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Meril Life Sciences receives CE mark for Bioresorbable Scaffold

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Meril's MeRes100 has received DCGI approval and CE (European Conformity) marking

Meril Life Sciences announced that MeRes100 BRS, its indigenously designed and manufactured scaffold, became the first thin-strut bioresorbable scaffold to receive CE marking.

Meril's MeRes100 has received both DCGI and CE (European Conformity) marketing approval. Backed by rigorous research and encouraging clinical trial data, MeRes100 is planned to be launched in various countries, including European countries, later this year.

Cardiovascular diseases (CVDs) such as coronary artery disease are the biggest cause of mortality in India and there is evidence that CVD begins to affect Indians at least a decade earlier than it affects Europeans. Stents are widely accepted as a primary intervention for treating coronary artery disease and associated lesions or blockages due to fat deposition and plaque formation. Metallic drug eluting stents (DES) have a metallic platform with drug coating. The role of a DES is to provide temporary scaffolding to the blockage or lesion site and also to deliver a drug to facilitate healing. After healing is complete, the metallic stent remains in the body as a permanent implant. Such metallic DES are associated with incremental risk of clinical or adverse events: on an average, 2-3% of patients with metallic DES implants may require a repeat intervention year on year. MeRes100 was designed as a solution to bridge this gap between the temporary treatment horizon for opening a blockage and the undesirably permanent nature of a metallic DES implant.

Across clinical trials, MeRes-1 (the first in-human study conducted in India) and MeRes-1 Extend (conducted in Brazil, Europe and Asia), MeRes100 BRS has shown long-term positive safety and sustained efficacy outcomes for patients with coronary artery disease in treatment of de-novo coronary artery lesions. Its proprietary hybrid-cell design has optimal strut thickness and improved crossing profile for better deliverability.

The scaffold strut thickness is 100 microns, which leads to faster endothelialization and healing, resulting in lower risk of scaffold thrombosis. Both trials have also validated this benefit, by demonstrating zero scaffold thrombosis and very low major adverse cardiac event (MACE) rate of 1.87% with MeRes100 BRS in MeRes-1 Study at three years and 1.61% MACE in MeRes-1 Extend Study at two years.

The data was recently presented by Co-principal Investigator of MeRes-1 Study, Dr. Praveen Chandra, Chairman of Interventional Cardiology at Medanta – The Medicity, Gurgaon, India, who commented, “The cumulative major adverse cardiac event (MACE) rate, which includes cardiac death, heart attack, and Ischemia-driven TLR/ repeat procedures, is better at 3 years for MeRes100 as compared to previous generation BRS technology.”

“First generation bioresorbable scaffolds have not shown the most favourable results at long term horizons. The next generation bioresorbable scaffold with reduced strut thickness, improved profile for better deliverability, faster degradation and possibly lower scaffold thrombosis is a revolutionary advance in interventional cardiology” said Principal Investigator for the MeRes-1 trial Dr. Ashok Seth, Chairman of Fortis Escorts Heart Institute in New Delhi, India.

Sanjeev Bhatt, Vice President-Corporate Strategy, Meril Life Sciences said, “Intensive research and development efforts exerted by 150 scientists, chemists, engineers and researchers at Meril’s research facilities in Vapi, Gujarat over five years have culminated to multiple regulatory approvals and over seven patents. This is the first time three-year data of a next generation thin strut BRS has been presented in the world with consistency in safety and efficacy (0% stent thrombosis and low MACE rate of 1.87%) – a truly proud moment for Meril Life Sciences. We have certainly created a device with excellent characteristics, which promises to be effective as well as safe when implanted for the treatment of coronary artery disease.”

Long-term three-year follow-up data of the MeRes-1 study, published in EuroIntervention, which includes a combination of clinical follow-ups as well as angiographic and intravascular imaging demonstrated the high efficacy of MeRes100 at two years with low late lumen loss (0.24±0.34mm), virtually complete strut coverage (99.24%) and sustained mean flow area with very low percentage volume obstruction (7.5%). Strut coverage indicates the extent of healing; it is a key measure of efficacy and MeRes100 was designed with a thinner strut and highly biocompatible material to ensure high strut coverage, which also indicates lowered risk of adverse cardiac events and also reduced probability of repeat procedures.