**ELU-FRα-1: First-in-Human Study of ELU001, a Targeted C’Dot Drug Conjugate, in Subjects with Folate Receptor (FRα) Overexpressing Solid Tumors**

Wien Wee Ma1, Anthony W. Tolcher1, Cesar A. Perez2, Douglas Orr3, Erikita Hamilton3, Jiye Zhao4, Yonina R. Murciano-Gorriti5, Carey Anderson1, Gregory Paul Adams3, Catherine W. Reddick6, Heather Woe-McIntosh6 & Eliot Bayer7 on behalf of all ELU-FRα-1 Investigators. 

1Cleveland Clinic, 2NEXT Oncology, 3Mary Crowley Cancer Center, 4Sarah Cannon Research Institute at Florida Cancer Specialists, 5Sarah Cannon Research Institute at Tennessee Oncology, 6Mayo Clinic Florida, 7Memorial Sloan Kettering Cancer Center, 8Duke Cancer Institute, 9Elucida Oncology, Inc.

**Study sponsored by Elucida Oncology, Inc.**

**METHODS / DESIGN**

**Phase 1 / 2 multicenter, open label clinical trial:**
- **Part 1, Dose Escalation,** basket of cancers likely to overexpress FRα (retrospective FRα analysis). Escalating doses of ELU001, administered once a week (QW) or 1.94 mg/m² for 3 weeks, 1 week rest), every other week (Q2W) (1.5-2.25 mg/m²), or every three weeks (Q3W) (2.75-3.5 mg/m²).
- **Part 2, Dose Expansion,** specific groups of cancers at 2 mg/m² Q2W Exploratory Dose.

**STUDY OBJECTIVES**

**Study Part** | **Primary** | **Secondary**
--- | --- | ---
Part 1 | Dose Escalation | MTD and/or RP2D | ORR, PFS, TFST, PFSD, PK, Biomarkers, Immunogenicity
Part 2 | Tumor Group Expansion | ORR | Safety, Tolerability, PFS, TFST, PFSD, OS, PK, Biomarkers, Immunogenicity

**STUDY OBJECTIVES**

**Part 1 – Tumor Group Expansion**
- **2 mg/m² Q2W Exploratory Dose in adult patients with 1-4 prior therapies:**
  - Group 1: Ovarian High FRα (>75%)
  - Group 2: Ovarian Low/Moderate FRα (25% < & < 75%)
  - Group 3: Endometrial Positive FRα (≥ 25%)
- Future: TNBC or NSCLC metastasized to the brain

**INITIAL PK & ADA DATA**

Concentrations of ELU001 C’Dot, Total Exatecan and Released Exatecan were assessed in patient plasma (currently ongoing). Preliminary data for the first 31 patients reveals dose proportionality for the C’Dot portion of ELU001 and the Total Exatecan payload and that ELU001’s volume of distribution is primarily limited to the circulatory system. Released payload was ~5% of total payload.

No anti-drug antibodies have been detected to date.

**ELU001 SAFETY**

**Objective Response by RECIST v1.1**

**ALL INDICATIONS (N=42)**

**Duration on Study by Schedule and Dose**

**ELU001 STUDY DEMOGRAPHICS OVERVIEW - PART 1 DOSE ESCALATION**

**Prior Lines of Therapy** | **Range** | **Median**
--- | --- | ---
QW / N=11 | 3 – 11 | 5
Q2W / N=17 | 2 – 8 | 4
Q3W / N=10 | 2 – 8 | 4.5
Overall / N=42 | 2 – 11 | 4.5

**Subject population only included those who had no other meaningful life-prolonging therapy option available.**

**Data presented at AACR Annual Meeting 2022, Adams, G P, et al., Abstract 1077.**

**ELU001 SAFETY**

<table>
<thead>
<tr>
<th>Grade ≥ 3 Treatment Emergent AEs</th>
<th>Total Patients N=42</th>
<th>19%</th>
<th>31%</th>
<th>33%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wt loss</td>
<td>5%</td>
<td>1%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fatigue</td>
<td>5%</td>
<td>12%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nv-2</td>
<td>5%</td>
<td>0%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nv-3</td>
<td>5%</td>
<td>0%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nv-4</td>
<td>5%</td>
<td>0%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nv-5</td>
<td>0%</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**NONCLINICAL TOXICOLOGY STUDIES**

IND-enabling nonclinical toxicity studies were performed in Wistar Han Rats and Beagle Dogs prior to initiating the clinical study described here. The toxicity study also included non-GLP cohorts of rats treated with free exatecan and revealed that both free exatecan and ELU001 had the same pattern of toxicity in normal tissues - limited to the bone marrow and the GI tract. No anti-drug antibodies were induced by treatment with ELU001.

**DISCLOSURES**

Copies of this poster obtained through Q领跑 (Quick Response) and/or text key codes are for personal use only and may not be reproduced without written permission of the authors.

- CFI affiliation: No author has a conflict of interest
- Corresponding authors may be reached at Wien Ma, MBB, (wma@clinicastrand.com) and Eliot Bayer, CMO (ebayer@elucidaoncology.com)
- ELU-FRα-1 is registered on www.clinicaltrials.gov (NCT04932181)
- MSECT has institutional financial interest relative to Elucida Oncology, Inc.