ForPatients
by Roche

Breast Cancer

A study to find out whether a new medicine (DHES0815A) was safe and effective in patients with breast cancer

Safety, Tolerability, and Pharmacokinetic (PK) Study of DHES0815A in Participants With Human Epidermal Growth Factor Receptor (HER)2-Positive Breast Cancer

Trial Status	Trial Runs In	Trial Identifier
Completed	2 Countries	NCT03451162 GO39869

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 I, Open-Label Study Evaluating the Safety, Tolerability, and Pharmacokinetics of Escalating Doses of DHES0815A in Patients With HER2-Positive Breast Cancer

Trial Summary:

This first-in-human, Phase 1, open-label, multicenter, dose-escalation study will evaluate the safety, tolerability, and PK of DHES0815A as a single agent in participants with advanced and/or metastatic HER2-positive breast cancer for whom established treatment has proven ineffective or intolerable or is unavailable. The study may include a dose-expansion cohort (based on an ongoing assessment of the totality of data obtained in this study) to further assess safety, tolerability, PK, and preliminary anti-tumor activity.

Genentech, Inc. Sponsor	**Phase 1** Phase

NCT03451162 GO39869
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	# 18 Years	No

This clinical trial was done to study a new medicine called, “DHES0815A”, for the treatment of patients with a certain type of breast cancer called “HER2+ breast cancer”. This study was done to find the dose of DHES0815A that was safe for treating patients.

Researchers were also interested in finding signs that showed that DHES0815A was useful to patients. Fourteen patients took part in this study at six study centers in two countries.

Inclusion Criteria:

- Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1
- Measurable disease by RECIST v1.1 with at least one measurable target lesion
- Locally advanced or metastatic HER2-positive breast cancer that has relapsed or is refractory to established therapies
- Adequate hematologic and end-organ function
- For dose-expansion cohort only: no more than two prior systemic chemotherapy-containing regimens in the advanced/metastatic setting (excluding trastuzumab emtansine, which is considered a targeted cytotoxic agent)

Exclusion Criteria:

- Treatment with chemotherapy, hormonal therapy (except hormone replacement therapy, oral contraceptives), immunotherapy, biologic therapy, radiation therapy (except palliative radiation to bony metastases), or herbal therapy as cancer therapy within 4 weeks prior to initiation of DHES0815A
- History of exposure to the protocol specified doses of anthracyclines
- Pregnancy, lactation, or breastfeeding
- Major surgical procedure within 4 weeks prior to Day 1
- Evidence of a significant uncontrolled concomitant disease of the nervous system, pulmonary, autoimmune, renal, hepatic, endocrine, or gastrointestinal disorders; or a serious non-healing wound or fracture
- Known active bacterial, viral, fungal, mycobacterial, or other infection
- Clinically significant history of liver disease, including active viral or other hepatitis, current alcohol abuse, or cirrhosis
- Untreated or active central nervous system (CNS) metastases
- Cardiopulmonary dysfunction, including inadequate left ventricular ejection function at baseline, less than 50% by either echocardiogram (ECHO) or multiple-gated acquisition scan (MUGA)
- QT interval corrected through use of Fridericia's formula (QTcF) > 470 milliseconds (ms)