ForPatients
by Roche

Solid TumorsCancer

A Safety and Efficacy Extension Study of Pertuzumab in Patients With Solid Tumors Previously Enrolled in a Hoffmann-La Roche-Sponsored Pertuzumab Clinical Trial

Trial Status	Trial Runs In	Trial Identifier
Active, not recruiting	15 Countries	NCT02320435 2014-002048-42 2023-505102-42-00 MO29406

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 Single-Arm Open-Label Multi-Centre Extension Study of Pertuzumab Administered As a Single Agent or in Combination With Other Anti-Cancer Therapies in Patients Previously Enrolled in a Hoffmann-La Roche-Sponsored Pertuzumab Study

Trial Summary:

This is a single-arm, multi-center, open-label extension study designed to provide continued pertuzumab therapy to patients receiving pertuzumab as an investigational medicinal product (IMP) in a Roche-sponsored global study and who continue to receive pertuzumab at the end of the Parent study, as well as to collect long-term safety and efficacy data of pertuzumab therapy. Patients with solid tumors who have not experienced progressive disease in the Parent study and, in the investigator's opinion, may potentially benefit from continued pertuzumab treatment, will continue to receive pertuzumab until disease progression, unacceptable toxicity, investigator/patient decision, patient non-compliance, patient death, patient request to withdraw, or study termination by the Sponsor, whichever occurs first.

Hoffmann-La Roche	Phase 3
Sponsor	Phase

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Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

- Informed consent
- Prior eligibility for, and receiving pertuzumab as an investigational medicinal product in, a Roche-sponsored study (either as a single agent or in combination with other anti-cancer drugs used in the Parent study) at the time of the Parent study closure
- Investigator's opinion that the patient continues to benefit from treatment

Exclusion Criteria:

- Meets any of the exclusion criteria of the Parent protocol at the time the patient is considered for entry in the extension study
- Evidence of disease progression assessed according to Parent protocol before enrollment in to the extension study
- Permanent discontinuation of pertuzumab for any reason during the Parent study, or between the end of the Parent study and before enrollment into the extension study
- Any unresolved or irreversible toxicities during the Parent study that require permanent discontinuation of pertuzumab, according to Parent protocol or local label. Delay of treatment to wait for resolution of toxicities is allowed as long as it is within the guidelines of the respective Parent protocol and does not contradict exclusion criterion below.
- More than 9 weeks between the last dose of pertuzumab in the Parent study and the first dose pertuzumab in the extension study
- Left ventricular ejection fraction </= 50%
- Any serious uncontrolled concomitant disease that would contraindicate the use of pertuzumab or that would put the patient at high risk for treatment-related complications
- Treatment with any anti-cancer treatment (other than any treatment given as permitted in the Parent protocol) in the time period between last treatment in the Parent study and the first dose pertuzumab in the extension study (i.e. up to 9 weeks)
- Positive serum pregnancy test
- Women of child-bearing potential and men with partners of childbearing potential who do not agree to use a highly-effective non-hormonal form of contraception or two effective forms of non-hormonal contraception by the patient and/or partner for the duration of study treatment and for at least 7 months after the last dose of study medication. Male patients who do not agree to refrain from donating sperm during this same period. Male patients whose partner is pregnant who do not agree to use condoms for the duration of the pregnancy.
- Concurrent participation in any therapeutic clinical trial (other than the Parent study)
- Assessed by the Investigator to be unable or unwilling to comply with the requirements of the protocol