



Data Presented at EuroPCR 2017 Reinforce Positive Clinical Benefits of CeloNova BioSciences' COBRA PzF™ NanoCoated Coronary Stent

PARIS – May 23, 2017 – CeloNova BioSciences, Inc. (CeloNova) announced positive clinical results from two multicenter trials reinforcing the safety and effectiveness of its first-in-class COBRA PzF™ NanoCoated Coronary Stent (NCS). Updated results from both the post market e-COBRA study and the pivotal PzF™ SHIELD clinical trial were presented this week at the annual EuroPCR Scientific Program in Paris.

Preliminary data was presented from the multicenter, prospective e-COBRA study, which evaluated 835 real world and all-comers complex patients with heart disease from 17 centers in France, demonstrating a low rate of major adverse cardiac events (MACE) in patients receiving the COBRA PzF NCS at 30 days post-implant (2.5 percent). MACE related events included myocardial infarction, target lesion revascularization and cardiac death. Additionally, the trial showed a low definite and probable stent thrombosis (0.8 percent) at 30-days post-intervention with the COBRA PzF NCS.

Approved this year by the U.S. Food and Drug Administration (FDA) to treat patients with symptomatic ischemic heart disease, including those with diabetes mellitus, COBRA PzF NanoCoated Coronary Stent allows physicians to safely and effectively treat their patients who benefit from a short, minimum duration of 1-month dual antiplatelet therapy (DAPT) according to ACC/AHA and ESC Guidelines. While DAPT is known to prevent stent thrombosis and myocardial infarction following a stenting procedure, prolonged DAPT substantially increases the risk of bleeding and mortality, especially among the elderly patient population and those with co-morbidities and high bleeding risk.¹

“The e-COBRA registry provides a comprehensive look at the application of the COBRA PzF NCS in real world and complex patients with heart disease,” said Dr. Luc Maillard, MD, principal investigator and Director of the Department of Cardiology, Clinique Axiom, Aix-en-Provence, France. “We are pleased with the 30-day results, as they continue to confirm the overall safety and effectiveness of this novel stent system, specifically in patients who are at high risk of bleeding and therefore require a shortened DAPT regimen.”

Additionally, results from the optical coherence tomography (OCT) cohort of the pivotal PzF SHIELD clinical trial, presented this week in a poster session, demonstrated excellent device performance associated with the COBRA PzF NCS, with no adverse arterial response at 9 months post-intervention. Of the 296 patients enrolled in the global, prospective PzF SHIELD trial, 75 patients took part in the official OCT cohort of the study. The OCT analysis at 9-month follow-up, showed neointimal coverage was nearly completed, and uncovered struts and incomplete strut apposition (ISA) were only 0.3% and 0.1%, respectively. No late-acquired ISA, strut fracture, nor intra-stent thrombus was detected at 9-month follow-up.

The COBRA PzF NCS combines a unique, highly deliverable cobalt chromium platform design with a proprietary Polyzene-F™ nano-thin polymer. Polyzene-F nanocoating is designed to be durable, elastic and biocompatible, acting as a barrier between metal, blood and circulating elements. The ultra-pure, nano-thin characteristics of Polyzene-F nanocoating have shown thrombo-resistance, reduced inflammation and rapid and complete strut coverage when tested in pre-clinical studies.^{2, 3, 4, 5, 6, 7}

“We are encouraged by the excellent results from both studies evaluating our COBRA PzF NCS, as they further solidify the robust clinical benefits associated with this new category of stent, which has the potential to transform the way we approach the treatment of coronary artery disease,” said Jason Cone, CEO, CeloNova BioSciences. “With an active presence in Europe, we continue to gain traction in the U.S. market, as we work with physicians across the country to incorporate the COBRA PzF NCS into their treatment strategies for the many patients who would benefit from a minimum 1-month DAPT regimen.”

CeloNova is continuing to study the COBRA PzF NCS in the COBRA REDUCE trial, which began enrollment in February 2016. The trial will evaluate whether the stent can help reduce bleeding as compared to DES, by shortening the duration of DAPT to 14 days in patients who are on oral anticoagulants and require treatment for coronary artery disease.

The COBRA PzF NCS was awarded FDA approval in 2017 and CE Mark approval in 2012. For more information on the stent, including important patient safety information, please visit www.celonova.com.

About the COBRA PzF NanoCoated Coronary Stent

The COBRA PzF NanoCoated Coronary Stent combines a unique highly deliverable cobalt chromium platform with a Polyzene-F nano-thin polymer. Polyzene-F nanocoating is a proprietary, ultra-thin polymer that is designed to be durable, elastic and biocompatible, acting as a barrier between metal, blood and circulating elements. The COBRA PzF NanoCoated Coronary stent 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 <http://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.

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¹ Généreux P, Giustino G, Witzenbichler B, et al. Incidence, Predictors, and Impact of Post-Discharge Bleeding After Percutaneous Coronary Intervention. JACC Cardiovasc Interv. 2015;66:1036-45. doi: 10.1016/j.jacc.2015.06.1323.

² Koppara T, Sakakura K, Pacheco E, et al. Preclinical evaluation of a novel polyphosphazene surface modified stent. *International Journal of Cardiology*. 2016; 222: 217-225. doi: 10.1016/j.ijcard.2016.07.181.

³ Mrowietz C, Franke R, Seyfert U, et al. Haemocompatibility of polymer-coated stainless steel stents as compared to uncoated stents. *Clinical Hemorheology and Microcirculation*. 2005; 32:89–103.

⁴ Richter G, Stamp U, Stamp S, et al. A New Polymer Concept for Coating of Vascular Stents Using PTFEP (poly(bis(tri uoroethoxy)phosphazene) to Reduce Thrombogenicity and Late In-Stent Stenosis. *Investigative Radiology*. 2005; 40(4):210-218.

⁵ Radeleff B, Thierjung H, Stampfl U, et al. Restenosis of the CYPER-Select, TAXUS-Express, and Polyzene-F NanoCoated Cobalt-Chromium Stents in the Minipig Coronary Artery Model. *Cardiovasc Intervent Radiol*. 2007 DOI 10.1007/s00270-007-9243-y

⁶ Adapted from Claudia R. Gries, Univ. of Heidelberg. Doctoral dissertation, 2001 (Data on File)

⁷ DATA ON FILE (TRD 0007)