Promesa DES-1 Study

Study Highlights

- The objective of the study is to evaluate the safety and performance of Promesa™ DES Sirolimus-eluting self-expandable nitinol peripheral stent system for treating superficial femoral artery and iliac artery lesions

❖ Study Design

- **Prospective, multicentre, single-arm, open-label clinical study**

A total 50 subjects to be enrolled at 5 sites across India

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

❖ Study Endpoints

Primary Endpoints
• Primary patency at 6 months
Secondary Endpoints
• Major adverse events at 1 month and 12 months • All-cause death at post-procedure,1,6,12 and 24 months • Clinically-driven Target Lesion Revascularisation at post-procedure, 1,6,12 and 24 months • Target limb amputation at post-procedure, 1,6,12 and 24 months • Primary patency at 12 months • Change in Rutherford Classification at baseline, 1,6,12 and 24 months • Hemodynamic improvement at baseline, 1,6,12 and 24 months • Walking Impairment Questionnaire at 1,6,12 and 24 months • User Rating on Technical Properties at index procedure • Technical Success at index procedure • Procedural Success at post-procedure