Results from Part 1 Safety Run-in Period of a 2-part, Phase 2, Multicenter, Open-label, Proof-of-Concept Study to Evaluate the Safety, Pharmacokinetics, and Efficacy of VP-315 in Subjects with Basal Cell Carcinoma

INTRODUCTION

- VP-315 is a de-novo designed, intratumoral injected, chemotherapeutic oncolytic peptide in development for basal cell carcinoma (BCC).
- VP-315 has proven to be effective against a panel of drug resistant cancer cells (including multidrug resistant phenotypes) and activates the adaptive immune system by inducing lysis and immunogenic cell death through release of potent immuno-stimulants and a repertoire of tumor antigens.\(^1\)\(^,\)\(^2\)
- LTX-315 is being developed for BCC as VP-315.

OBJECTIVES & ENDPOINTS

- The primary objectives of this study were to assess safety, tolerability, and maximum tolerated dose (MTD) of ascending dose strengths of VP-315 as a monotherapy in adult subjects with biopsy proven BCC.
- Primary endpoints of the study included discontinuations due to adverse events (AEs), occurrence of dose-limiting toxicity (DLT), and assessment of expected cutaneous reactions related to treatment at different doses, including lesion necrosis.

METHODS

- This is Part 1 of a 2 part dose-escalation study.
- Part 1: N=10 (total study N=80).
- Subjects received treatment comprised of ascending once daily dosing, up to 3 consecutive treatment days in a 7-day treatment week, followed by no treatment for ≥ 4 days.
- Subjects were treated up to 6 treatments over a 2-week period, in ≤ 2 lesions.

DEMographics

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>%</th>
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<tbody>
<tr>
<td>Gender at birth (N=10)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>5</td>
<td>50</td>
</tr>
<tr>
<td>Male</td>
<td>5</td>
<td>50</td>
</tr>
<tr>
<td>Body Area (N=12)</td>
<td></td>
<td></td>
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<td>16.7</td>
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<tr>
<td>Back</td>
<td>6</td>
<td>50</td>
</tr>
<tr>
<td>Chest</td>
<td>1</td>
<td>8.3</td>
</tr>
<tr>
<td>Clavicle</td>
<td>1</td>
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<tr>
<td>Neck</td>
<td>1</td>
<td>8.3</td>
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<tr>
<td>Shoulder</td>
<td>1</td>
<td>8.3</td>
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* FST=Fitzpatrick Skin Type. Two subjects had 2 lesions treated.

RESULTS

- All 10 subjects completed treatment with VP-315.
- The full target range of doses were well tolerated.
- A maximum dose of 8 mg did not reach a MTD in any subject.
- No subjects experienced DLTs.
- Most treatment-related adverse events (TRAEs) were mild to moderate, and expected.
- Expected cutaneous reactions were observed.
- No treatment-related serious adverse events (SAEs) were reported.

CONCLUSIONS

- VP-315 demonstrated a tolerable safety profile.
- Subjects receiving the higher range of dosing experienced a consistent response of clinical tumor necrosis.
- VP-315 warrants continued research as a potential non-surgical immunotherapy for BCC.

REFERENCES


DISCLOSURES

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