BioMime Morph BGM

Study Highlights

The objective of the study is to evaluate safety and performance of the BioMime™ Morph Sirolimus-Eluting Coronary Stent System in very long (length ≤ 56 mm) coronary lesions in native coronary arteries with reference vessel diameter of 2.25 mm to 3.50 mm in real-world settings

❖ Study Design

- **Prospective, single-centre, observational, real-world, post-marketing surveillance study**

A total of 88 subjects to be enrolled from one centre in India

Follow-up at 1-month, 6-month, 12-month, 24-month and 36-month post-procedure

❖ Study Endpoints

Safety Endpoints
• Major adverse cardiac events at 1, 6, 12, 24 and 36 months — Composite of cardiac death, myocardial infarction and ischemia-driven target lesion revascularization • Stent thrombosis
Performance Endpoints
• Freedom of target lesion failure at 1, 6, 12, 24 and 36 months • Target vessel failure at 1, 6, 12, 24 and 36 months • Procedural success within 24 hours • Device success

❖ Reference:

1. Clinical Trial Registry – India: CTRI/2017/03/008167 http://ctri.nic.in/Clinicaltrials/showallp.php?mid1=17116&EncHid=&userName=CTRI/2017/03/008167.