A phase 1 dose-escalation and expansion study of CUE-101, a novel HPV16 E7-pHLA-IL2-Fc fusion protein, given alone and in combination with pembrolizumab in patients with recurrent/metastatic HPV16+ head and neck cancer.

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1. Head and neck carcinomas (HNSCC) are the 8th most common cancer in the world [1]. A significant subset of the cases of HNSCC include human papillomavirus (HPV) associated squamous cell tumor, with HPV-16 prevalence in 30-50% of these cases [2]. Despite current standard of care treatments, ~55% of patients with advanced HNSCC will experience recurrence presenting a significant unmet need.

• Immuno-STATs are rationally engineered biologics comprised of a biologically active human protein, and 4 molecules of reduced affinity IL-2 that is designed to bind, expand, and activate HPV16-specific CD8+ T cells for the treatment of recurrent/metastatic HPV16+ head and neck cancer.

CUE-101 is given intravenously once every 3 weeks either alone (Parts A and B) or immediately following infusion of pembrolizumab 200 mg, Q3W in Parts C and D. pembrolizumab 200 mg, Q3W for Parts A and B, pembrolizumab 200 mg, Q3W for Parts C and D.

Methods

• CUE-101 in a Phase 1 open label 4-study in HNSCC patients with HPV-16+ HNSCC.

CUE-101 was designed to deliver alternated interleukin-2 (IL-2) selectively to tumor-specific CD8+ T cells [3, 4].

CUE-101, the first Immuno-STAT in clinical trials, is composed of a HLA-A21 complex, a peptide derived from the HPV16 E7 protein, and 4 molecules of reduced affinity IL-2 that is designed to bind, expand, and activate HPV-16-specific CD8+ T-cells for the treatment of HPV-16+ cancers.

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