This is a single arm, phase II, randomized, double-blind, placebo-controlled, multi-center study designed to evaluate dalantercept monotherapy administered subcutaneously (SC) every 21 days for 21 cycles.

**Study Design**

- 40 patients were enrolled at 80 mg Q3W, 120 mg Q3W, and 240 mg Q3W, where two dose levels were evaluated (80 mg and 120 mg).
- After the first two patients were enrolled at 80 mg, the protocol was amended to increase weight-based dosing (mg/kg) and two dose levels were evaluated (0.6 mg/kg and 1.2 mg/kg).
- One patient in the 1.2 mg/kg dose achieved PR (90% reduction in tumor measurements) for 7 months (95% CI: 5.2 – not reached).
- Among the HPV positive patients, the median OS was numerically superior to that of HPV negative patients (7.6 months vs. 5.8 months).

**Results: Response Rate**

- The disease control rate was greater in HPV-positive patients (57.9%) compared to HPV-negative patients (20%).

**Safety Summary**

- The most common treatment-related adverse events occurring in > 15% of patients were fatigue, peripheral edema, headache, and hypertension.
- There were no treatment-related deaths. No prior anti-angiogenic therapy

**Pharmacokinetics**

- DALantercept levels increased following repeat administration, and the terminal half-life was consistent across all dose levels.
- The median dalantercept exposure at steady-state was dose proportional.

**Conclusions and Discussion**

- In this heavily pretreated (median 3 prior regimens) RM-SCCHN population, dalantercept monotherapy demonstrated modest dose-dependent activity with an overall disease control rate of 40% (95% CI: 0.3 – 0.7).
- 3 patients receiving 2.7 mg/kg achieved a PR (1.3%) and was on treatment for 8 months.
- Despite the majority of patients receiving prior cetuximab (60.9%) in this study, the median OS (9.5 months) is similar to that observed in the 2010-2011 JCO population receiving cetuximab after platinum-based therapy but

**References**

5. Copies of this poster obtained through QR
6. This study appears to be dose dependent and was not reached)
7. NAVICINE is over- expressed in SCHHN.
8. Limited treatments exist for patients with recurrent or metastatic squamous cell carcinoma of the head and neck (RM-SCCHN).