ForPatients
by Roche

HER2-Positive Breast Cancer

RO7771950 Versus Tucatinib in Combination With Trastuzumab and Capecitabine in People With Locally Advanced or Metastatic Breast Cancer That is Human Epidermal Growth Factor Receptor 2 (HER2)-Positive

Trial Status	Trial Runs In	Trial Identifier
Not yet recruiting		NCT07413939 2025-524498-17-00 WO46069

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 Two-part, Seamless, Multicenter, Randomized, Open-label, Adaptive Phase II/III Study of the Blood-brain Barrier Penetrant RO7771950 Versus Tucatinib, Both in Combination With Trastuzumab and Capecitabine, in Patients With Pretreated Unresectable Locally Advanced or Metastatic HER2-Postivie Breast Cancer, With or Without Central Nervous System Metastases

Trial Summary:

The purpose of this study is to assess the efficacy and safety of RO7771950 in combination with trastuzumab and capecitabine, compared to tucatinib in combination with trastuzumab and capecitabine.

Hoffmann-La Roche
Sponsor

Phase 2/Phase 3
Phase

NCT07413939 2025-524498-17-00 WO46069
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

- Pathologically documented locally advanced inoperable (LAI) or metastatic breast cancer (MBC) with confirmed HER2-positive status by central laboratory
- Measurable disease only as per by RECIST v1.1/RANO-BM in stage 1. Non-measurable disease allowed in stage 2.
- Previously treated (stable or progressive) or previously untreated CNS metastases, or leptomeningeal metastases
- At least one prior line of anti-HER2-based therapy for LAI or metastatic disease
- Prior anti-HER2 antibody-drug conjugate (ADC), such as trastuzumab-deruxtecan (T-DXd) or trastuzumab emtansine (T-DM1), in any treatment setting. Participants for whom prior ADC therapy was not appropriate (e.g., due to lack of access or being medically unfit) may be considered for enrollment.
- Prior tyrosine kinase inhibitor (TKI) in the (neo)adjuvant setting provided completion is > 12 months ahead of LAI occurrence. Prior treatment with TKIs for LAI/MBC is not permitted.
- Has protocol-defined adequate organ and bone marrow function
- Eastern Cooperative Oncology Group (ECOG) performance status 0 or 1
- Baseline left ventricular ejection fraction (LVEF) >/= 50%

Exclusion Criteria:

- Concurrent anti-cancer treatment, or treatment with investigational therapy within 28 days prior to initiation of study treatment
- Known active/untreated hepatitis B or C or chronic liver disease
- Clinically significant cardiovascular disease or risk, including heart failure (New York Heart Association (NYHA) # II), ischemic heart disease or recent coronary events/interventions, clinically significant arrhythmias or electrocardiogram (ECG) abnormalities, QT prolongation or risk of ventricular dysrhythmias, poorly controlled hypertension, peripheral arterial disease, dilated cardiomyopathy, or unstable angina
- Clinically significant electrolyte abnormalities (e.g., hypokalemia, hypomagnesemia, hypocalcemia), or family history of sudden unexplained death or long QT syndrome
- Concomitant use of any drug or herbal medicine known to strongly inhibit or induce CYP3A4 or CYP2C8 activity, oral coumarin-derivative anticoagulants