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 source of the below information is the publicly available website ClinicalTrials.gov. It has been summarised and edited into simpler language.

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.