Abstract LB-009 Figure 3

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LB-010

FIVE-YEAR RESULTS OF THE SCENT TRIAL WITH SURPASS FLOW DIVERTERS TO TREAT LARGE OR GIANT WIDE-NECK ANEURYSMS

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Introduction The Surpass Flow Diverter provides a minimally invasive, single flow diverter treatment option for patients suffering from large or giant intracranial aneurysms (IA) arising from the internal carotid artery (ICA) to the ICA terminus. Long-term clinical outcomes following the Surpass Flow

Diverter treatment of large or giant wide-neck aneurysms has not been demonstrated.

Objective To report on 5-year safety and efficacy outcomes of patients treated in the Surpass Intracranial Aneurysm Embolization System Trial to treat large or giant wide-neck aneurysms (SCENT Trial).

Methods In this multi-center and prospective trial, 180 aneurysms in 180 subjects were treated with the flow diverter system. Patients were followed per a standardized protocol at 1 month, 6 months and every year through 5 years. Aneurysm occlusion, in-stent stenosis, modified Rankin Scale scores, and complications were recorded.

Results From October 2012 through November 2015, 180 subjects were treated at 26 sites. Five-year clinical follow up completion rate was 96.7%. The primary endpoint of complete aneurysm occlusion without clinically significant parent artery stenosis or retreatment at one year (62.8%) was previously reported. Aneurysm occlusion (Raymond Class I) for those patients with angiographic follow-up progressively increased over time to 77.8% (91/117) and 90.2% (74/82) at 3 and 5 years. The cumulative proportion of subjects experiencing new or worsening major ipsilateral stroke, as adjudicated by the CEC, was 12.2% (22/180) and 12.8% (23/180) subjects at 3 and 5 years. Four patients (2.2%, 4/180) experienced aneurysm rupture within the first-week post target aneurysm treatment. No additional late aneurysm ruptures occurred through the five-year follow-up. Five aneurysms (2.8%) were retreated in the study. New serious adverse events at 3 and 5 years were noted in 15.4% (23/149) and 9.8% (12/123) of subjects. Five neurological deaths occurred within one year, and one additional neurological death was reported after the subject's 5-year follow up.

Conclusions Our 5-year findings demonstrate the long-term safety and effectiveness of the Surpass Flow Diverter for intracranial aneurysm treatment, supported by high occlusion rates and low rates of delayed adverse events in this study.

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