Evaluation of the safety and efficacy of the Cobra PzF NanoCoated Coronary Stent (NCS) in 1 000 all-comers, consecutive, prospective, high risk patients: The e-Cobra Registry

Luc Maillard, MD, PhD, Loic Belle, MD, Jacques Berland, MD, Axel De Labriolle, MD for the e-Cobra investigators

LM is consultant for Celonova
**Title:** Safety And Effectiveness Evaluation Of Cobra PzF™ Coronary Stent System: A French Observational Postmarketing Registry (phase 4)

**Device:** COBRA PzF™ CORONARY STENT SYSTEM

**Overall Design:** All comers Prospective, French, Multicentric, observational registry (18 sites en France)

**Registry Population:** All patients undergoing treatment of “de novo” lesions in native coronary vessels, saphenous vein graft and/or arterial bypass conduits with the COBRA PzF™ coronary stent system non indicated for a DES

**Primary Registry Objectives:** To assess the rate of MACE at twelve months. MACE is a composite clinical endpoint of cardiac death, myocardial infarction, and clinically driven target lesion revascularization

**Secondary Registry Objectives:** Definite and probable stent thrombosis (according to ARC definition) Clinical driven target vessel and lesion revascularization Mean length of dual antiplatelet therapy Proportion of patients treated with mono antiplatelet therapy

**Number of Patients:** 1000 patients during the enrollment period at the participating sites

**Follow-up:** Consecutive patient data should be collected at discharge, 30 days, 6 months and 12 months post-implant.

**Start Date:** September 2015

**Anticipated End Date:** December 2017
73 years male, anemia, hématuria, Bladding neoplasia Positive stress test at 60 watts

**Cobra 2.5x30 / POT Side RePOT**

*Clopidogrel alone 3 weeks*

*Then Aspirin 1 week*

*Surgery*
Baseline and Angiographic Characteristics
(1000 pts / 1440 stents)

- Mean age: 73.3
- Male gender: 71 pts (%)
- Diabetes: 15.6 (%) 
- Hypertension: 55.5 (%) 
- Past Smoker: 23.6 (%) 
- Dyslipidemia: 38 (%) 
- AF: 6.9 (%) 

Technical success

*Device Success:* stent delivery to the target lesion

995 pts (99,5 %)
1435 stents (99,7 %)
Conclusions

- High risk of both bleeding and thrombotic patients non indicated to receive a conventional DES
- Very severe population at high risk of complications
- Excellent preliminary results
- Current events are pending for adjudication