CeloNova Biosciences Receives FDA Approval of COBRA PzF™ Stent System

Nano-Coated Stent Provides Excellent Safety Profile, Very Low Restenosis and Short 30 Day Dual Antiplatelet Therapy (DAPT) Regimen

SAN ANTONIO, TX. – March 1, 2017 – CeloNova BioSciences, Inc. (CeloNova) today announced that it has received U.S. Food and Drug Administration (FDA) approval of its first-in-class COBRA PzF™ NanoCoated Coronary Stent System. Regulatory approval of the novel stent system was based on findings from the pivotal PzF SHIELD clinical trial, which successfully met its primary safety and effectiveness endpoints at 9-month follow-up, demonstrating no stent thrombosis and low clinically driven target lesion revascularization (TLR) of 4.6 percent.[i] Coated with a proprietary nano-thin polymer that is designed to be highly biocompatible, the COBRA PzF stent requires a minimum 30-day dual antiplatelet therapy (DAPT) regimen following intervention.[ii]

The COBRA PzF stent is indicated for improving coronary luminal diameter in patients, including those with diabetes mellitus, with symptomatic ischemic heart disease due to de novo lesions in native coronary arteries with reference vessel diameter (RVD) of 2.5-4.0mm and lesion length of ≤24mm.

"There continues to be an unmet clinical need for patients who may not be candidates for drug-eluting stents or longer term dual antiplatelet therapy," said Donald Cutlip, M.D., principal investigator and professor of medicine at Beth Israel Deaconess Medical Center and Harvard Medical School in Boston. "Given the observed low rates of stent thrombosis and target lesion revascularization that need to be confirmed in future studies, the COBRA PzF stent system may hold potential unique benefit for these patients."

COBRA PzF combines a unique, highly deliverable cobalt chromium platform design with a proprietary Polyzene-F nano-thin polymer. When tested in pre-clinical studies, the ultra-pure, nano-thin characteristics of Polyzene-F nanocoating have shown thrombo-resistant, anti-inflammatory and rapid healing effects.[iii, iv, v,vi]

"The stent's Polyzene-F nanocoating is truly cutting-edge with good biocompatibility," said Renu Virmani, M.D., President of the CV Path Institute in Gaithersburg, MD, the leading nonprofit medical research and education organization offering histology services studying cardiac and vascular diseases. "We continue to observe its thrombo-resistant and rapid endothelialization properties, which give us confidence to believe that COBRA PzF is a good stent option for patients who are at a high-risk for bleeding following coronary intervention." [vi. *]

"Today's FDA approval of the COBRA PzF Stent System marks a significant milestone for our company, as we bring a new category of stent with proven clinical promise to the U.S. market," said Dennert Ware, Executive Chairman and acting CEO, CeloNova Biosciences. "We look forward to working with physicians throughout the country to integrate COBRA PzF into their care plans for the growing number of patients who would benefit from very low stent thrombosis, low TLR and a minimum 30 day DAPT regimen."

Currently, the company is further studying the COBRA PzF stent in the COBRA REDUCE trial, which began enrollment in February 2016. This randomized controlled trial will evaluate whether the COBRA PzF stent, with its novel Polyzene-F nanocoating and advanced thin-strut design, can help reduce bleeding as compared to drug eluting stents, by shortening the duration of DAPT to 14 days in patients who are at high-risk for bleeding and require treatment for coronary artery disease.

The COBRA PzF NanoCoated Coronary stent was awarded CE Mark approval in 2012 and launched in Europe and the Middle East in 2013.

For more information on the COBRA PzF 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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[i] Cutlip et al. Journal of the American College of Cardiology (JACC): Cardiovascular Interventions. 2017; V10; I2: 160-167.
[ii] 2016 ACC/AHA Guideline Focused Update on Duration of Dual Antiplatelet Therapy in Patients With Coronary Artery Disease. Accessed on February 16, 2017 at http://dx.doi.org/10.1016/j.jacc.2016.03.513.
[iii] 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.
[iv] Sakakura K, Cheng Q, Fumiyuki O, et al. Thrombogenicity of Novel Polyphosphazene Surface-modified Coronary Stent Compared To Standard Bare Metal Stent in Swine Shunt Model. Journal of the American College of Cardiology. 2013; 62(18): B244-B245. doi:10.1016/j.jacc.2013.08.1559 (28 day ex vivo swine arterio-venous shunt model)
[v] Tamburino et al. Interventional Cardiology. 2011; 3: 451-460.
[vi] Data on File
* Correlation between bench testing, animal studies and humans have not been determined.