BioMime Branch -1 Study

To evaluate the safety and performance of BioMime Branch - Sirolimus Eluting Coronary Side Branch Stent System and BioMime™ in main branch vs. XIENCE family DES in side branch and main branch in patients with coronary bifurcation lesions

Study Design

- A prospective, active control, open-label, multi-centre, randomized clinical trial
- 183 subjects to be enrolled at 6 sites across India

CTRI Number	**CTRI/2017/10/010239**
Study Objective	**To compare and evaluate the safety and performance of BioMime Branch - Sirolimus Eluting Coronary Side Branch Stent System and BioMime in main branch vs. XIENCE family DES in side branch and main branch in patients with coronary bifurcation lesions**
Primary Safety Endpoint	**Incidence of Ischemia Driven Target Lesion Failure (ID-TLF)**
Secondary Safety Endpoints	• **Major Adverse Cardiac Events** • **Stent Thrombosis Rate (As per Academic Research Consortium)** • **Ischemia-driven Target Vessel Revascularization**

OCT Endpoints	• **Out of total enrolled patients, 20% of the patients – (2:1) BioMime Branch in side branch and BioMime in main branch (n=24) Vs. XIENCE family DES in side branch and main branch (n=13) will be assessed for OCT analysis from pre-designated site(s) and based on availability of OCT console at the site and patient's consent [Time Frame: Post-procedure and 6 months (±28 days)]**
Other Endpoints	• **User ratings on technical properties [Time Frame – Baseline]** • **Procedure time** • **Quantum of contrast agent or dye used** • **Flouro Time**
Clinical Sites	**6 centres across India**
Sample Size	**A total of 183 subjects will be enrolled**
Follow-Up	**Follow-up visits at 1 ,6 , 12 and 24 month**
Study Duration	**Study start date: March 2018** **Estimated study completion: December 2021**

❖ **Reference:**

1. Clinical Trial Registry- India (CTRI) http://ctri.nic.in/Clinicaltrials/pmaindet2.php?trialid=20006&EncHid=&userName=CTRI/2017/10/010239