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Concept Medical

Concept Medical Inc. Granted "Breakthrough Device Designation" From FDA for Its MagicTouch Sirolimus Coated Balloon

Concept Medical Inc. (CMI) has been granted 'Breakthrough Device Designation' from the US Food and Drug Administration (FDA) on 30th April 2019 for MagicTouch, its sirolimus drug-coated balloon (DCB) catheter, for the treatment of coronary in-stent restenosis (ISR).

Tampa, Florida, May 2, 2019

Concept Medical Inc. (CMI) has been granted 'Breakthrough Device Designation' from the US Food and Drug Administration (FDA) for MagicTouch, its sirolimus drug-coated balloon (DCB) catheter, for the treatment of coronary in-stent restenosis (ISR).
In-Stent Restenosis (ISR) is the gradual re-narrowing of a stented coronary artery lesion, due to subsequent tissue proliferation at the stented site. ISR is observed in about 10% of patients who undergo a drug eluting stent (DES) implantation and in >30% of patients who undergo bare-metal stent (BMS) implantation. Such patients, who come back with re-clogging of the coronary arteries following an earlier procedure of a bare metal or a drug-eluting stent implant, are candidates for treatment with the MagicTouch.

The goal of the FDA 'Breakthrough Devices Program' is to provide patients and health-care providers in the US with timely access to these medical devices by speeding up their development, assessment, and review, while preserving the statutory standards for premarket approval, 510(k) clearance, and De Novo marketing authorization, consistent with the Agency's mission to protect and promote public health.

The Breakthrough Devices Program offers manufacturers an opportunity to interact with the FDA's experts through several different program options to efficiently address topics as they arise during the premarket review phase, which can help manufacturers receive feedback from the FDA and identify areas of agreement in a timely way. Manufacturers can also expect prioritized review of their submission. Under the program, FDA will provide CMI with priority review and interactive communication regarding device development and clinical trial protocols, through to commercialization decisions.

"I was very impressed by the angiographic and IVUS results of MagicTouch in ISR in the Brazil-ISR study. I didn't encounter any safety or toxicity concerns in the course of the trial" said Dr Alexandre Abizaid, the Chief of Coronary Interventions at Institute Dante Pazzanese de Cardiologia in Sao Paulo, Brazil.

"It took years of research to master the Limus drug delivery platform technology to devise an innovative product like MagicTouch" said the Founder President and CEO, Dr. Manish Doshi. "MagicTouch has been commercially used in >25,000 patients worldwide, with highest usage in patients in the European region. Besides commercial sales, MagicTouch has been evaluated extensively in clinical studies conducted in countries like UK, Italy, and Brazil. MagicTouch is also commercially available for patients in India. We are now excited to begin our work with the US FDA in bringing our technology to serve the patients in USA", Manish added.

“The FDA's designation of MagicTouch for the Breakthrough Device Program will allow CMI to meet its ambition to provide this promising technology and innovative treatment for ISR patients in the USA. Our confidence in MagicTouch emanates from the positive feedback that we are receiving from the users of our product from current and ongoing commercial sales of MagicTouch in many European countries" said cardiologist Dr. Kiran Patel, Chairman of CMI. He also added, "CMI is encouraged that the selection of MagicTouch, with its unique drug delivery technology, for the FDA's Breakthrough Device Program may allow timely access of this promising new technology to the US patients with coronary ISR with a potential to provide safe and effective treatment”.

About Concept Medical Inc:

CMI is headquartered in Tampa, Florida and has operational offices in The Netherlands, Singapore and Brazil. The manufacturing premises are located in India. CMI specializes in developing drug- delivery systems and has unique and patented technology platforms that can be deployed to deliver any drug / pharmaceutical agent across the luminal surfaces of blood vessels.

CMI has received >100 patents grant (in 11 patent family) in various countries. Patents include process, product and apparatus patents in field of nanocarrier based drug delivery. The Company has commercially available products outside of the United States in peripheral vascular indications like below-the-knee (BTK), Arterio-Venous Fistula (AVF), Superficial Femoral Artery (SFA) artery diseases. CMI also has a significant pipeline of products under active development.

About MagicTouch:

MagicTouch is the only commercially available Sirolimus coated balloon with CE approval in the world. It has been used in >25,000 patients in major global markets. The unique drug delivery technology platform coated onto MagicTouch balloon is designed to deliver sub-micron particles of Sirolimus which are then encapsulated in a biocompatible drug carrier. The drug and carrier complex are designed to reach the inner layers of the vessel walls and act as a reservoir for long-term release of Sirolimus. CMI has accumulated significant clinical data and initiated many ambitious ongoing / upcoming clinical programs for MagicTouch.