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PVSS7: The Phase I Multicenter Trial of the Aptus™ Endovascular Repair System: Results at 6 months and 1 year.

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Objective: This FDA Phase I IDE study evaluated the primary endpoints of safety (major device-related adverse events at 30 days) and feasibility (successful deployment of all endograft components) of the Aptus™ Endovascular AAA Repair System to treat abdominal aortic aneurysms (AAA).

Methods: A prospective, single arm FDA Phase I IDE study was performed. The Aptus™ endograft is a three-piece modular device with an unsupported main body and two fully supported limbs in a 5.3 mm O.D. (16Fr) delivery system. EndoStaples that measure 4 mm (length) by 3 mm (diameter) provide transmural graft fixation and are applied independent of the endograft system. Inclusion criteria included a proximal aortic neck length of 12mm and iliac landing zone of 10 mm. Secondary endpoints included freedom from endoleaks, rupture, migration and device integrity.

Results: Twenty-one (21) patients enrolled at six centers. All patients received the Aptus™ endograft and EndoStaples without conversion. Ninety-six EndoStaples (range: 2-10, median:4) were implanted. All patients (n=21) completed one month and six month follow-up evaluation and eleven completed one-year follow-up. Endoleak and aneurysm diameter changes are listed in Table 1. Two proximal cuffs and one limb extension were used as adjunctive devices at implantation. Three secondary interventions were performed in two patients for limb thrombosis. There were no EndoStaple adverse events, device integrity failures or migration.

Conclusions: These results document the acute safety and feasibility of the Aptus™ endograft and EndoStaples. Early follow-up demonstrates excellent six-month and one-year results. A pivotal Phase II trial is underway at 25 U.S. centers.

| AAA change > 5mm | 30 Days n=21 | 6 months n=19 | 1 Year n=11 |
|----------------------------|-----------------|------------------|----------------|
| Reduction | N/A | 7 (21%) | 8 (73%) |
| No Change | N/A | 12 (7%) | 3 (27%) |
| Enlargement | N/A | 0 | 0 |
| Endoleak | 30 Days n=21 | 6 months n=19 | 1 Year n=11 |
| Type I | 0 | 0 | 0 |
| Type II | 4 (19%) | 4 (19%) | 1 (9%) |
| Type III | 0 | 0 | 0 |
| Type IV | 0 | 0 | 0 |

Table 1: Aneurysm Diameter Change and Endoleak