A Post Marketing Surveillance on Piqray in Korea

Last Update: Jan 14, 2025
A Post Marketing Surveillance on Piqray (Alpelisib) in Korea
ClinicalTrials.gov Identifier:
NCT05293470
Novartis Reference Number:CBYL719CKR01
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

This is a prospective, multicenter, open-label, non-comparative, non-interventional, observational study to assess te safety and effectiveness of Piqray in the real-world setting The observation duration will be up to 24 weeks after enrollment, which is sufficient to provide adequate information about the safety and effectiveness of Piqray. If the subject does not return for a follow-up visit or stops taking Piqray for any reason, all data collected until the date of the last contact of the subject will be used. Patients will be followed up (safety follow up) for 30 days afetr either 24 weeks-treatment or early withdrawal.

Condition
Breast Cancer
Overall Status
Recruiting
Number of Participants
900
Start Date
Jun 29, 2022
Completion Date
May 12, 2027
Gender
All
Age(s)
18 Years - 100 Years (Adult, Older Adult)

Interventions

Other

Piqray

There is no treatment allocation. Patients administered Piqray by prescription will be enrolled.

Eligibility Criteria

Inclusion Criteria:

Subjects eligible for this study must meet all of the following criteria:

1. Postmenopausal women and men who have a confirmed diagnosis of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, PIK3CA mutated, advanced or metastatic breast cancer.
2. Patients who have progressed on prior endocrine based therapy and are going to start Piqray treatment for the first time in accordance with the locally approved label.
3. Patients who are willing to provide written informed consent

Exclusion Criteria:

Subjects eligible for this study must not meet the following criteria:

1. Patients with contraindication according to prescribing information for Piqray in Korea.

- Severe hypersensitivity to Piqray or to any of its components
2. Female subjects who are pregnant and nursing (lactating)
3. Patients who are sexually active but not willing to follow contraceptive precautions during taking Piqray.
4. Participants who receive or are going to receive any investigational medicine during surveillance period.

Korea, Republic of

Novartis Investigative Site

Recruiting

Seoul,06351,Korea, Republic of

Novartis Investigative Site

Recruiting

Busan,602-030,Korea, Republic of

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Worldwide Contacts

If the location of your choosing does not feature any contact detail, please reach out using the information

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Source URL: *https://prod1.novartis.com/clinicaltrials/study/nct05293470*

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