Study of PIK3CA Mutations and Effectiveness and Tolerability Outcomes of Alpelisib in Real-world

Last Update: Jan 14, 2025
A Descriptive Study of PIK3CA Mutations and Outcomes With Alpelisib in Patients With HR-positive and HER2-negative Advanced Breast Cancer (ABC)/ Metastatic Breast Cancer (MBC) in India
ClinicalTrials.gov Identifier:
NCT05022342
Novartis Reference Number:CBYL719CIN02
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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

SPEAR is a non-interventional / observational, prospective, multicenter study planned to be conducted across \~ 30 sites in India, among HR-positive and HER2-negative ABC/MBC patients. This being a non-interventional study, no investigational drug or intervention will be administered as a part of the study participation. All the therapeutic decisions, as well as the type and timing of disease monitoring, laboratory tests or medical procedures will be at the discretion of the treating physician and upon patient's consent. No visits will be scheduled as a part of this non-interventional study, however, data by visits for variables will be collected for all the enrolled patients. Overall, this study will have 2 parts (Part A and Part B). However, it is to be noted that, these parts (Part A and Part B) are independent of each other and can run in parallel. The purpose of the Part A of study is to determine the proportion of PIK3CA mutation positive patients among the HR-positive and HER2-negative ABC/MBC diagnosed patients in India. The Part B of the study aims to evaluate the clinical effectiveness and tolerability of alpelisib plus fulvestrant among men, pre-menopausal women (ovarian ablation) or post-menopausal women who are PIK3CA mutation positive patients with HR-positive and HER2-negative ABC/MBC diagnosis among Indian population, in the real-world setting.

Part A- This will involve enrolling of approximately 1200 patients (males, post-menopausal women or pre-menopausal women who are receiving ovarian ablation) with a documented diagnosis of HR-positive HER2-negative ABC/MBC. The data on PIK3CA mutation status will be collected only for those patients who signs ICF for participation in the study. Once, patient signs ICF, their samples will be sent for PIK3CA mutation status testing, that will be performed at central laboratory and the results on mutation status will be reported to the investigator.

Part B- This part aims to enroll approximately 200 patients who are PIK3CA mutation positive. The patients enrolled into the Part B of the study can either be continued from Part A of the study or be a direct enrollment into the Part B of the study. For the patient's entering directly into Part B of the study, positive PIK3CA status should be available prior to study entry. All the patients entering into part B of the study must be alpelisib treatment naïve. The patients enrolled into Part B of the study, should have already been planned to receive treatment with alpelisib plus fulvestrant, based on their treating physician's discretion and upon patient's consent. The treatment decision by the physician are to be made independent of the patient's inclusion in this

observational study. During the Part B of the study, data by visits for variables will be collected for the enrolled patients at every 3 months interval (±1 month), if feasible or until a maximum of 24 months observational period or lost to follow-up (End-of-study \[EoS\] assessment will be performed), or death, or disease progression, whichever occurs first.

Condition
Breast Cancer
Overall Status
Recruiting
Number of Participants
200
Start Date
Oct 27, 2021
Completion Date
Sep 30, 2025
Gender
All
Age(s)
18 Years - 100 Years (Adult, Older Adult)

Interventions

Other

alpelisib plus fulvestrant

Prospective observational study. There is no treatment allocation. Patients administered alpelisib plus fulvestrant, that have started before inclusion of the patient into the study will be enrolled.

Eligibility Criteria

Inclusion Criteria:

PART A:

1. Males (≥18 years of age), post-menopausal* females or pre-menopausal** females with ovarian ablation (as per physician decision).
2. Patients with confirmed diagnosis of ABC/MBC (locoregionally recurrent not amenable to curative therapy or metastatic)
3. Patient with histologically and/or cytologically confirmed diagnosis of HR-positive (ER+ and/or PgR+), as well as HER2-negative breast cancer by local laboratory (HER2- by Immunohistochemistry \[IHC\], for borderline2+ Fluorescence In Situ Hybridization \[FISH\])
4. A separate signed patient ICF for Part A of the study must be obtained prior to any data collection and sample shipment to the central designated laboratory
5. Patient's tumor tissue (archival or fresh) is available to be sent to a central laboratory for PIK3CA testing. In case, tissue sample (archival or fresh) is not available or feasible, liquid biopsy may be allowed.

PART B:

1. Males (≥18 years of age), post-menopausal* females or pre-menopausal** females with ovarian ablation

(as per physician decision).
2. Patients with confirmed diagnosis of ABC/MBC (locoregionally recurrent not amenable to curative therapy or metastatic) - for direct enrollment patients into Part B of the study.
3. Patient with histologically and/or cytologically confirmed diagnosis of HR-positive (ER+ and/or PgR+), as well as HER2-negative breast cancer by local laboratory (HER2- by Immunohistochemistry \[IHC\], for borderline2+ Fluorescence In Situ Hybridization \[FISH\]) - for direct enrollment patients into Part B of the study.
4. Participants with confirmed positive PIK3CA mutation status prior to study entry.
5. A separate signed ICF for Part B of the study must be obtained by all the patients, prior to any data collection, irrespective of patients who are being enrolled from Part A of the study or who are being enrolled directly into Part B of the study.
6. Physician decision to treat patients with alpelisib plus fulvestrant, according to the prescribing label and the local practicing guidelines.
7. Patient should be alpelisib treatment naïve.

Exclusion Criteria:

PART A:

1. Prior or current enrollment in any interventional clinical trial for ABC/MBC.

Part

PART B:

1. Patients' who had prior or current exposure to alpelisib or had prior or current exposure to any other PIK3CA inhibitor should be excluded.
2. Known hypersensitivity to alpelisib or fulvestrant, or to any of the excipients of alpelisib or fulvestrant.
3. Participant with type I or uncontrolled type II diabetes mellitus (HbA1c \>7, \[as per ADA/ACP guidelines 2020\]).
4. Participant has a history of severe cutaneous reactions like Stevens-Johnson-Syndrome (SJS), Erythema Multiforme (EM), Toxic Epidermal Necrolysis (TEN), or Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS).
5. Participant has documented pneumonitis/interstitial lung disease which is active and requiring treatment.
6. Participant with unresolved osteonecrosis of the jaw.
7. Participant reports history of acute pancreatitis within 1 year of screening or past medical history of chronic pancreatitis, major surgery, any relevant medical condition, gastrointestinal (GI) condition preventing absorption, Child Pugh score B or C etc.

India

Novartis Investigative Site

Recruiting

Bhubaneswar,751005,India

Novartis Investigative Site

Recruiting

New Delhi,Delhi,110092,India

Novartis Investigative Site

Recruiting

Kolkata,700016,India

Novartis Investigative Site

Recruiting

Mumbai,Maharashtra,400071,India

Novartis Investigative Site

Recruiting

Pune,Maharashtra,411004,India

Novartis Investigative Site

Recruiting

Bhubaneshwar,Orissa,751007,India

Novartis Investigative Site

Recruiting

Chandigarh,Punjab,160055,India

Novartis Investigative Site

Recruiting

Kolkata,West Bengal,700063,India

Worldwide Contacts

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

Novartis Pharmaceuticals

Phone: +41613241111
Email: novartis.email@novartis.com

Source URL: *https://prod1.novartis.com/clinicaltrials/study/nct05022342*

List of links present in page

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