OPTIMIZED DURATION OF CLOPIDOGREL THERAPY FOLLOWING TREATMENT WITH THE ENDEAVOR ZOTAROLIMUS-ELUTING STENTS IN THE REAL-WORLD CLINICAL PRACTICE (OPTIMIZE) TRIAL: RATIONALE, DESIGN AND PRELIMINARY RESULTS OF A LARGE-SCALE, RANDOMIZED, MULTICENTER STUDY

i2 Poster Contributions
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Authors: Fausto Feres, Ricardo A. Costa, Alexandre Abizaid, Instituto Dante Pazzanese de Cardiologia, Sao Paulo, Brazil, Cardiovascular Research Center, Sao Paulo, Brazil

Background: Prolonged dual antiplatelet therapy (DAPT) w/ clopidogrel+aspirin (≥1 year) has been recommended for all pts undergoing drug-eluting stent (DES) implantation to prevent late stent thrombosis (ST). Whether such measure improves safety w/ Endeavor zotarolimus-eluting stent (ZES) - a 2nd generation DES w/ phosphorylcholine (a non-thrombogenic polymer with improved biocompatibility as compared to first generation DES Cypher/Taxus), remains controversial.

Methods: The OPTIMIZE trial is a prospective, randomized, multicenter, physician-initiative study designed to evaluate the impact of short-term (3-month) vs long-term (12-month) DAPT post-ZES in the real-world clinical practice. Pts will be randomized in a 1:1 ratio at 30 sites in Brazil, and sample size (n=3,120) has been powered to demonstrated non-inferiority of short-term vs long-term (standard therapy) DAPT on the combined 1yr endpoint of: death, myocardial infarction, cerebral vascular accident, and major bleeding at 12-month follow-up. By protocol, there are no pre-specified restrictions regarding the number of lesions/vessels that can be treated with the study device. Key exclusion criteria are: STEMI presenting for primary intervention, saphenous vein grafts, and prior DES implant. Data management (event adjudication) and angiographic analysis will be independently performed at the Cardiovascular Research Center, Sao Paulo, Brazil.

Results: A total of 413 pts have been enrolled and randomized to date (enrollment ongoing since April/2010).

Conclusions: The large, prospective, randomized, multicenter, physician-initiative OPTIMIZE trial will determine the implications of the DAPT duration in real-world pts undergoing percutaneous coronary intervention with Endeavor ZES. Complete blinded results of the first 600 pts will be presented at the meeting.