BACKGROUND: SLC44A4 is a 710 amino acid protein expressed on prostate, pancreas and other cancers. Background: SLC44A4 is a 710 amino acid protein expressed on prostate, pancreas and other cancers. It is a membrane protein with ten transmembrane domains.

PHARMACOKINETICS

Serum Concentration Time Profiles for ASG-5ME

<table>
<thead>
<tr>
<th>Cohort</th>
<th>Dose (mg/kg)</th>
<th>Event</th>
<th>T1/2 (hours)</th>
<th>Relationship</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>0.3</td>
<td>3</td>
<td>11.6</td>
<td>Linear</td>
</tr>
<tr>
<td>2</td>
<td>0.6</td>
<td>4</td>
<td>6.87</td>
<td>Linear</td>
</tr>
<tr>
<td>3</td>
<td>1.2</td>
<td>5</td>
<td>14.1</td>
<td>Linear</td>
</tr>
</tbody>
</table>

ASG-5ME: an antibody-drug conjugate (ADC), Time to maximum observed concentration (Tmax), area under the curve (AUC), total antibody (TAb), and monomethyl auristatin E (MMAE), Abbreviation key:  Area under the curve (AUC), maximum observed concentration (Cmax), total antibody (TAb), and monomethyl auristatin E (MMAE), Abbreviation key:  Area under the curve (AUC), maximum observed concentration (Cmax), total antibody (TAb), and monomethyl auristatin E (MMAE), Abnormal changes in radiological images per RECIST (version 1.1) are the primary endpoint of this study. The secondary endpoint is to evaluate the proportion of patients achieving disease stabilization (SD) or better at 12 weeks post the start of infusion.

STUDY DESIGN

Enrollment:

Subjects were enrolled on a 3+3 design with each dose level enrolling 3 subjects. After the completion of the first 3 subjects, the dose escalation was continued until 3 DLTs were observed or the maximum tolerated dose (MTD) was reached. The study was designed to determine the dose-expansion cohort based on MTD. This clinical study is enrolling. After enrolling 3 chemo naïve subjects, the study is planned to enroll 23 additional subjects.

CONCLUSIONS

ASG-5ME was well tolerated across all dose levels with the exception of dose level 6 (3.0 mg/kg). There were no treatment-related deaths or serious adverse events. The most frequent treatment-related adverse events included decreases in several patients.

Definition of Dose Limiting Toxicities (DLTs)

• Grade 4 anemia
• Grade 4 thrombocytopenia
• Grade 3 hemorrhagic cyst
• Grade 3 cardiac troponin increases with grade 3 heart failure
• Grade 3 constipation or diarrhea
• Unfavorable grade 3 changes in radiological images per RECIST (version 1.1)

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