Doctor's Note — Clinical Trial Summary

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TRIAL

Efficacy of Tislelizumab and Spartalizumab Across Multiple Cancer-types in Patients with PD1-high MRNA Expressing Tumors

NCT ID: NCT04802876 Phase: PHASE2 Sponsor: SOLTI Breast Cancer Research Group Status: Active Not Recruiting

SUMMARY

This is an open-label, parallel group, non-randomized, multicenter phase II study to evaluate the efficacy of spartalizumab (cohorts 1 and 2) and tislelizumab (cohort 3) in monotherapy in patients with PD1-high-expressing tumors.

KEY ELIGIBILITY CRITERIA

- 1. Male/female participants who are at least 18 years of age on the day of signing informed consent with histologically confirmed diagnosis of PD1 mRNA high-expression (cohort 1, 3) or PD1 mRNA low-expression (cohort 2) determined on the tumor sample will be enrolled in this study. Enrollment of patients \> 75 years of age is allowed after consultation and approval of the study medical monitor.
- 2. Life expectancy \> 3 months as per investigator opinion.
- 3. The participant (or legally acceptable representative if applicable) provides written specific informed consent for the remaining screening tests and study procedures before inclusion in the trial.
- 4. Have measurable disease based on RECIST 1.1 or RANO criteria, as appropriate to tumor type. Lesions situated in a previously irradiated area are considered measurable if progression has been demonstrated in such lesions.
- 5. Have radiologic evidence of disease progression or recurrence after the previous oncologic treatment
- 6. Have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 1. Evaluation of ECOG is to be performed within 10 days prior to the date of allocation.
- 7. Have adequate organ function. Specimens must be collected within 28 days prior to the start of study treatment.
- 8. Patients could have received a maximum of 3 lines of prior standard of care chemotherapy in the inoperable/metastatic setting.
- 9. Treatment-related toxicities (except alopecia) must d Grade 1 at the time of allocation according to CTCAE version 5.0.
- 1. A Women of childbearing potential who has a positive urine pregnancy test within 72 hours prior to allocation. If the urine test is positive or cannot be confirmed as negative, a serum pregnancy test will be required.

Total sites: 1 | 0 currently recruiting