Protocol Title: A Phase 1 Dose-Escalation Study of Advaxis (ADXS) NEO Expressing Personalized Tumor Antigens in Subjects with Metastatic Microsatellite Stable Colon Cancer, Metastatic Squamous Histology Head and Neck Cancer, and Metastatic Non-Small Cell Lung Cancer

Target Population:
- Metastatic Colon Cancer (CRC)
- Metastatic Head and Neck Cancer (SCCHN)
- Metastatic Non-Small Cell Lung Cancer (NSCLC)

Summary: This is a phase 1, open-label, uncontrolled, multicenter study in 3 distinct solid tumors. The study design is dose-escalation/de-escalation using a standard 3 + 3 design to evaluate the safety profile of ADXS-NEO, to select a recommended Phase 2 dose, and identify initial signs of clinical activity in each of the 3 tumor-specific cohorts.

Key Inclusion Criteria:
- ECOG Performance Status of 0 to 1.
- Prior exposure to immunotherapy including, but not limited to, anti-PD1 or anti-PDL1 antibodies is allowed but not required.
- Histological or cytological diagnosis of metastatic solid tumor that has progressed or has become intolerant to standard therapy, and whose disease may allow management with other available therapies. Solid tumor must be one of the following:
  - Metastatic Colorectal Cancer (CRC) [excluding known microsatellite instable sub-types]
  - Metastatic Squamous Cell Carcinoma of the Head and Neck (SCCHN)
  - Metastatic Non-Small Cell Lung Cancer (NSCLC)
- Baseline tumor biopsy must be adequate.
- Has evaluable or measurable disease for response assessment.
- Females - not pregnant and willing to follow contraceptive guidance.
- Males - willing to follow contraceptive guidance.

Key Exclusion Criteria:
- Is not expected to be available to receive study drug within 16 Weeks from the time of baseline biopsy for any reason.
- Has a newly diagnosed tumor and a curative treatment option or approved therapy is available.
- Known active CNS metastases and/or carcinomatous meningitis.
- Any active autoimmune disease.
- Any other diseases that, in the opinion of the investigator and Sponsor's medical monitor would pose a risk to the subject safety.

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For additional information: https://clinicaltrials.gov/ct2/show/NCT03265080