TAPISTRY (Roche)

Tumor-Agnostic Precision Immuno-Oncology and Somatic Targeting Rational for You (TAPISTRY) Platform Study. This is the trial summary as assessed on clinicaltrials.gov on 27/05/2021.

Minor changes in the protocol may occur. You can check this on this direct link: https://clinicaltrials.gov/ct2/show/NCT04589845

Trial Design:

Arm	Intervention
Experimental: Cohort B: NTRK1/2/3 fusion-positive tumors	Entectinib BSA >/= 1.51 m2: orally at home at a dose of 600 mg/day (three 200-mg capsules per day). BSA < 1.51 m2: orally at home in mini-tablet formulation at a dose of 400 mg/day (BSA=1.11-1.50 m2) or 300 mg/day (BSA=0.81-1.10 m2) or 200 mg/day (BSA=0.51-0.80 m2) or 100 mg/day (BSA=0.43-0.50 m2)
Experimental:Cohort E: AKT1/2/3 mutant-positive tumors	Ipatasertib 12-17 years of age, the starting dose of 200 mg for participants < 35 kg, 300 mg for participants >/= 35 and < 45 kg, 400 mg for those >/= 45 kg orally QD beginning of Cycle 1 on Days 1-21 of each 28-day cycle until the participant experiences disease progression, intolerable toxicity, or withdraws consent
Experimental: Cohort F: HER-2 mutant-positive tumors	Trastuzumab emtansine will be administered at 3.6 mg/kg by IV infusion every 21 days until disease progression or unacceptable toxicity. The dosage and administration method also applies for pediatric participants 12-17 years of age
Experimental: Cohort H: PIK3CA multiple mutant-positive tumors	Inavolisib will be administered QD at a starting dose of 9 mg PO in repeated 28-day cycles. The dosage and administration method also applies for pediatric participants 12-17 years of age

Inclusion criteria:

- Histologically or cytologically confirmed diagnosis of advanced and unresectable or metastatic solid malignancy
- Measurable disease as defined by Response Evaluation Criteria in Solid Tumors, Version 1.1 (RECIST v1.1), Response Assessment in Neuro-Oncology (RANO) criteria, or International Neuroblastoma Response Criteria (INRC)
- Performance status as follows: Participantss aged >= 18 years: Eastern Cooperative Oncology Group (ECOG) Performance Status 0-2; Participantss aged 16 to < 18 years: Karnofsky score >= 50%; Participants aged < 16 years: Lansky score >= 50%
- For participants aged >= 18 and <18 years: adequate hematologic and end-organ function
- Disease progression on prior treatment, or previously untreated disease with no available acceptable treatment
- Adequate recovery from most recent systemic or local treatment for cancer
- Life expectancy >= 8 weeks
- Ability to comply with the study protocol, in the investigator's judgment
- For female participants of childbearing potential: Negative serum pregnancy test <= 14 days prior to initiating study treatment; agreement to remain abstinent or use single or combined contraception methods that result in a failure rate of < 1% per year for the period defined in the cohort-specific inclusion criteria; and agreement to refrain from donating eggs during the same period
- For male participants: Willingness to remain abstinent or use acceptable methods of contraception as defined in the cohort-specific inclusion criteria
- In addition to the general inclusion criteria above, participants must meet all of the cohort-specific inclusion criteria for the respective cohort

Exclusion criteria:

- Current participation or enrollment in another therapeutic clinical trial
- Any anticancer treatment within 2 weeks or 5 half-lives prior to start of study treatment
- Whole brain radiotherapy within 14 days prior to start of study treatment
- Stereotactic radiosurgery within 7 days prior to start of study treatment
- Pregnant or breastfeeding, or intending to become pregnant during the study
- History of or concurrent serious medical condition or abnormality in clinical laboratory tests that, in the investigator's judgment, precludes the participant's safe participation in and completion of the study or confounds the ability to interpret data from the study
- Incomplete recovery from any surgery prior to the start of study treatment that would interfere with the determination of safety or efficacy of study treatment
- Significant cardiovascular disease, such as New York Heart Association cardiac disease (Class II or higher), myocardial infarction, or cerebrovascular accident within 3 months prior to enrollment, unstable arrhythmias, or unstable angina
- History of another active cancer within 5 years prior to screening that may interfere with the determination of safety or efficacy of study treatment with respect to the qualifying solid tumor malignancy
- In addition to the general exclusion criteria above, in order to be enrolled in a treatment cohort of the study, participants must not meet any of the cohort-specific exclusion criteria