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**Primary Analysis Results of the Phase 3 Archway Trial of the Port Delivery System With Ranibizumab (PDS) for Patients With Neovascular AMD (nAMD)**

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**Purpose:**

The PDS is an investigational drug delivery system for the continuous intravitreal delivery of a customized formulation of ranibizumab. The Archway phase 3 trial is evaluating safety and efficacy of the PDS for nAMD.

**Methods:**

Archway (NCT03677934) is an ongoing, phase 3, randomized, active treatment-controlled trial. Eligible patients had nAMD diagnosed within 9 months of screening and were responsive to anti-VEGF treatment. Patients were randomized 3:2 to treatment with the PDS with ranibizumab 100 mg/mL with fixed 24-week (Q24W) implant refills or monthly intravitreal ranibizumab 0.5 mg injections. The trial is designed to evaluate noninferiority (NI) of PDS 100 mg/mL Q24W versus monthly ranibizumab 0.5 mg; primary endpoint is change in BCVA score from baseline averaged over weeks 36 and 40 with an NI margin of 4.5 letters.

**Results:**

Archway is ongoing; an updated abstract with data will be submitted once results are available. Additional data points may be added if available at time of resubmission.

Archway enrolled XX patients in the PDS 100 mg/mL Q24W (PDS) arm and XX patients in the monthly ranibizumab 0.5 mg arm. Baseline demographic and ocular characteristics were generally XXXX across treatment arms. Change in BCVA score from baseline averaged over weeks 36 and 40 (95% CI) was XX.X (XX.X, XX.X) and XX.X (XX.X, XX.X) letters in the PDS and monthly ranibizumab 0.5 mg arms, respectively; with a difference (95% CI) of XX.X (XX.X, XX.X) between treatment arms, results indicate statistical XXXX of PDS to monthly ranibizumab 0.5 mg treatment. Change from baseline in center point thickness at week 36 was XX.X μm in the PDS arm and XX.X μm in the monthly ranibizumab 0.5 mg arm. Through week 40, XX.X% of PDS patients required supplemental ranibizumab treatment. Assessment of ocular adverse events of special interest indicate that PDS 100 mg/mL Q24W was XXXX. Systemic safety findings were XXX between the PDS and monthly ranibizumab 0.5 mg arms.

**Conclusions:**

The phase 3 Archway trial of the PDS XXXX its primary endpoint and demonstrated statistical XXXXXXXXXXXX of PDS 100 mg/mL Q24W to monthly intravitreal ranibizumab 0.5 mg. Overall, PDS treatment was XXXX (safety statement).