

NEWS RELEASE

**A Prospective, Randomised and Multicentre Trial Comparing Titan2 Bio Active Stent (BAS) and Xience V Drug Eluting Stent (DES): The BASE-ACS Trial.**

**EuroPCR Late Breaking Trials, Hot Line Session, Tuesday, 17<sup>th</sup> May 2011, Main Arena**

**Chairpersons: P.W. Serruys, T.Lüscher**

**Panellists: P.Agostini, R.Byrne, M.J. Kern, L.Mauri, G.Montalescot**

During the late-breaking clinical trials sessions held in the main arena during the EuroPCR 2011 congress, the results of the multicenter, prospective, randomised controlled trial "BASE-ACS" were presented by Dr Pasi Karjalainen (Heart center, Satakunta Hospital, Pori, Finland).

The "Titan2 Bio Active Stent" (BAS), from Hexacath France, coated with a drug free, biologically active compound called Titanium-Nitride-Oxide has shown to be non-inferior to the market leading drug eluting stent Xience V (Abbott, USA) with comparable rates of major adverse cardiac events (MACE) for both groups in a complex population of acute coronary syndrome patients at a 12-month follow up.

This trial randomized 827 patients to either Titan2 or the Xience V in 14 centers located in Finland, Spain, Belgium, Switzerland, UK and Indonesia.

The baseline patients, procedural and lesions characteristics were comparable in both groups.

The mean duration of clopidogrel was 8.7 months in the Titan2 group and 10.2 months in the Xience V group.

At 12 months, the cumulative incidence of primary endpoint (MACE) was 9.6% in the Titan2 group and 9.0% in the Xience V group ( $p=0.81$ ), results that met the criteria for non-inferiority. The MACE composition was also comparable between both groups with the only exception of AMI which was 5.9% in the Xience V group and 2.2% in the Titan2 group, a difference favoring significantly Titan2 ( $p=0.007$ ).

The definite stent thrombosis was also in favor of the Bio Active Stent with only 0.7% for Titan2 and 2.2% for the Xience V ( $p=0.07$ ).

The BASE-ACS trial provides new additional data confirming the efficacy and safety of the Titan2 Bio Active Stent in one of the highest risk populations: Acute Coronary Syndrome patients.

The Titan2 stent from Hexacath France, is a unique category of coronary stent which is neither a bare metal stent (BMS) nor a drug eluting stent (DES). This stent is coated with a biological active compound called Titanium-Nitride-Oxide. The mechanism of action of this compound while being less aggressive is similar to that found with several of the drugs used with (DES) whilst not carrying the side effects inherent to such drugs. The bio active coating has shown to inhibit platelet

aggregation, fibrin deposition, promote re-endothelialization and minimize inflammation. Bio Active Stents coated with Titanium-Nitride-Oxide have demonstrated efficacy reducing neointimal proliferation and late loss versus uncoated bare metal stents (BMS) in previous published studies.

Unlike drug eluting stents, the Titan2 Bio Active Stent is free of polymer, cytotoxic or cytostatic drugs which have been associated with impaired re-endothelialization explaining the compulsory need of prolonged dual antiplatelet treatment with current drug eluting stents to avoid late stent unwanted re-occlusion called thrombosis.

The BASE-ACS trial, reinforces the existing body of evidence (17 existing scientific publications) supporting the efficacy and the safety profile of the Titan2 Bio Active Stent (BAS).

#### **About Hexacath**

Based in Rueil-Malmaison (Paris area), France, Hexacath is dedicated to the development, manufacture and distribution of innovative cardiovascular products to improve patients treatments. Hexacath has expanded its product portfolio with vascular stents made from nitinol and cobalt chromium platforms coated with its patented biological active coating titanium nitride oxide. During the last 16 years, Hexacath has opened direct subsidiaries in France, Spain, Italy, UK, Belgium, Sweden, Finland, India, China, Brazil, Canada, Hong Kong, and also has a network of distributors in 30 other countries.

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