Now Enrolling in Locally Advanced or Metastatic Breast Cancer

Phase III • NCT05894239 • WO44263

A Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Efficacy and Safety of Inavolisib in Combination With Pertuzumab, Trastuzumab and Hyaluronidase-zzxf Versus Placebo in Combination With Pertuzumab, Trastuzumab and Hyaluronidase-zzxf as Maintenance Therapy After First Line Induction Therapy in Participants With PIK3CA-Mutated HER2-Positive Locally Advanced or Metastatic Breast Cancer

- Adenocarcinoma of the breast with metastatic or locally advanced disease not amenable to curative resection
- Confirmation of HER2 biomarker eligibility based on valid results from central testing of tumor tissue documenting HER2-positivity
- Confirmation of PIK3CA-mutation biomarker eligibility based on valid results from central testing of tumor tissue documenting PIK3CA-mutated tumor status

Induction

Pertuzumab, Trastuzumab and Hyaluronidase-zzxf + Taxane-Based Chemotherapy

Randomized

Maintenance

Inavolisib + Pertuzumab, Trastuzumab and Hyaluronidase-zzxf

Placebo + Pertuzumab, Trastuzumab and Hyaluronidase-zzxf

Study Endpoints

Primary Outcome Measure:

- Progression-free survival*

Secondary Outcome Measures:

- Overall survival
- Objective response rate*
- Duration of response*
- Clinical benefit rate*
- Progression-free survival 2*
- Mean and mean changes from baseline score in function and HRQoL
- Percentage of participants with adverse events
- Plasma concentration of Inavolisib at specified timepoints

Select Eligibility Criteria

Key Inclusion Criteria:

- ECOG Performance Status 0 or 1
- Disease-free interval from completion of adjuvant or neoadjuvant systemic non-hormonal treatment to recurrence of ≥6 months
- LVEF (left ventricular ejection fraction) of at least 50% as measured by ECHO or MUGA
- Adequate hematologic and organ function prior to initiation of study treatment

Key Exclusion Criteria:

- Prior treatment in the locally advanced or metastatic setting with any PI3K, AKT, or mTOR inhibitor or any agent whose mechanism of action is to inhibit the PI3K-AKT-mTOR pathway
- Any prior systemic non-hormonal anti-cancer therapy for locally advanced or metastatic HER2-positive breast cancer prior to initiation of induction therapy
- History or active inflammatory bowel disease
- Disease progression within 6 months of receiving any HER2-targeted therapy
- Type 2 diabetes requiring ongoing systemic treatment at the time of study entry; or any history of Type 1 diabetes
- Any history of leptomeningeal disease or carcinomatous meningitis

Find out if your patients with breast cancer are eligible for enrollment. For more information

Visit:
ClinicalTrials.gov

Call:
Genentech Trial Information Support Line at **1-888-662-6728** (US and Canada)

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*Investigator-Assessed.

AKT=Alpha-serine/Threonine Kinase; **ECHO**=echocardiogram; **ECOG**=Eastern Cooperative Oncology Group; **HER2-**=human epidermal growth factor receptor 2 negative; **HRQoL**=health-related quality of life; **mTOR**=mammalian target of rapamycin; **MUGA**=multiple-gated acquisition scan; **P13K**=phosphoinositide 3-kinase; **P1K3CA**=phosphatidylinositol-4,5-bisphosphate 3-kinase catalytic subunit alpha.

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