A Phase 1 Study of SQZ-PBMC-HPV in Patients with HPV16+ Recurrent, Locally Advanced or Metastatic Solid Tumors

Study Design

A Phase 1 study with dose escalation and dose expansion of SQZ-PBMC-HPV as monotherapy and in combination with atezolizumab. Patients have to be HLA-A*02-positive (human leukocyte antigens make up a person's tissue type and can be found on the surface of most cells in the body). The study is open for patients with HPV16-positive anal, rectal, cervical, head and neck, penile, vulvar, or vaginal cancer.

Cells from the patient's blood is collected for manufacturing. This is organized and done at the sites once your qualification for the study is determined. Patients will be assigned to different monotherapy escalation cohorts and the treatment SQZ-PBMC-HPV will be administered every 3 weeks for up to a year. In addition, a second, high dose cell cohort will test the impact of a double-prime regimen where SQZ-PBMC-HPV is administered on two consecutive days followed by doses every 3 weeks for a maximum of a year.

Endpoints (what is measured in the study):

- Safety (how often patients have adverse reactions to SQZ-PBMC-HPV)
- Tolerability (how often patients need to modify or discontinue SQZ-PBMC-HPV dosing)
- Pharmacodynamic effects (what SQZ-PBMC-HPV does to the patient's body)
- Effect on tumor (how much SQZ-PBMC-HPV reduces the tumor size)
- Recommended Phase 2 dose (which dose of SQZ-PBMC-HPV should be further studied)

Eligible patients must meet certain criteria including:

- Male or female patients 18 years of age or older who are HLA-A*02 positive
- Histologically confirmed incurable or metastatic solid tumors that are HPV16+
- Cancer must have progressed after at least 1 available standard therapy for incurable disease, or the patient is intolerant to or refuses standard therapy(ies) or has a tumor for which no standard therapy(ies) exist
- Ability to undergo a leukapheresis 1 to 2 weeks prior to the start of the study treatment

  A leukapheresis is a blood filtration through a machine which collects white blood cells from the blood similar to donating blood and takes about 4 hours
- Patients must agree to venous access for the leukapheresis and be willing to have a central line inserted if venous access is an issue.

Enrolling sites:

- HonorHealth, Scottsdale, Arizona
- University of Colorado, Aurora, Colorado
- University of Kansas Cancer Center, Kansas City, Kansas
- Dana Farber Cancer Institute, Boston, Massachusetts
- Providence Cancer Institute, Portland, Oregon
- Vanderbilt University Medical Center, Nashville, Tennessee
- MD Anderson Cancer Center, Houston, Texas
- Cedars-Sinai Medical Center, Los Angeles, California

More information about this study, including a list of available clinical trial sites, is available for patients or physicians at **clinicaltrials.gov/ct2/show/NCT04084951**.

For additional assistance, please reach out to **patientadvocacy@sqzbiotech.com**.

For more information about SQZ Biotech, visit **www.sqzbiotech.com**.

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