EXCEL trial will determine safety and efficacy of drug-eluting stents vs. bypass surgery

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The announcement of a new clinical trial, EXCEL (Evaluation of Xience Prime versus Coronary Artery Bypass Surgery for Effectiveness of Left Main Revascularization), that will compare drug-eluting stents to coronary artery bypass graft surgery in patients with left main coronary artery disease, was made today at "Optimizing PCI Outcomes: Evolving Paradigms," a symposium presented by the Cardiovascular Research Foundation.

"While the SYNTAX trial suggested that percutaneous coronary intervention (PCI) with drug-eluting stents may be safe and effective in selected patients with left main coronary artery disease, the trial was not powered specifically to address this set of patients," said Gregg W. Stone, MD, Professor of Medicine at Columbia University Medical Center, Director of Cardiovascular Research and Education at the Center for Interventional Vascular Therapy at NewYork-Presbyterian Hospital/Columbia University Medical Center and Co-Director of the Medical Research and Education Division at the Cardiovascular Research Foundation.

In addition, since the SYNTAX trial, advances have been made drug-eluting stent technology, PCI procedural guidance, in bypass surgery techniques and optimal medical therapies.

"We are pleased to announce that EXCEL will address those limitations,

as a landmark trial which will randomize 2,500 selected patients with left main disease," Dr. Stone said. "This trial has the appropriate magnitude, geographic representation and organization to determine the optimal revascularization strategy for patients with left main coronary artery disease."

The primary endpoint is the composite incidence of death, myocardial infarction (MI) or stroke at a median follow-up duration of 3 years, powered for sequential non-inferiority and superiority testing. The major secondary endpoint is the composite incidence of death, MI, stroke or unplanned repeat revascularization. Measures of cost-effectiveness and quality of life at several time points also constitute important secondary endpoints. All patients will be followed for a total of 5 years.

The global trial, sponsored by Abbott Vascular, will be academically organized and run by four principal investigators (including 2 cardiac surgeons and 2 interventional cardiologists), the Cardiovascular Research Foundation and Cardialysis, along with many other physician scientists. Patients will be enrolled from the United States, Canada, Europe, South America (Brazil and Argentina), and South Korea. Additional countries may be added in the future.

Provided by Cardiovascular Research Foundation