INAVO122: A study of inavolisib + PH FDC SC in patients with *PIK3CA*-mutated, HER2+ locally advanced or metastatic breast cancer

Recruiting

INAVO122/WO44263: A Phase III, randomised, double-blind, placebo-controlled study evaluating the efficacy and safety of inavolisib + fixed-dose combination of pertuzumab + trastuzumab for subcutaneous injection (PH FDC SC) vs. placebo + PH FDC SC as maintenance therapy after first-line induction therapy in patients with *PIK3CA*-mutated, HER2+ locally advanced or metastatic breast cancer (LA/mBC)

Patients with *PIK3CA*-mutated, HER2+ LA/mBC
- Disease-free interval of ≥6 months from completion of prior neo/adjuvant non-hormonal therapy

N ≈ 230

Induction therapy

Intravenous or subcutaneous pertuzumab + trastuzumab (q3w) + taxane-based* chemotherapy 4–8 cycles

R 1:1

Maintenance therapy

Inavolisib 9 mg PO qd + PH FDC SC (q3w)†

Placebo PO qd + PH FDC SC (q3w)†

Treatment until disease progression, unacceptable toxicity or withdrawal of consent

* Investigator's choice of docetaxel, paclitaxel or *nab*-paclitaxel per SoC.

† Concomitant endocrine therapy during maintenance therapy is allowed at the physician's discretion (tamoxifen, anastrozole, letrozole, exemestane or fulvestrant).

Primary endpoint

- Investigator-assessed progression-free survival defined as the time from randomisation to the first occurrence of disease progression (per RECIST v1.1) or death from any cause (whichever occurs first)

Secondary endpoints

- Overall survival
- Investigator-assessed objective response rate
- Investigator-assessed duration of response
- Investigator-assessed clinical benefit rate
- Investigator-assessed time to second disease progression
- Patient-reported outcomes/health-related quality of life
- Safety
- Pharmacokinetics

Key inclusion criteria

- ECOG PS 0 or 1
- Centrally confirmed HER2+ *PIK3CA*-mutated disease
- Histologically or cytologically confirmed LA/mBC not amenable to curative resection (adenocarcinoma)
- Disease-free interval of ≥6 months from completion of neo/adjuvant systemic non-hormonal treatment to recurrence
- LVEF of ≥50% (by ECHO or MUGA)
- Adequate haematological and organ function

Key exclusion criteria

- Prior treatment in the LA/mBC setting with any agent whose mechanism of action is to inhibit the PI3K/AKT/mTOR pathway
- Systemic non-hormonal anti-cancer therapy for HER2+ LA/mBC prior to initiation of induction therapy
- History of, or active, inflammatory bowel disease
- Disease progression within 6 months of receiving HER2-targeted therapy
- Type 2 diabetes requiring ongoing systemic treatment at study entry or any history of Type 1 diabetes
- Clinically significant and active liver disease, including severe liver impairment, viral or other hepatitis, current alcohol abuse or cirrhosis
- Symptomatic active lung disease, including pneumonitis or interstitial lung disease
- History of leptomeningeal disease or carcinomatous meningitis
- Serious infection requiring intravenous antibiotics within 7 days prior to Day 1 of Cycle 1
- Active inflammatory or infectious eye conditions or eye conditions requiring medical or surgical intervention during study treatment

INAVO122 is enrolling in: United States, Argentina and South Korea

Link for more information: https://classic.clinicaltrials.gov/ct2/show/NCT05894239

Please reach out to your local Roche/Genentech contact for more information

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