

TREATMENT WITH INTRAVESICAL VICINIUM™ RESULTS IN DURABLE RESPONSES IN PATIENTS WITH CARCINOMA IN SITU (CIS) PREVIOUSLY TREATED WITH BACILLE CALMETTE-GUÉRIN (BCG)

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ABSTRACT

Introduction and Objective: Vicinium™ is a fusion protein comprised of a humanized scFv, specific for EpCAM (epithelial cell adhesion molecule), and a truncated fragment of *Pseudomonas* exotoxin A. EpCAM is highly expressed on transitional cell carcinomas (TCC) of the bladder. Vicinium specifically targets and induces apoptosis in EpCAM positive tumors. Efficacy and safety results for all 46 patients from a Phase II trial of intravesical Vicinium will be presented, including durability of response data to 12 months.

Materials and Methods: 46 BCG refractory or intolerant patients with CIS of the bladder, were entered into the study. The first 23 patients received induction therapy with Vicinium weekly for 6 weeks. At 3 months, patients with disease < T2 received a repeat induction course, whereas patients who were free of disease received maintenance dosing with Vicinium weekly for 3 weeks at 3 month intervals. Patients who were free of disease continued to receive maintenance dosing up to a maximum of 12 months. The second 23 patients received induction therapy for 12 weeks. At 3 months, patients who were free of disease received maintenance dosing weekly for 3 weeks at 3 month intervals. Patients who were free of disease continued to receive maintenance dosing up to a maximum of 12 months. Toxicities were assessed according to the NCI CTC AE v3. Efficacy was determined via biopsies, cystoscopy, and urine cytology.

Results: All patients have been enrolled. Current data support an excellent safety and tolerability profile. Efficacy data show a complete response in 9 of 22 evaluable patients at 3 months, for the first cohort who received the 6 week induction regimen. The complete response was maintained in 6 of 19 evaluable patients at 6 months and in 3 of 19 evaluable patients at 12 months. Efficacy data available to date, show a complete response in 9 of 23 patients at 3 months for the 12 week induction regimen.

Conclusions: These results demonstrate an excellent safety and tolerability profile for Vicinium. Durable responses are achieved in a subset of patients out to 12 months. This data support Vicinium's further development as a potential therapy for non muscle-invasive TCC.