



## **CeloNova's COBRA PzF NanoCoated Coronary Stent (NCS) Being Studied with 14-day DAPT in High Bleeding Risk Patients**

*COBRA REDUCE Trial to be Highlighted at TCT Conference in Denver, Colorado*

**San Antonio, TX – October 26, 2017** – [CeloNova BioSciences, Inc.](#) (CeloNova), a global medical device company that offers a family of innovative products based upon its proprietary Polyzene™-F nanocoating technology, today announced that the U.S. Federal Drug Administration (FDA) approved expansion of CeloNova's ongoing clinical trial of its proprietary COBRA PzF™ NanoCoated Coronary Stent (NCS) with 14-day dual antiplatelet therapy (DAPT) in complex patients, such as those who are at high bleeding risk.\* The COBRA REDUCE trial is the world's first and only randomized control trial to assess 14-day DAPT after percutaneous coronary intervention (PCI).

"High bleeding risk patients currently have limited stent treatment options available to them primarily due to the duration of DAPT required," stated Robert Byrne, MD, Senior Physician at the German Heart Center in Munich, Germany and co-lead investigator of the COBRA REDUCE trial. "The COBRA REDUCE trial aims to provide clinical insights into optimal stent selection and eliminate the compromise between the risk of bleeding or stent thrombosis."

The COBRA REDUCE trial is evaluating whether COBRA PzF NCS with its ultra-pure, ultra-thin Polyzene-F fluoropolymer can optimize clinical outcomes with 14-day DAPT as compared to FDA-approved drug eluting stents (DES) with 3 or 6-months of DAPT. The COBRA REDUCE trial will enroll up to 996 patients across 60 centers in the U.S. and Europe. Clinical data from CeloNova's previous trial, known as the PzF SHIELD study, demonstrated that COBRA PzF NCS supports very low risk for late ischemic events and low risk for clinically driven TLR with a short, 1-month DAPT minimum.<sup>1,2</sup>

"The highly-anticipated COBRA REDUCE trial aims to expand upon the SHIELD study's exceptional clinical results and demonstrate COBRA PzF NCS as a safe and effective stent option when combined with 14-days of DAPT," said Donald Cutlip, MD, Executive Director of the Baim Institute for Clinical Research (formerly Harvard Research Institute). "I have many patients at high risk of bleeding or who have difficulty maintaining even short-term DAPT regimens. Being able to provide a therapy that is personalized to the patient is of great clinical value."

COBRA PzF NCS and the COBRA REDUCE trial will be featured in several sessions at the upcoming [Transcatheter Cardiovascular Therapeutics](#) (TCT) conference in Denver, Colorado on October 29-November 2, 2017.

"We are pleased that the COBRA PzF stent and the COBRA REDUCE trial are part of the important DAPT discussion taking place at the upcoming TCT conference," stated Jason Cone, CEO of CeloNova. "Results from this first-of-its-kind study will offer insight into how CeloNova can further improve individualized care and optimize outcomes in this patient population."

### **About the COBRA REDUCE Trial**

The COBRA REDUCE trial is a multi-center, randomized control trial of 996 patients in up to 60 centers in the U.S. and Europe. The trial is evaluating patients undergoing coronary intervention who are receiving oral anticoagulation, 14-days of DAPT\*\* after stenting with COBRA PzF NCS provides superior outcomes in bleeding (BARC  $\geq$  2) and non-inferior outcomes in composite of death, myocardial ischemia, stent thrombosis (definite and



probable), ischemic stroke vs. 3 or 6-months of DAPT\*\* after stenting with standard FDA-approved DES. For more information about this clinical trial, please visit [ClinicalTrials.gov](https://ClinicalTrials.gov) or [click here](#) to contact CeloNova directly.

### **About the COBRA PzF NanoCoated Coronary Stent**

The COBRA PzF NanoCoated Coronary Stent (NCS) is a new category of stent that allows physicians to safely and effectively treat patients who may benefit from 1-month DAPT minimum and is being studied with 14-day DAPT in the COBRA REDUCE trial.<sup>2</sup> COBRA PzF NCS combines a unique highly deliverable cobalt chromium platform with a Polyzene-F nano-thin fluoropolymer. Polyzene-F nanocoating is an ultra-pure polymer that is designed to be durable, elastic and biocompatible, acting as a barrier between metal, blood and circulating elements. COBRA PzF NCS is approved for use in the United States, Europe and the Middle East.

### **About CeloNova BioSciences**

CeloNova BioSciences, Inc., is a global medical device company that develops, manufactures and markets a family of products based upon its novel Polyzene-F nanocoating technology. The next generation nanocoating is the result of years of rigorous scientific research and German-engineering, and has been extensively published in numerous academic articles to date. For additional information about CeloNova BioSciences, please visit the company website at [www.celonova.com](http://www.celonova.com).

---

Forward-looking statements contained herein are based on estimates and assumptions of CeloNova management and are believed to be reasonable, though they are inherently uncertain and difficult to predict.

1. Cutlip D, Garrat K, Novack V, et al. 9-Month Clinical and Angiographic Outcomes of the COBRA Polyzene-F NanoCoated Coronary Stent System. *JACC Cardiovasc Interv.* 2017;10(2):160-167.
2. Levine G, Bates E, Bittl J, et al. 2016 ACC/AHA Guideline Focused Update on Duration of Dual Antiplatelet Therapy in Patients with Coronary Artery Disease. *Circulation.* 2016;134(10):e123-55.

\*High bleeding risk patient population includes patients with ischemic symptoms (stable or unstable angina or NSTEMI<sup>†</sup> without thrombosis of the target lesion on coronary angiography) or evidence of myocardial ischemia undergoing PCI. Patients receiving oral anticoagulation currently or with a new indication for oral anticoagulation.

\*\*DAPT + OAC

<sup>†</sup>NSTEMI, 6-months DAPT; limited to 40 patients implanted with COBRA PzF NCS in the US

Indications for Use: The COBRA PzF NanoCoated Coronary Stent System is indicated for improving coronary luminal diameter in patients, including patients with diabetes mellitus, with symptomatic ischemic heart disease due to de novo lesions in native coronary arteries. The COBRA PzF NanoCoated stent is intended for use in patients eligible for percutaneous transluminal coronary angioplasty (PTCA) with reference vessel diameter (RVD) of 2.5-4.0mm and lesion length of  $\leq 24$ mm.

[Click here](#) for IMPORTANT SAFETY INFORMATION

Contraindications: The COBRA PzF NanoCoated Coronary Stent System is contraindicated for use in patients with known sensitivity to L605 cobalt-chromium alloy (including its major elemental constituents cobalt, chromium, tungsten, and/or nickel). Contraindication to coronary artery stenting: Patients with lesions that may prevent complete inflation of an angioplasty balloon, proper placement of the delivery device or stent deployment, Patients are unable to receive recommended anti-platelet and/or anti-coagulant therapy. Known severe reaction to contrast agents that cannot be adequately pre-medicated prior to the COBRA PzF NanoCoated Coronary Stent System placement procedure. See the Instructions for Use for complete information regarding the procedure, indications for use, contraindications, warnings, precautions, and potential adverse events. Rx Only