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NPPA grants non-applicability of DPCO 2013 to Meril Life Sciences for MeRes100 BRS

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MeRes100 BRS addresses a specific unmet clinical need and there is rigorous research to back its benefits

In February 2017, all stents were subject to price regulation as per the provisions of Drug Price Control Order (DPCO) 2013. However, Para 32 of DPCO 2013, allows innovative products exemption from applicability of all DPCO 2013 provisions for a period of 5 years from the commencement of commercial production in India.

To qualify, the product must be a new drug, as well as patented under the Indian Patent Act (1970). Since its innovative product MeRes100TM BRS - Sirolimus Eluting Bioabsorbable Vascular Scaffold System fulfils these criteria, Meril Life Sciences applied to NPPA for non-applicability of DPCO 2013 on May 28, 2018, and the exemption has been granted on February 25th 2020.

Sanjeev Bhatt, Vice President-Corporate Strategy, Meril Life Sciences said, “The positive decision by NPPA confirming non-applicability of DPCO 2013 under Para 32 for MeRes100 BRS, made post an exhaustive multi-stakeholder review, demonstrates the commitment of the Indian Government to encourage not only ‘Make in India’, but also ‘Research in India’. An extensively researched innovation, MeRes100 BRS is backed by 3-year efficacy and safety clinical trial data, has received 8 patents worldwide, CE mark approval and a DCGI granted 122E new drug approval that attests to its efficacy and safety for the indicated use. We are committed to introducing MeRes100 BRS in India and the world responsibly by undertaking a range of measures to ensure effective access and right use, including conducting a 2000-patient large scale randomized study, building 1000-patient Indian and global patient registries and ongoing education of interventional cardiologists.”

MeRes100 BRS addresses a specific unmet clinical need and there is rigorous research to back its benefits. The rate of coronary heart disease in young Indian men is almost twice as high as that in their western counterparts and there is evidence that CVD begins to affect Indians at least a decade earlier than it affects Europeans. Implanting metallic stents permanently in younger patients is undesirable, as there is a risk of adverse events occurring year on year. Moreover, multiple studies have proven that thinner stents promote faster healing (endothelialization) and are associated with reduced risk of clinical events such as stent thrombosis, restenosis and revascularization i.e., repeat procedures. By defining this clear unmet clinical need – on the one hand to provide a bioresorbable scaffold, and on the other to ensure thin struts to reduce risk, Meril leveraged its expertise in innovation and R&D to develop MeRes100 BRS – the world's first thin-strut BRS.

There is extensive evidence to show the therapeutic advantages MeRes100 BRS offers, based on which MeRes100 BRS has obtained DCGI 122E new drug approval and CE (European conformity) marking approval. Across MeRes-1 (a trial conducted in India) and MeRes-1 Extend (a trial 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.

Both trials have validated the intended benefits by demonstrating virtually complete strut coverage, zero scaffold thrombosis and very low major adverse cardiac event (MACE) rates of 1.87% in MeRes-1 at three years and 1.61% in MeRes-1 Extend at two years.

Given the innovative nature of this technology, Meril Life Sciences decided to go beyond the regulatory requirement of 1-year follow-up data to produce longer-term data on the safety of MeRes100 BRS. Now, with even 3-year follow-ups confirming the initial findings of zero stent thrombosis and extremely low MACE, Meril Life Sciences is ready to launch this technology shortly.

In parallel to commercial launch, the following actions will be taken:

- Establishment of a 1000 patient registry in India and 1000 patient registry globally. This will enable acute and long-term surveillance, safety and efficacy assessments and assessment of performance in a real-world clinical setting.
- Conducting randomized long-term clinical trials in India and globally across US, China and other sites to further establish the efficacy and safety of BRS. This will include a 2000 patient randomized controlled trial comparing BRS to best in class metallic DES technology.
- Supporting the use of MeRes100 BRS through ongoing doctor education, including training of HCPs in profiling and selection of the right patients to ensure use as per indication, as well as implantation and imaging protocols that are crucial for successful implantation of BRS.
- Ensuring sequential hospital roll-out, which will facilitate development and cascade of clinical best practices across centers of excellence to other hospitals, ultimately to ensure the best possible outcomes for patients.

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