

M2D2 Participation Application

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I. Overview of Product

Product Name : PowerStent® Drug Eluting Stent

Medical Issue Addressed: Coronary Artery Disease (CAD) is the number one killer in the United States since 1900 and still remains the most common cause of death in the western world despite the therapeutic advances. Drug Eluting Stent (DES) is the major therapies for CAD with over two millions stents implanted annually. In-stent Restenosis and late-stage Thrombosis, the two major problems associated with non-biodegradable polymer occurred in existing drug eluting stents derive a need for a new generation DES made or coated by biodegradable materials. However, all current biodegradable materials used in making DESs are not successful due primarily to their severe inflammatory response to stented arterial walls. PowerStent® drug eluting stent—a 2nd generation of drug eluting stent developed by VasoTech, Inc under NIH Fast-track SBIR funding is aimed at overcoming these medical issues.

Technical Description of Device: PowerStent is the combination of an inflammatory-free biodegradable polymer, a potent anti-restenosis drug formulation and a featuring designed drug delivery platform. In PowerStent, the specifically formulated BioDe® polymer will not only prevent the polymer-associated long-term issues such as late-stage thrombosis existed in current non-biodegradable stents, but also eliminate the short-term inflammatory responses associated with the polymer's degradation. The Combo® drug formulation can block both signal transduction ways of Rapamycin and Paclitaxel and, therefore, the anti-restenosis effects of PowerStent theoretically should be better than any single Cypher® or Taxus® stent has. Finally, the featuring designed VasoTech® metal stent provides PowerStent a most deliverable and conformable platform with sufficient supporting force for diseased arteries.

Current Stage of Product Development: The product is currently in its late stage development. VasoTech has finalized its design, performed preliminary bench and preclinical testing and will further performing-test its efficacy and safety in larger animal model under NIH SBIR funding. The purpose of this proposal is to request bridge funds from M2D2 to initiate its manufacturing and clinical trial.

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II. Medical Significance

Medical Problems Addressed By the Device: Coronary Artery Disease (CAD) is the number one killer in the United States since 1900 and still remains the most common cause of death in the Western world despite the therapeutic advances. Approximately 14 million Americans have CAD, 500,000 people die from acute myocardial infarction, and one million more survive but with a 1.5 to 15 times greater risk of mortality or morbidity than the rest of the population each year. The annual health care cost for the disease is in excess of \$112 billion. The current level of certain predictors of heart disease risk, such as obesity, diabetes, and smoking suggests that this will continue to be a significant public health problem for the foreseeable future. Therefore, the development of a new Drug Eluting Stent such as PowerStent can not only provide clinical cardiologist an effective device for those 14 million Americans who suffered from the disease, but also can significantly reduce patient's health care cost, is extremely significance.

Current Status and Potential Effectiveness: The proposed PowerStent® drug eluting stent is the 2nd generation of drug eluting stent. Currently, we have confirmed device's feasibility through series experiments including both in-vitro bench testing and in-vivo animal studies. All these preliminary work are attached in the Appendix. Since the beginning of this years, we start to fully explore the safety and efficacy of the device according to FDA regulatory guidance under NIH funding. VasoTech plans to initiate the clinical trial around the end of year 2009 with the bridge funding from M2D2.

PowerStent® drug eluting stent (figure 1) is designed to overcome those existing problem in current drug eluting stents. Its features and capabilities exceed any currently commercially available and investigational stents. The stent is composed of three major technologies breakthrough: 1) an inflammatory-free biodegradable polymer, 2) a potent anti-restenosis drug formulation, and 3) a featuring designed drug delivery platform. In PowerStent, the specifically formulated BioDe® polymer will not only prevent the polymer-associated long-term issues such as late-stage thrombosis existed in current non-biodegradable stents, but also eliminate the short-term inflammatory responses associated with the polymer's degradation. The Combo® drug formulation can block both signal transduction ways of Rapamycine and Paclitaxel and, therefore, the anti-restenosis effects of PowerStent theoretically should be better than any single Cypher® or Taxus® stent has. Finally, the featuring designed VasoTech® metal stent provides PowerStent a most deliverable and conformable platform with sufficient supporting force for diseased arteries. All these potential effectiveness of the device for coronary arterial occlusion has been preliminarily confirmed by in-vivo pig coronary arterial implantation studies.

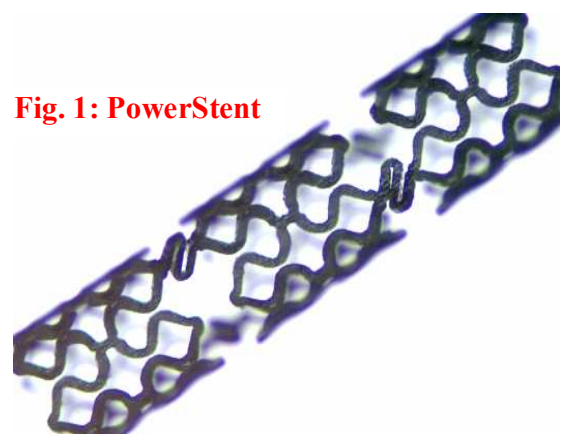


Fig. 1: PowerStent