ForPatients
by Roche

Solid Tumors

A clinical trial to understand how genetic testing can help doctors to decide which treatment is best for patients with solid tumours (TAPISTRY)

Tumor-Agnostic Precision Immuno-Oncology and Somatic Targeting Rational for You (TAPISTRY) Platform Study

Trial Status	Trial Runs In	Trial Identifier
Recruiting	24 Countries	NCT04589845 2020-001847-16 BO41932

The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

Official Title:

Tumor-Agnostic Precision Immunooncology and Somatic Targeting Rational for You (TAPISTRY) Phase II Platform Trial

Trial Summary:

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. Participants with solid tumors will be treated with a drug or drug regimen tailored to their NGS assay results at screening. Participants will be assigned to the appropriate cohort based on their genetic alteration(s). Treatment will be assigned on the basis of relevant oncogenotype, will have cohort-specific inclusion/exclusion criteria, and, unless otherwise specified, will continue until disease progression, loss of clinical benefit, unacceptable toxicity, participant or physician decision to discontinue, or death, whichever occurs first.

We are able to provide travel reimbursement or travel services for patients located in remote locations or in areas that do not have trial locations. For more information about the trial, please contact mississauga.canada_medinfo@roche.com or 1-888-762-4388.

Hoffmann-La Roche **Phase 2**

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Phase

NCT04589845 2020-001847-16 BO41932
Trial Identifiers

Eligibility Criteria:

Gender
All

Age

Healthy Volunteers
No

How does the TAPISTRY clinical trial work?

This clinical trial is recruiting people who have advanced solid tumours that cannot be surgically removed. You must have had genetic testing on your solid tumour that shows a positive result for one of the genetic changes, also known as biomarkers, being tested in this trial.

The purpose of this clinical trial is to compare the effects, good or bad, of different targeted therapies and immunotherapies in patients with solid tumours showing specific biomarkers, which cannot be surgically removed.

How do I take part in this clinical trial?

To be able to take part in this clinical trial, you must have been diagnosed with an advanced solid tumour that has grown or spread, cannot be removed completely with surgery and shows one of the specific biomarkers being tested in this clinical trial:

- *ROS1* fusion-positive tumours (excluding non-small cell lung cancer [NSCLC])
- *NTRK1/2/3* fusion-positive tumours
- *ALK* fusion-positive tumours (excluding NSCLC)
- TMB-high tumours
- *AKT1/2/3* mutant-positive tumours
- *HER2* mutant-positive tumours
- *PIK3CA* multiple mutant-positive tumours
- *BRAF* class II mutant/fusion-positive tumours
- *BRAF* class III mutant-positive tumours
- *RET* fusion-positive tumours (excluding NSCLC)

Your doctor will be able to give you more information on the type of biomarker your solid tumour shows.

You must be in otherwise good health to take part. You will not be able to take part if you are pregnant or breastfeeding, or if you have received any recent treatment for your

cancer. Some of the groups may have other specific requirements. Your doctor will be able to give you more information on this.

If you think this clinical trial may be suitable for you and would like to take part, please talk to your doctor. If your doctor thinks that you might be able to take part in this clinical trial, they may refer you to the closest clinical trial doctor. They will give you all the information you need to make your decision about taking part in the clinical trial. You can also find the clinical trial locations on this page.

Your doctor will conduct some tests to make sure you will be able to take the treatments given in this clinical trial. Some of these tests or procedures may be part of your regular medical care. They may be done even if you do not take part in the clinical trial. If you have had some of the tests recently, they may not need to be done again.

Before starting the clinical trial, you will be told about any risks and benefits of participating in the trial. You will also be told what other treatments are available so that you may decide if you still want to participate.

While taking part in the clinical trial, you will need to either not have heterosexual intercourse or use contraception for safety reasons.

What treatment will I be given if I join this clinical trial?

If you join this clinical trial, you will be entered into one of ten groups, depending on which biomarker your solid tumour has:

- **Group A:** People with *ROS1* fusion-positive tumours (excluding NSCLC). You will receive entrectinib as capsules to take by mouth with or without food every day for as long as it can help you
- **Group B:** People with *NTRK1/2/3* fusion-positive tumours. You will receive entrectinib as capsules to take by mouth with or without food every day, for as long as it can help you
- **Group C:** People with *ALK* fusion-positive tumours (excluding NSCLC). You will receive alectinib as capsules to take by mouth with food twice a day, for as long as it can help you
- **Group D:** People with TMB-high tumours. You will receive atezolizumab as an infusion into the vein once every three weeks, for as long as it can help you
- **Group E:** People with *AKT1/2/3* mutant-positive tumours. You will receive ipatasertib as a tablet to take by mouth with fluid, with or without food once a day, for as long as it can help you
- **Group F:** People with *HER2* mutant-positive tumours. You will receive trastuzumab emtansine as an infusion into the vein once every three weeks, for as long as it can help you

- **Group H:** People with *PIK3CA* multiple mutant-positive tumours. You will receive GDC-0077 (inavolisib) as a tablet to take by mouth once a day, for as long as it can help you
- **Group I:** People with *BRAF* class II mutant/fusion-positive tumours. You will receive belvarafenib as tablets to take by mouth with water twice a day within 30 minutes of a meal, for as long as it can help you
- **Group J:** People with *BRAF* class III mutant-positive tumours. You will receive belvarafenib as tablets to take by mouth with water twice a day within 30 minutes of a meal, for as long as it can help you
- **Group K:** People with *RET* fusion-positive tumours (excluding NSCLC). You will receive pralsetinib as capsules to take by mouth with water once a day without food, for as long as it can help you

This clinical trial is 'open-label', which means that everyone involved will know which group they are in and what treatment they are receiving.

Group G (people with *MDM2*-amplified *TP53* wild-type tumours) has been closed for enrollment – no patients were enrolled in this cohort.

How often will I be seen in follow-up appointments and for how long?

You will be given the clinical trial treatment for as long as it can help you. During the clinical trial, you will need to attend regular visits for treatments and assessments to see how you are responding to the treatment and any side effects that you may be having. You are free to stop this treatment at any time. After you have finished treatment, the clinical trial staff will still follow up with you approximately every three months, as long as you agree with it.

What happens if I am unable to take part in this clinical trial?

If this clinical trial is not suitable for you, you will not be able to take part. Your doctor may suggest other clinical trials that you may be able to take part in or other treatments that you can be given. You will not lose access to any of your regular care.

For more information about this clinical trial see the **For Expert** tab on the specific ForPatient page or follow this link to ClinicalTrials.gov: https://clinicaltrials.gov/ct2/show/NCT04589845

Trial-identifier: NCT04589845

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