

Gene Therapy for HER-Positive Cancer (SENTRY-HER2)

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Age: ≥18 years of age * Histologically or cytologically confirmed diagnosis of HER-2 positive solid tumor as defined in the protocol * Part 1: presence of advanced or metastatic disease that has progressed during or following previous treatment * Part 2: Early stage HER-2 positive cancers with high risk for relapse following completion of SOC or after neoadjuvant systemic treatment * AAV specified capsid total antibody ≤1:400 * ECOG performance status of 0 or 1 * Life expectancy ≥3 months * Protocol-specified ranges for renal, liver, cardiac and pulmonary function * Protocol-specified ranges for hematology parameters

Exclusion Criteria:

* Hepatotoxicity (AST or ALT > 2x upper limit of normal) * Known active CNS or leptomeningeal disease * History of thrombotic microangiopathy or cardiomyopathy, or evidence of sensory neuropathy * Pregnant or nursing (lactating) women * History of other malignancy within 5 years prior to screening as defined in protocol * History of hypersensitivity to corticosteroids or history of corticosteroid-related toxicity Concurrent anti-cancer treatment in another investigational trial

Conditions & Interventions

Interventions:

GENETIC: Dose Level 1, VNX-202, GENETIC: Dose Level 2, VNX-202, GENETIC: Dose Level 3, VNX-202, GENETIC: Dose Level 4, VNX-202

Conditions:

HER2 Expressing Solid Tumors

Keywords:

HER2+ breast cancer, HER2+ gastric cancer, Other HER+ cancer, HER2-low cancer

More Information

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IRB

Number:

System ID: NCT07192432

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