures -

BOSTON – May 25, 2010 - [The Harvard Clinical Research Institute \(HCRI\)](#) announced today that the [DAPT Study](#) has expanded into seven countries in the European Union. John Irving, MBChB, MRCP, M.D., consultant cardiologist at Ninewells Hospital in Dundee, United Kingdom, was the first European investigator to enroll patients into the study. Enrollment is opening at multiple centers across the EU and will include participation in the following countries: the Czech Republic, France, Germany, Hungary, Poland, Romania and the United Kingdom. Enrollment into the DAPT Study was initiated in the United States in [October 2009](#).

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 European Society of Cardiology currently recommends 3-4 weeks of dual antiplatelet therapy for patients undergoing percutaneous coronary intervention (PCI) with bare metal stent placement and 6-12 months of dual antiplatelet therapy following drug-eluting stent placement. The American College of Cardiology and American Heart Association currently recommend 12 months of dual antiplatelet therapy after placement of a drug-eluting stent.

Principal investigator of the DAPT Study, Laura Mauri, M.D., 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 lack of definitive data regarding the risks versus benefits of continuing dual antiplatelet therapy beyond one year to prevent stent thrombosis remains a critical issue that has caused uncertainty in the global cardiology community. The expansion of the DAPT Study into the EU is an important milestone in support of our goal of enrolling over 20,000 subjects and obtaining a diversity of data that reflects real-world clinical practice."

"The DAPT Study addresses a critical gap in current scientific evidence," said Ph. Gabriel Steg, M.D., DAPT national coordinator for France, DAPT Executive Committee member, and an interventional cardiologist at Hospital Bichat in Paris, France. "This international study will help

understand the benefits and the risks associated with prolonged dual antiplatelet therapy beyond one year after stenting. The study promises greater clarity to an area of uncertainty in patient care worldwide."

The DAPT Study is being conducted through a public-private collaboration involving HCRI; four major stent manufacturers: Abbott (XIENCE V[®]), 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 will assess the benefit 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 will be a four-year, prospective, randomized, double-blind trial that is expected to enroll over 15,000 subjects being treated with a drug-eluting stent (DES) at over 200 international centers. A cohort of approximately 5,000 subjects treated with a bare metal stent (BMS) will also be enrolled. All subjects will receive 12 months of open-label thienopyridine/antiplatelet treatment in addition to aspirin. After 12 months, subjects who are free from all MACCE or major bleeding events will be 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 will be 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 and the DAPT Study protocol and patient eligibility information are available on www.clinicaltrials.gov.

[About The Harvard Clinical Research Institute \(HCRI\)](#)

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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