Elucida Oncology Announces First Patient Dosed with ELU001 in Expansion Cohort of its Phase 1/2 Clinical Trial

MONMOUTH JUNCTION, N.J., July 20, 2023 (GLOBE NEWSWIRE) — Elucida Oncology, a clinical-stage biotechnology company developing the next frontier in targeted cancer therapy, announced today that the first patient has been treated with ELU001, its proprietary folate receptor alpha (FRα)-targeted C'Dot drug conjugate (CDC), in one of three Tumor Group Expansion Cohorts in its Phase 1/2 trial. These initial Tumor Group Expansion Cohorts will evaluate ELU001 for efficacy and safety in patients with advanced, recurrent, or refractory ovarian and endometrial cancer with all levels of FRα expression (low, moderate, and high).

The initiation of the Expansion Cohorts follows the completion of the Dose Escalation portion of the study that identified a dose of 2.0 mg/m² every two weeks (Q2W) of ELU001 for further evaluation. As recently reported at the American Association for Cancer Research (AACR) 2023 Annual Meeting, multiple dosing schedules, particularly the Q2W, demonstrated a positive ELU001 safety profile with side-effects confined to predictable, manageable, and generally reversible hematologic and gastrointestinal adverse events consistent with its exatecan payload.

Importantly, there has been no evidence of interstitial lung disease, peripheral neuropathy, liver, renal, cardiac, or clinically significant ocular toxicities observed to date, which have been seen with the use of some antibody-drug conjugates (ADC). Additionally, the early anti-tumor activity observed during the Dose Escalation phase in patients with low, moderate, and high FRα target antigen expression, is yet another potential differentiating factor between this particular CDC and ADCs that target the FRα antigen.

Initial efficacy data from the Dose Escalation phase will be presented at a medical conference in the second half of 2023.

“This is a notable milestone for the company, as we continue to progress our lead CDC candidate, ELU001, in this important Phase 1/2 trial. The safety data to date has been differentiating for ELU001 when compared to ADCs, including those targeting the same folate receptor alpha target, and we look forward to presenting ELU001 clinical data at a major medical conference later this year,” stated Geno Germano, President and CEO of Elucida Oncology.

About ELU001

ELU001, Elucida Oncology’s lead clinical candidate, is a C’Dot drug conjugate (CDC) that contains ~20 molecules of the topoisomerase-1 inhibitor exatecan-linked via a proteolytic cleavable linker and ~13 folic acid molecules to target cancers that express folate receptor alpha (FRα). ELU001’s multi-valent targeting, greater payload delivery, deep tumor
penetration, and ability to access difficult to target tumors in the brain, are important properties distinguishing it from antibody-drug conjugates (ADC). Pre-clinical studies across multiple cancer models demonstrate the significant ability of ELU001 to target both high and lower FRα expressing tumor cells, resulting in enhanced cell killing as compared to an ADC designed to target the same FRα antigen. FRα is overexpressed on a variety of tumors yet is minimally expressed on normal tissues making it an attractive tumor-associated antigen for targeted drug delivery.

**About Elucida Oncology**

Elucida Oncology, Inc., is a clinical-stage biotechnology company pioneering the next frontier in targeted cancer therapy with its first-in-class, ultra-small nanoparticle C'Dot drug conjugate (CDC) platform. CDCs are designed to penetrate deeper into tumors and deliver a significantly higher payload compared to antibody drug conjugates (ADCs). This combined with greater avidity for the target antigen, longer retention in tumors with minimal systemic exposure due to rapid renal clearance confers unique Target or Clear® properties. In preclinical studies, this has resulted in enhanced efficacy irrespective of antigen expression levels with reduced off-target toxicity, thereby potentially addressing the limitations of ADCs and other novel drug carriers. For more information, please visit www.elucidaoncology.com.

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Source: Elucida Oncology, Inc.