BACKGROUND

Vicinium is a fusion protein consisting of an Epithelial Cell Adhesion Molecule (EpCAM)-specific antibody fragment fused to Pseudomonas Exotoxin A, a potent inhibitor of protein synthesis. Vicinium is being developed for the treatment of Bacillus Calmette-Guérin (BCG)-unresponsive, high grade non-muscle invasive bladder cancer (NMIBC). In Phase I and 2 studies, intravesical Vicinium demonstrated excellent safety profile and meaningful clinical activity as assessed by the complete response (CR) rate at 3 months of 29-40% in subjects with carcinoma in situ (CIS) NMIBC. The major objective of this pivotal phase 3 study is to confirm the clinical benefit of Vicinium in subjects with BCG-unresponsive NMIBC.

3-MONTH CR RATE IN CIS

- 39% of 129 subjects treated with Vicinium had a complete response rate at 3 months
- 80% of subjects within 12 months of receiving Vicinium had a complete response rate

VICTA TRIAL PHASE 3 STUDY DESIGN

- Single-arm, open-label, multi-center registration study in BCG-unresponsive NMIBC (high grade Ta, any T1 and CIS with or without papillary disease) (NCT02449239)
- Eligibility: ≥ 2 courses of full dose BCG and recurrent papillary NMIBC ≤ 30 weeks or with CIS ≤ 50 months after last BCG
- Dosing: 30mg Vicinium intravesical instillation in 50 ml buffered saline held for 2 hours
- Induction (weekly for 6 weeks) → weekly for 4 weeks; once CR, proceed to maintenance every other week for 2 years
- Primary endpoint: Complete response rate and duration of response in Cohort 1 (CR defined as negative urine cytology, pathology and local cystoscopy)
- Key Secondary Endpoints: event-free survival (EFS) in all subjects, time to disease recurrence, time to cystectomy, progression-free survival, overall survival, safety and tolerability

3-MONTH EFFICACY RESULTS IN PAPILLARY ONLY

- 68% recurrence-free rate at 3 months in papillary only subjects (n=34)
- Subjects deemed to have no visible evidence of disease when starting Vicinium treatment

ALL SAMPLES SCREENED IN PHASE 3 TRIAL EXPRESS EPICAM

<table>
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<th>SCREENING EPICAM</th>
<th>Number of Subjects</th>
<th>Final EpICAM by TREATMENT FAILURE (at end of induction)</th>
<th>Final EpICAM by DISEASE RECURRENCE (at time of recurrence)</th>
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SUMMARY AND CONCLUSIONS

1. 3-month data from the VISTA Trial demonstrate 42% CR rate in subjects with CIS recurring within 12 months of last BCG treatment
2. Recurrence of 12 months of BCG treatment is consistent with US FDA guidelines
3. The novel mechanism of Vicinium coupled with the promising clinical benefit may provide an important alternative to existing therapies, including radical cystectomy
4. Vicinium is a fusion protein consisting of an Epithelial Cell Adhesion Molecule (EpCAM)-specific antibody fragment fused to Pseudomonas Exotoxin A, a potent inhibitor of protein synthesis. Vicinium is being developed for the treatment of Bacillus Calmette-Guérin (BCG)-unresponsive, high grade non-muscle invasive bladder cancer (NMIBC). In Phase I and 2 studies, intravesical Vicinium demonstrated excellent safety profile and meaningful clinical activity as assessed by the complete response (CR) rate at 3 months of 29-40% in subjects with carcinoma in situ (CIS) NMIBC. The major objective of this pivotal phase 3 study is to confirm the clinical benefit of Vicinium in subjects with BCG-unresponsive NMIBC.
5. Vicinium has a familiar and convenient administration schedule similar to BCG-like instillation.

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