ForPatients
by Roche

Advanced Solid TumorsHER2-Positive Breast Cancer

A Phase 1 Trial of ZN-A-1041 Enteric Capsules or Combination in Participants With Human Epidermal Growth Factor Receptor 2 (HER2)-Positive Advanced Solid Tumors

Trial Status	Trial Runs In	Trial Identifier
Active, not recruiting	7 Countries	NCT05593094 ZN-A-1041-101-US 2023-508459-37-00 XO45189

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 Phase 1 Clinical Study to Evaluate the Safety, Tolerability, Pharmacokinetics (PK), and Efficacy of ZN-A-1041 Enteric Capsules as a Single Agent or in Combination in Patients With HER2-Positive Advanced Solid Tumors

Trial Summary:

This will be a Phase 1, multicenter, open-label trial to evaluate the safety, tolerability, PK and efficacy of ZN-A-1041 as a monotherapy or in combination in participants with HER2-positive advanced solid tumors with or without brain metastases. The study will consist of three phases: Phase 1a (dose escalation with ZN-A-1041 monotherapy), Phase 1b (dose escalation with ZN-A-1041 combination therapy) and Phase 1c (dose expansion with ZN-A-1041 combination therapy).

Hoffmann-La Roche	Phase 1/Phase 2
Sponsor	Phase

NCT05593094 ZN-A-1041-101-US 2023-508459-37-00 XO45189
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

- Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1
- Life expectancy of at least 6 months, as determined by the investigator
- Histologically or cytologically confirmed with unresectable or metastatic HER2-positive advanced solid tumors
- Must be relapsed or refractory after prior treatment for metastatic disease that included a taxane and trastuzumab or must have received first-line induction therapy for advanced disease a pertuzumab plus trastuzumab-based regimen or a T-DXd-based regimen
- Participants with new, untreated, progressive, or stable brain metastases are eligible

Exclusion Criteria:

- Participation in any other clinical study involving an investigational drug or device within 4 weeks prior to the first dose of study treatment
- Any intracranial lesion (brain metastasis) that requires immediate local therapy, such as surgery or radiation, or systemic corticosteroids at the time of enrollment