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Drug-coated Balloon SeQuent® Please Shows Positive Results in Largest Randomized Clinical Trial

Munich, August 28th: Prof. Raban Jeger from the University Hospital Basel (Switzerland) reported the late breaking results from the BASKET-SMALL 2 trial at the ESC congress in Munich, Germany. BASKET-SMALL 2 represents the largest randomized clinical study with a drug-coated balloon (DCB) in the treatment of coronary arteries. The study was powered to answer the question whether drug coated balloon angioplasty – as a stent free option to treat coronary lesions - is non-inferior to permanent-implants using contemporary drug eluting stents with a clinical endpoint of major cardiac adverse events (MACE) at 12 months.

About BASKET-SMALL 2

Primary investigator Prof. Raban Jeger explained: “The aim of the BASKET-SMALL 2 trial is to assess the safety and efficacy of the paclitaxel-coated SeQuent® Please DCB in comparison to second generation drug-eluting coronary stents”.

A total of 758 patients were randomized to either DCB angioplasty with the paclitaxel coated balloon (SeQuent® Please, B. Braun Melsungen AG, Germany) or second-generation drug eluting stents (DES).

“The BASKET-SMALL 2 trial met its primary endpoint of non-inferiority of the

DCB vs. second generation DES. There was no difference in 12-month major adverse cardiovascular events (MACE) between patients receiving the permanent implant DES (7.5%) and DCB angioplasty (7.6%) for the treatment of de-novo lesions in coronary vessels with a size of less than 3.0 mm in diameter“, Prof. Jeger states.

About the Results

The co-author of the simultaneous online publication in the renowned journal The Lancet, Prof. Bruno Scheller from Saarland University, Homburg/Saar, Germany points out that “there were no acute and subacute vessel occlusions in the DCB group, proving the safety of the standalone DCB procedure, provided that the lesion is carefully prepared. After one year, ‘DCB only’ has the same event rate as modern DES, which so far has been regarded as the standard of care for this indication. In addition, the absence of a permanent implant may provide a long-term benefit of DCB therapy compared to stent implantation, what will be investigated in the long-term observation of the study.”

The result of the BASKET-SMALL 2 trial with SeQuent® Please is a very exciting news for the cardiological community” said the Senior Vice President of B. Braun Vascular Systems Gerd Wacker. “With the new clinical evidence, SeQuent Please can be considered as a reasonable “implant free” alternative to drug-eluting stents for a good number of patients with coronary artery disease; it is the most advanced solution for the treatment of patients with high bleeding risks and currently represents the most promising therapeutic alternative to reduce the number of unnecessary stent implantations.”

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