Study to Allow Patients Previously Participating in a Novartis Sponsored Trial to Continue Receiving Capmatinib Treatment as Single Agent or in Combination With Other Treatments or the Combination Treatment Alone

Last Update: Apr 17, 2025
An Open-label, Multi-center, Global, Rollover Study for Patients Who Have Previously Been Treated With Capmatinib (INC280) as Monotherapy or in Combination in a Novartis Sponsored Trial.
ClinicalTrials.gov Identifier:
NCT03040973
Novartis Reference Number:CINC280A2X02B
See if you Pre-qualify
All compounds are either investigational or being studied for (a) new use(s). Efficacy and safety have not been established. There is no guarantee that they will become commercially available for the use(s) under investigation.

Study Description

The purpose of this study is to assess long-term safety and provide continued study treatment access to eligible participants who are judged by the Investigator to benefit from continued treatment with capmatinib monotherapy or in combination with other treatments or with the combination treatment alone in a Novartis sponsored study This is an open-label, multi-center, rollover study to assess long-term safety in participants who have completed a prior Novartis-sponsored study, that have fulfilled the eligibility requirements and are judged by the Investigator to benefit from continued treatment with capmatinib given as monotherapy or in combination with other treatments or with the combination treatment alone.

There will be no screening period for this study. After providing informed consent, all eligible participants will begin their treatment within the rollover study. Participants should return to the study center for resupply of the study medication/s and for safety assessment following the usual local practice. During a public health emergency as declared by local or regional authorities (i.e. pandemic, epidemic or natural disaster) that limits or prevents on-site study visits, alternative methods of providing continuing care may be implemented by the Investigator as the situation dictates.

Participants will continue to be treated until they are no longer benefitting from the study treatment in the opinion of the treating physician, develop unacceptable toxicities that preclude further treatment with the study treatment, disease progression, withdrawal of consent, discontinuation at the discretion of the Investigator, initiation of new anticancer therapy, until the study treatment is commercially available and reimbursed or/and available under any other local mechanism (such as compassionate use, named patient program) for the appropriate indication and/or discontinuation for any other reason. Participants receiving capmatinib as part of a combination therapy could continue treatment only with capmatinib or with the combination treatment as single agent in case one of the two compounds is permanently discontinued, if in the opinion of the treating

physician they are still benefitting from the treatment.

A patient will reach the end of rollover study when study treatment is permanently discontinued and the end of treatment visit has been performed. All participants will be followed up for safety for 30 days after the last dose of study treatment or until SAE is resolved as required, whichever is later.

The study is expected to remain open for up to 10 years or until such time that all enrolled participants no longer need treatment with study treatment(s) or Novartis decides to stop the development program, whichever comes first.

Condition
Advanced Solid Tumors Which Are cMET-dependent
Phase
Phase2
Overall Status
Recruiting
Number of Participants
40
Start Date
Jul 04, 2017
Completion Date
Jul 30, 2027
Gender
All
Age(s)
18 Years - 100 Years (Adult, Older Adult)

Interventions

Drug

Capmatinib

Tablet for oral use; 150 mg, 200 mg; twice a day
Drug

Gefitinib

tablets for oral use; 250mg; once a day
Drug

Nazartinib

Capsule for oral use; 25 mg, 50 mg; once a day
Drug

Osimertinib

Tablets for oral use; 40 mg, 80 mg; once a day.

Eligibility Criteria

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Inclusion criteria:

1. Participant is currently receiving capmatinib treatment (within Novartis-sponsored study which is eligible and approved to transition participants to rollover study) as single agent or in combination or is receiving a combination treatment alone. This includes all participants treated with capmatinib in combination with other treatment that permanently discontinued capmatinib for any reason but are still receiving the combination treatment as single agent. In order to receive the combination treatment as single agent in the rollover study, the treatment needs to be not accessible to the participant outside a clinical trial (e.g. commercially not available or reimbursed).
2. Participant is currently deriving clinical benefit from study treatment as determined by the Investigator
3. Willingness and ability to comply with scheduled visits, treatment plans and any other study procedures
4. Written informed consent obtained prior to enrolling in the rollover study and receiving study medication. If consent cannot be expressed in writing, it must be formally documented and witnessed, ideally via an independent trusted witness.

Exclusion criteria:

1. Participant is currently not receiving any study treatment due to unresolved toxicities for which study treatment dosing has been interrupted or permanently discontinued in the parent protocol (participants meeting all other eligibility criteria may be enrolled once toxicities have resolved to allow study treatment dosing to resume)
2. Pregnant or nursing (lactating) women
3. Women of child-bearing potential, defined as all women physiologically capable of becoming pregnant, unless they are using highly effective methods of contraception while taking study treatment and for at least 7 days or following combination treatment parent trial recommendation (whichever is longer) of study treatment after stopping medication. Highly effective contraception methods include:
4. Concurrent participation in another clinical study other than a parent clinical study
5. Participants who received live vaccines (e.g., intranasal influenza, measles, mumps, rubella, oral polio, BCG, yellow fever, varicella, TY21a typhoid vaccines and COVID-19 vaccines) within 30 days prior to the first dose of study treatment

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