ForPatients
by Roche

Melanoma

A clinical trial to compare the effectiveness and safety of different doses of RO7247669 in people with melanoma that cannot be removed by surgery or has spread to other organs

A Study of Multiple Doses of RO7247669 in Participants With Previously Untreated Unresectable or Metastatic Melanoma

Trial Status	Trial Runs In	Trial Identifier
Active, not recruiting	10 Countries	NCT05419388 BP43963

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:

A Randomized, Open-Label, Multicenter, Phase II Study of Multiple Doses of RO7247669 in Participants With Previously Untreated Unresectable or Metastatic Melanoma

Trial Summary:

The purpose of this study is to assess the efficacy, safety, pharmacokinetics (PK), and pharmacodynamics of two dose levels of RO7247669 in participants with unresectable or metastatic melanoma to select the recommended dose for further development.

Hoffmann-La Roche	Phase 1/Phase 2
Sponsor	Phase

NCT05419388 BP43963
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Why is the BP43963 clinical trial needed?

Melanoma is a type of skin cancer that can be difficult to treat if it cannot be removed by surgery (unresectable melanoma) or if it spreads to other organs in the body (metastatic melanoma). However, new medicines, such as cancer immunotherapies, have shown

encouraging results in the treatment of melanoma. Cancer immunotherapies use the body's immune system to destroy cancerous cells.

Researchers hope that an experimental cancer immunotherapy drug called RO7247669 will provide better health outcomes for people with unresectable or metastatic melanoma.

How does the BP43963 clinical trial work?

This clinical trial is recruiting people who have a type of skin cancer called melanoma. People can take part if they have been diagnosed with unresectable or metastatic melanoma and have not received previous treatment.

The purpose of this clinical trial is to test the effectiveness and safety of RO7247669 at different doses and to understand the way the body processes RO7247669.

Participants will be given the clinical trial treatment RO7247669 for a maximum of 2 years or until cancer symptoms get worse or unacceptable side effects are experienced. RO7247669 will be given in a hospital as an infusion (into a vein) every 3 weeks (also known as treatment "cycles"). Participants will be seen by the clinical trial doctor:

- Every week for the first treatment cycle (Cycle 1)
- On Day 1 and Day 5 of Cycle 2
- On Day 1 of Cycles 3 and 4
- On Days 1, 8 and 15 of Cycle 5
- On Day 1 of each following treatment cycle

These hospital visits will include checks to see how the participant is responding to the treatment and any side effects they may be having. Participants' total time in the clinical trial will be roughly 2 years and 1 month. Participants are free to stop trial treatment and leave the clinical trial at any time.

What are the main endpoints of the BP43963 clinical trial?

The main clinical trial endpoint (the main result that is measured in the trial to see if the medicine has worked) is how long participants live without their cancer worsening (known as 'progression-free survival').

The other clinical trial endpoints include the number and seriousness of any side effects, how many participants have a reduction in the size of their tumour (known as 'objective response rate'), and how the body processes and responds to RO7247669.

Who can take part in this clinical trial?

People can take part in this trial if they are at least 18 years old and have been diagnosed with either unresectable or metastatic melanoma.

People may not be able to take part in this trial if they have certain other medical conditions, have previously received certain treatments, are pregnant or breastfeeding, or are planning to become pregnant.

What treatment will participants be given in this clinical trial?

Everyone who joins this clinical trial will receive RO7247669. Participants will be split into two groups randomly (like flipping a coin) and given either:

- RO7247669, given as an infusion into a vein at a low dose once every 3 weeks
- OR, RO7247669, given as an infusion into a vein at a high dose once every 3 weeks

Participants will have an equal chance of being placed in either group.

Neither participants nor the clinical trial doctor can choose the group participants are in. However, this is an open-label trial, which means everyone involved, including the participants and the doctors, know which clinical trial treatment participants have been given.

Are there any risks or benefits in taking part in this clinical trial?

The safety or effectiveness of the experimental treatment or use may not be fully known at the time of the trial. Most trials involve some risks to the participant, although it may not be greater than the risks related to routine medical care or the natural progression of the health condition. Potential participants will be told about any risks and benefits of taking part in the clinical trial, as well as any additional procedures, tests, or assessments they will be asked to undergo. These will all be described in an informed consent document (a document that provides people with the information they need to make a decision to volunteer for a clinical trial). A potential participant should also discuss these with members of the research team and with their usual healthcare provider. Anyone interested in taking part in a clinical trial should know as much as possible about the trial and feel comfortable asking the research team any questions about the trial.

Risks associated with the clinical trial

Participants may have side effects (an unwanted effect of a drug or medical treatment) from the drug used in this clinical trial. Side effects can be mild to severe and even life-threatening, and can vary from person to person.

RO7247669

Potential participants will be told about the known side effects of RO7247669, and where relevant, also potential side effects based on human and laboratory studies or knowledge of similar drugs.

RO7247669 will be given as an intravenous (into a vein) infusion. Participants will be told about any known side effects of intravenous infusion.

Potential benefits associated with the clinical trial

Participants' health may or may not improve from participation in the clinical trial, but the information that is collected may help other people who have a similar medical condition in the future.

For more information about this clinical trial see the **For Expert** tab on the specific ForPatients page or follow this link to ClinicalTrials.gov: https://clinicaltrials.gov/ct2/show/NCT05419388

Inclusion Criteria:

- Histologically confirmed unresectable or metastatic melanoma, per the American Joint Committee on Cancer (AJCC) staging system (unresectable Stage III or Stage IV)
- Radiologically measurable disease according to Response Evaluation Criteria in Solid Tumors (RECIST) v1.1
- Eastern Cooperative Oncology Group (ECOG) Performance Status 0-1
- Known v-Raf murine sarcoma viral oncogene homolog B1 (BRAF) V600 mutation status
- Adequate cardiovascular, hematological, hepatic and renal function
- Willingness to abide by contraceptive measures for the duration of the study
- Participants must have known PD-L1 status

Exclusion Criteria:

- Pregnancy, lactation, or breastfeeding
- Known hypersensitivity to any of the components of RO7247669
- Participants must not have ocular melanoma
- Symptomatic central nervous system (CNS) metastases
- Significant cardiovascular/cerebrovascular disease within 6 months prior to randomization

- Known active or uncontrolled bacterial, viral, fungal, mycobacterial, parasitic, or other infection or any major episode of infection requiring treatment with intravenous (IV) antibiotics or hospitalization within 28 days prior to randomization
- Major surgical procedure or significant traumatic injury (excluding biopsies) within 28 days prior to randomization, or anticipation of the need for major surgery during the course of the study
- Active or history of autoimmune disease or immune deficiency with some exceptions
- Prior systemic anticancer therapy for unresectable or metastatic melanoma
- Prior anticancer therapy with any-immunomodulatory agents including CPIs (such as anti-programmed death-ligand 1[PD-L1]/PD-1 and anti-cytotoxic T lymphocyte-associated antigen [CTLA-4]) with some exceptions if used as prior adjuvant or neoadjuvant melanoma therapies
- Prior treatment with anti-LAG3 therapy