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FDA APPROVES NANOCOATED CORONARY STENT SYSTEM USING DSG'S ECLINICAL SYSTEMS

March 23, 2017 -MALVERN, PA - CeloNova Biosciences, Inc., leveraging products and services provided by DSG, Inc., a leading eClinical software technology and data management global services firm, recently received US Food and Drug Administration (FDA) approval of its first-in-class COBRA PzF™ NanoCoated Coronary Stent System.

The COBRA PzF stent, which is coated with a biocompatible proprietary nanothin polymer, requires a minimum 30-day dual antiplatelet therapy regimen after intervention, according to a press release issued by the company.

"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 needs to be confirmed in future studies, the COBRA PzF stent system may hold potential unique benefits for these patients."

The stent is designed to improve coronary luminal diameter in patients with symptomatic ischemic heart disease, including diabetics, due to *de novo* lesions in native coronary arteries with reference vessel diameter of 2.5 mm to 4 mm and lesion length 24 mm or less, according to the release.

"DSG's eCaseLink EDC allowed CeloNova Biosciences to manage subject enrollment and capture data efficiently in the global clinical trial of the COBRA PzF Coronary Stent. DSG handled all aspects of clinical study data management from database setup through lock. DSG's data management team added value to their eCaseLink EDC solution by providing CeloNova Biosciences with clean, timely, and cost-effective deliverables and week-to-week metrics showing their own progress throughout the lifespan of the study," said Mark Barakat, MD, Senior Director, Medical Affairs at CeloNova. "DSG's clinical trial software and service experience really shined. They expertly customized databases, designed eCRFs with smart data validation and verification programming, gave us comprehensive data management plans, performed ongoing review of data and logic checks, data management, data encoding, reconciliation of serious adverse events, and database lock, submission and archiving."

"Cardiovascular implantable electronic device trials remain an important therapeutic area of work for DSG," said Tony Varano, CEO. "Over the past 25 years in business we have played a critical role in improving the quality of life for many NYHA class III and similar patients. The drive to help people

remains at the heart of what we do every day. We thank the fantastic team at CeloNova for making DSG a part of their wonderful success story."

DSG eClinical Systems have been used in over a hundred approvals by worldwide regulatory authorities to date.

About DSG

DSG, Inc. supports clinical data capture and management with a proprietary, organically integrated suite of award-winning user-friendly technology solutions, including flagship eCaseLink™ EDC, Risk-Based Monitoring, eSource, ePRO, IWRS Randomization-Clinical Supply Systems, Drug Safety System, and CTMS. Since 1992, DSG has successfully supported thousands of clinical trials for over 400 companies and 25,000 sites across 93 countries, headquartered in Malvern, PA with additional offices in the US and Asia: www.dsg-us.com.