Protocol Title: CANscriptTM Clinical Outcomes in a Real-World Setting (ANCERS)-2: A Prospective, Multicenter, Observational Study Examining the Clinical Utility of CANscriptTM in Routine Clinical Practice

Target Population: Adults with Solid Tumors

Summary: The purpose of this study is to test the CANscriptTM sensitivity assay, which is a new and different assay developed to test the sensitivity of different cancer types to physician selected therapies indicated for the stage and type of cancer for treatment.

Key Inclusion Criteria:
- Male or Female patient ≥ 18 years old.
- ECOG Performance Score of ≤ 2.
- Patient’s tumor must be amenable to a tumor biopsy sampling, so that CANscript can be performed.
- The patient’s tumor must have disease that is measurable by standard imaging techniques, per the RECIST 1.1.
- Histologically or cytologically confirmed:
  - Locally advanced or metastatic HNSCC
  - Locally advanced or metastatic TNBC
  - Locally advanced or metastatic Stage 3b or 4 NSCLC after failure of appropriate 1st line therapy; Patients with EGFR or ALK mutations must have received previous appropriate therapy
  - Locally advanced or metastatic epithelial ovarian, fallopian lube, or primary peritoneal carcinoma, after failure of 1st time platinum-based chemotherapy; Recurrent or persistent stage 3 or 4 disease requiring relapse histologic documentation
  - Stage IV metastatic CRC.

Key Exclusion Criteria:
- Patient has persistent clinically significant toxicities (Grade ≥2) from previous anticancer therapy.
- Patient has received treatment with chemotherapy, external-beam radiation, or other systemic anticancer therapy within 14 days prior to study entry.
- Patient has an additional active malignancy that may confound the assessment of the study endpoints.
  - Patients with the following concomitant neoplastic diagnoses are eligible: non-melanoma skin cancer, carcinoma in situ, organ-confined prostate cancer with no evidence of progressive disease.
- Patient has clinically significant cardiovascular disease.
- Patient has uncontrolled, clinically significant pulmonary disease that in the opinion of the investigator would put the patient at significant risk for pulmonary complication during the study.
- Patient has known active or suspected brain or leptomeningeal metastases.
  - Patients with stable, treated brain metastases are eligible if there is no evidence of CNS disease growth on imaging for at least 6 weeks following XRT or other loco-regional ablative therapy to the CNS.
- Patient is receiving immunosuppressive therapy for prophylaxis following a prior organ transplant.
  - Corticosteroid therapy is permitted.
- Patient has uncontrolled intercurrent illness including, but not limited to, uncontrolled infection, disseminated intravascular coagulation, or psychiatric illness/social situations that would limit compliance with study.
- Patient is pregnant or breast-feeding.
- Patient has known positive status for HIV active or chronic Hepatitis B or C.

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For additional information: https://clinicaltrials.gov/ct2/show/NCT03253575