

## **A Phase I Study of VB4-845 in Patients with Advanced, Recurrent Head and Neck Cancer on a Weekly Dosing Scheme**

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### **ABSTRACT**

**Background:** VB4-845 (Proxinium) is a recombinant protein engineered from the fusion of a humanized scFv specific for the epithelial cell adhesion molecule, EpCAM, to a truncated form of *Pseudomonas* Exotoxin A. EpCAM is highly expressed on carcinoma cells of epithelial origin, with limited normal cell expression, VB4-845 selectively targets and kills EpCAM positive tumors. A phase I dose-escalation trial was completed to determine the safety, tolerability, pharmacokinetic (PK) profile and preliminary efficacy of intratumorally injected VB4-845 in patients with advanced Squamous Cell Carcinoma of the Head & Neck (SCCHN).

**Conclusions:** VB4-845 administered on a weekly basis for 4 weeks was safe and well tolerated. The MTD on this schedule was defined at 930 µg/day. Moreover, although this study was primarily designed to evaluate safety and tolerability, clinical observations indicate that VB4-845 demonstrated promising anti-tumor responses against EpCAM-positive SCCHN tumors in a highly treatment-refractory patient population. Further development is therefore warranted.