BASKET-SMALL 2: FIRST PATIENT ENROLLED IN LANDMARK CLINICAL TRIAL

Thursday 12th April, 2012

This study is the first randomized clinical trial for the Drug-Eluting Balloons (DEB) with a clinical endpoint.

Basel, April, 10th. Dr. Raban Jeger from the University Hospital in Basel enrolled the first patient in the BASKET-SMALL 2 trial. The purpose of this clinical trial is comparing two different treatment options for lesions in small coronary arteries. This landmark study is the first randomized clinical trial for the Drug-Eluting Balloons (DEB) with a clinical endpoint.

A total of 649 patients will be randomized for treatment with the drug-eluting balloon SeQuent Please (B. Braun Melsungen AG) versus a latest generation drug-eluting stent (DES). The treatment with the DEB will be done according to the "DEB-only" recommendations of the German Consensus Group to avoid unnecessary stenting. This trial will further investigate the cost effectiveness of the treatment with the DEB. Compared to the treatment with a DES the time period for prevention of stent thrombosis with dual anti-platelet therapy will be reduced from one year to four weeks only.

The primary endpoint of BASKET-SMALL 2 will be the rate of major adverse cardiac events at 12 months. BASKET-SMALL 2 will investigate the treatment of de-novo stenoses in small native vessels with a diameter < 3 mm in a real-world population undergoing percutaneous coronary intervention. SeQuent Please has previously demonstrated to reduce clinical event rates compared with DES for the treatment of in-stent restenosis. Prof. Bruno Scheller (Homburg, Germany), the inventor of the DEB concept, commented: "This might be the most important trial for the DEB". The drug-eluting balloon SeQuent Please in 2010 already received a recommendation in the guidelines of the European Societey of Cardiology for the treatment of in-stent restenosis. The Basket-Small 2 clinical trial will answer the question, if the DEB will be an alternative to the DES for the treatment of de-novo lesions. A positive outcome might have a significant impact on the market by reducing the number of stent implantations and associated co-medication time for the patient.

"SeQuent Please is a very exciting development for the cardiological community. With the current clinical evidence, SeQuent Please can be considered as a reasonable alternative to drug-eluting stents for selected patients with coronary artery disease; it is the most advanced solution for the treatment of patients with ISR and it represents currently the most promising therapeutic alternative to reduce the number of unnecessary stent implantations" said the Product Group Management Director of B. Braun Vascular Systems Dr. S. Kammerzell

About B. Braun Melsungen AG

B. Braun supplies the global healthcare market with products for anesthesia, intensive care, cardiology, extracorporeal blood treatment, and surgery and provides services for hospitals, private practitioners, and homecare. By maintaining an ongoing dialogue with the daily users of its products, B. Braun gains invaluable insight which in turn has a direct influence on product development. With its innovative products and services, the company helps optimize work flows in hospitals and practices worldwide while enhancing safety for both patients and medical staff. With some 43,676 employees in 50 countries, B. Braun generated sales of EUR 4.6 billion in 2011.

SOURCE: B. Braun