SYNERGY™ Bioabsorbable Polymer Drug-Eluting Stent System

Background Information

What is the SYNERGY™ Stent?

- The SYNERGY Bioabsorbable Polymer Drug-Eluting Stent System (BP-DES) is the first and only stent with bioabsorbable polymer coating which is FDA-approved for the treatment of coronary artery disease.

- The drug coating and the polymer – which holds the drug to the stent – are fully absorbed shortly after the drug completes elution at three months.

- This stent platform is designed to promote more rapid endothelialization and better healing as a result of eliminating long-term polymer exposure.

- The bioabsorbable polymer coating on the SYNERGY Stent outer surface is approximately four microns thick. In comparison, a human hair is about 70 microns thick.

- The SYNERGY Stent is a result of more than 10 years of physician input to Boston Scientific engineers and designers about how best to address the unmet clinical needs associated with drug-eluting stents.

Stent Options before SYNERGY:

- To date, the two most common types of stents available in the U.S. are bare-metal stents (BMS) and drug-eluting stents (DES). Both types of stents are metal mesh tubes inserted during a minimally invasive procedure to open a blocked artery.

- DES include a drug embedded in a polymer coating. The drug is released over time to help prevent the artery from re-narrowing.

- While DES offer clear benefits, the polymer remains on the stent after the drug is delivered. Long-term exposure to polymer has been shown to cause inflammation, which delays healing in the affected artery and has been associated with complications.

- Creating a stent that gradually releases medicine without long term polymer exposure has been a research priority for scientists and clinicians.

SYNERGY Clinical Results

- The SYNERGY Stent has been extensively studied in clinical trials:
    - The SYNERGY Stent demonstrated exceptional outcomes in the EVOLVE II Clinical Trial, the first successful U.S. pivotal trial of a bioabsorbable polymer technology. In the most complex patient population ever studied in a U.S. pivotal stent trial, the SYNERGY Stent reported no definite stent thrombosis (ST) after 24 hours.

    - Four year data from the EVOLVE Trial demonstrated a very low target lesion revascularization (TLR) rate of 1.1 percent and a continued 0 percent ST rate.

    - Independent intracoronary optical coherence tomography (OCT) studies demonstrated excellent early healing with the SYNERGY Stent, showing complete coverage as early as 30 days.

About Coronary Artery Disease

- Coronary artery disease is a narrowing of blood vessels that supply blood and oxygen to the heart. Patients with coronary artery disease may experience pain, shortness of breath and fatigue. They may also be at risk for a heart attack.[i]

- One treatment option is the placement of a stent in the artery to help keep it open and allow the blood to flow more freely.

SYNERGY Bioabsorbable Polymer Stent System Regulatory Status

- The SYNERGY Stent received CE mark in late 2012 and became commercially available in select CE mark countries in 2013. The SYNERGY Stent is available for sale in countries where CE mark is the

regulation in force. It was approved for use in the U.S. on October 5, 2015. Download an image of the SYNERGY Stent.

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[i] U.S. National Library of Medicine (NLM). A services of the National Institutes of Health (NIH); http://www.nlm.nih.gov/medlineplus/ency/article/007115.htm. Accessed August 14, 2015.