TAPISTRY (Roche)

TAPISTRY is a Phase II, global, multicenter, open-label, multi-cohort study designed to evaluate the safety and efficacy of targeted therapies or immunotherapy as single agents or in rational, specified combinations in participants with unresectable, locally advanced or metastatic solid tumors determined to harbor specific oncogenic genomic alterations or who are tumor mutational burden (TMB)-high as identified by a validated next-generation sequencing (NGS) assay.

This is the trial summary as assessed on clinicaltrials.gov on 21/06/2022.

Minor changes in the protocol may occur. You can check this on this direct link:

https://clinicaltrials.gov/ct2/show/NCT04589845

Trial Design:

Experimental: ***Cohort I: BRAF class II mutant or fusion-positive tumors***
Participants with BRAF class II mutant/fusion-positive tumors (adults and adolescents ≥ 40 kg) will receive 400 mg belvarafenib by mouth (PO) BID (twice a day) with adequate water (more than 200 mL). One cycle consists of 28 days. Administration of belvarafenib should occur BID on every day of each 28-day cycle.

Experimental: ***Cohort J: BRAF class III mutant-positive tumors***
Participants with BRAF class III mutant-positive tumors(adults and adolescents ≥ 40 kg) will receive 400 mg belvarafenib by mouth (PO) BID (twice a day) with adequate water (more than 200 mL). One cycle consists of 28 days. Administration of belvarafenib should occur BID on every day of each 28-day cycle.

Drug: Belvarafenib
Belvarafenib will be administered at a dose 400 mg (PO) BID with adequate water (more than 200 mL). One cycle consists of 28 days. Administration of belvarafenib should occur BID on every day of each 28-day cycle.

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:

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