PRESS RELEASE

For immediate release

MeRes100 BRS– the world’s first Thin Strut Sirolimus-Eluting Bioresorbable Vascular Scaffold shows very long-term positive safety and efficacy outcomes for patients with coronary artery disease

Very long-term follow-up data on the MeRes100 bioresorbable scaffold (BRS) demonstrated zero scaffold thrombosis and very low major adverse cardiac event rates up to three years

6 June 2019 – Data from the MeRes-1¹ and MeRes-1 Extend² clinical trials demonstrated sustained efficacy and safety for the recently CE-approved MeRes100 BRS– a next generation, Thin Strut Sirolimus-Eluting Bioresorbable Vascular Scaffold for the treatment of de-novo coronary artery lesions. Both trials demonstrated zero scaffold thrombosis and very low Major Adverse Cardiac Event (MACE) rate of 1.87% at three years as shown in MeRes-1 and 1.61% in MeRes-1 Extend at two years.

Results were presented at a late-breaking session at EuroPCR 2019 (21-24 May).

“I must compliment Meril Life Sciences for creating the first ever thin strut scaffold in the world – the MeRes100 BRS,” said principal investigator for the MeRes-1 trial Dr Ashok Seth, Chairman of Fortis Escorts Heart Institute in New Dehli, India. “First generation bioresorbable scaffolds have not shown the most favourable results at long term. MeRes100, a next generation bioresorbable scaffold, has been developed with reduced strut thickness, an improved profile for better deliverability, faster degradation and possibly lower scaffold thrombosis.”

MeRes-1

Long-term three-year follow-up data of the MeRes-1 first in-human study, presented by co-principal investigator Dr. Praveen Chandra, Chairman of Interventional Cardiology at Medanta – The Medicity, Gurgaon, India, and simultaneously published in *EuroIntervention*¹ also demonstrated the high efficacy of MeRes100 BRS with multimodality imaging at two years including:

- Low late lumen loss (0.24±0.34mm) with quantitative coronary angiography (QCA)
- Virtually complete strut coverage (99.24%) with optical coherence tomography (OCT)
- Sustained mean flow area and very low percentage volume obstruction (7.5%) with intravascular ultrasound (IVUS)

Dr Chandra said that the cumulative MACE for MeRes100, MACE is a combined endpoint that includes cardiac death, myocardial infarction (MI), and ischemia-driven target lesion revascularisation (TLR), is better at three years with 1.87%, as compared to data reported from the older generation BRS first-in-man trials with double digit MACE rates.

“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,” said Sanjeev Bhatt, Vice President-Corporate Strategy, Meril Life Sciences. “We are seeing that we have certainly
created a device with excellent characteristics, which has the greatest promise to be effective as well as safe when implanted for the treatment of coronary artery disease."

**MeRes-1 Extend**

Immediately following the MeRes-1 study, two-year data for MeRes-1 Extend, presented by principal investigator Prof Alexandre Abizaid, Chief of Coronary Interventions at Institute Dante Pazzanese de Cardiologia in São Paulo, Brazil, demonstrated relatively low late lumen loss (0.18±0.31mm) with a serial QCA analysis at six-month follow-up suggesting high efficacy on inhibiting NIH at late follow-up, and a sustained mean flow area and virtually complete strut coverage (97.9±3.7) shown in an OCT subset analysis at six months.²

MeRes-1 Extend is a global study which enrolled patients from Brazil, Europe and Asia.

"Data from MeRes-1 Extend are consistent with the results of the MeRes-1 first-in-human trial's three-year outcomes," said Prof Abizaid. "These studies provide positive evidence that not all bioresorbable scaffold technology are made the same and we should look forward to lower strut thickness bioresorbable technologies as the future of percutaneous coronary interventions."

"The encouraging results from MeRes100 BRS are changing the way we currently view bioresorbable scaffolds," said Dr Ashok Thakkar, Head Clinical Research at Meril Life Sciences. "We are aiming to continue further developing the clinical evidence of this next generation technology against a drug-eluting stent in a randomised setting in due course."

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About **MeRes100 BRS**

MeRes100 BRS— a product indigenously designed and manufactured in India by Meril Life Sciences; is a bioresorbable vascular scaffold system that fully resorbs naturally in the artery within a period of 2-3 years thus leaving the vessel in its true form and nature. This next generation bioresorbable technology with low strut thickness of 100microns leads to lower crossing profile for ease of delivery helps to minimise vascular injury and ensures early endothelialisation.

About **MeRes-1 study**

The MeRes-1 clinical trial was a prospective, multicentre, single-arm, open-label clinical trial of MeRes100 Thin Strut Sirolimus-Eluting Bioresorbable Vascular Scaffold system for the treatment of *de-novo* native coronary artery lesions. The trial enrolled 108 patients from 13 participating centres across India between May 2015 and April 2016. To be included in the trial, patients had up to two lesions in native arteries and one lesion per target vessel was allowed. The reference vessel diameter was 2.75-3.5mm and lesion length was ≤20mm. The primary safety endpoint was MACE at six months and secondary safety endpoints were device and procedure success and scaffold thrombosis. The efficacy endpoints were measured by multimodality imaging - QCA: late lumen loss, OCT: minimum lumen area and NIH area, IVUS: scaffold and lumen area volume, and CTA: mean/minimal lumen, plaque and vessel area, area stenosis and percentage of cross sections with calcified, mixed and non-calcified plaques.

About **MeRes-1 Extend**

The MeRes-1 Extend trial is a prospective, multinational, multicentre, single-arm, open-label, pilot clinical study of MeRes100 Thin Strut Sirolimus-Eluting Bioresorbable Vascular Scaffold system for the treatment of *de-novo* native coronary artery lesions. The study has enrolled 64 patients with a single, *de-novo* coronary lesion (in up to two vessels) treated by a single MeRes100 scaffold up to 24mm length. Participant regions include hospitals from Brazil, Europe and Asia. The primary safety endpoint was MACE at six months and the secondary safety endpoint was device and procedural success and scaffold thrombosis. The primary efficacy endpoints were late lumen loss determined by QCA and minimum lumen area (flow) determined by OCT.
About Meril
Founded in 2006, Meril is a global medical device company that is dedicated to innovate, design and develop novel, clinically relevant and state-of-the-art devices. Headquartered in Vapi, Gujarat, India with more than 4,000 employees, Meril currently conducts business in more than 100 countries with subsidiaries in India, USA, Germany, Brazil, China, Russia, Bangladesh, Australia and Turkey. Meril manufactures wide array of medical solutions from vascular intervention devices, Orthopaedic implants, in-vitro diagnostics, endo-surgery and ENT products. For more information about Meril, please visit https://www.merillife.com/. Follow Meril Life Sciences on LinkedIn here.

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**References**