CeloNova Announces Enrollment Completion of World's First Randomized Control, 14-Day DAPT Trial

First-of-its-kind study evaluates ultra-short DAPT in PCI patients at high bleeding risk compared to drug-eluting stents

San Antonio, TX – June 1, 2020 – 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 it has successfully completed enrollment of the COBRA REDUCE randomized control trial evaluating the safety and efficacy of the COBRA PzF NanoCoated Coronary Stent (NCS) with 14-day dual antiplatelet therapy (DAPT)* compared to FDA-approved drug-eluting stents (DES) with 3 or 6 months DAPT in 996 patients at high bleeding risk (HBR) across 60 global sites.

COBRA REDUCE is the world's first and only study to evaluate 14-day DAPT in HBR patients. All enrolled patients are on oral anticoagulation therapy (OAC), a major bleeding criteria, per the Academic Research Consortium for High Bleeding Risk (ARC-HBR), which is known to increase bleeding and subsequent complications.[1,2] Many patients also share a second major or minor bleeding criteria, such as recent ischemic stroke, cancer, anemia, or severe or end-stage chronic kidney disease.

"The outcome of the COBRA REDUCE trial represents a potentially game-changing approach to treating high bleeding risk patients," states Robert A. Byrne, M.D., Professor of Cardiovascular Research at the RSCI University of Health Sciences in Dublin, Ireland and Co-Principal Investigator of the trial, which is being coordinated by the ISAR Research Center in Munich, Germany. "Physicians are still in need of a safe and effective treatment option for their most urgent or non-compliant patients who are at high bleeding risk. Data from this study evaluating COBRA PzF NCS with 14-day DAPT will provide valuable information on treatment options for this underserved patient population."

"DAPT reduction strategies are of critical importance to the medical community," explained Roxana Mehran, M.D., Professor of Medicine and Director of Interventional Cardiovascular Research and Clinical Trials at the Zena and Michael A. Weiner Cardiovascular Institute at Mount Sinai School of Medicine. "We anxiously await the results of the COBRA REDUCE trial as it will play an important role regarding this unmet need."

"The bleeding risk of a PCI patient increases considerably when you factor in major criteria such as use of oral anticoagulants, recent stroke, or undeferrable surgery post-PCI. Unfortunately, these patients and others are excluded from participating in clinical studies due to their higher risk profile," stated Carl St. Bernard, President and Chief Executive Officer of CeloNova. "COBRA REDUCE's rigorous and randomized approach is designed to assess such 'worst-case' clinical bleeding scenarios and the impact of significantly fewer medications with COBRA PzF NCS compared to market-leading DES."

COBRA PzF NCS is the first non drug-eluting, nanocoated coronary stent clinically proven to help physicians safely and effectively treat patients who may benefit from short, 1-month minimum dual antiplatelet therapy (DAPT).[3,4] COBRA PzF NCS is nanocoated with Polyzene-F, a revolutionary surface coating that acts as a barrier between the device, intimal surface and circulating elements in the blood. It has demonstrated anti-inflammatory and thrombo-resistant properties and significantly faster, higher quality healing compared to market-leading DES in preclinical studies.[†5]

"We believe that Polyzene-F's unique healing properties holds tremendous clinical value to physicians and their patients," stated Mr. St. Bernard. "We look forward to learning more in the coming months about its role in safely and effectively treating patients with COBRA PzF NCS when combined with ultra-short 14-day DAPT."

About COBRA REDUCE Randomized Clinical Trial

The COBRA REDUCE randomized control trial enrolled high bleeding risk patients undergoing coronary intervention who are receiving oral anticoagulation with a non-vitamin K oral anticoagulant (NOAC) or a vitamin antagonist. The trial is designed to assess superiority in terms of bleeding reduction (BARC ≥ 2) and non-inferiority in the composite of death, MI, stent thrombosis, and ischemic stroke in patients assigned to 14-days DAPT* after stenting with COBRA PzF NCS vs 3 or 6-months of DAPT after stenting with standard FDA-approved DES.

About CeloNova BioSciences, Inc.

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 engineering and has been extensively published in numerous academic articles to date. For additional information about CeloNova, please visit our website at www.celonova.com.

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 ≤24mm. Click here for IMPORTANT SAFETY INFORMATION. Rx only.

* DAPT + OAC

† AS DEMONSTRATED IN PRECLINICAL STUDIES. Correlation between bench testing, animal studies and humans have not been determined.

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2. Genereux P, Giustino G2 Witzenbichler B, et al. Incidence, Predictors, and Impact of Post-Discharge Bleeding After Percutaneous Coronary Intervention. JACC. 2015;66:1036-45.
3. Levine G, 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.
4. 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.
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