ForPatients
by Roche

Breast Cancer

A Study Evaluating the Safety and Efficacy of Venetoclax in Combination With Trastuzumab Emtansine in Patients With Previously Treated HER2-Positive Locally Advanced or Metastatic Breast Cancer

Trial Status	Trial Runs In	Trial Identifier
Terminated	2 Countries	NCT04298918 2019-004200-35 CO41863

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 two-part study is composed of two stages: a Phase Ib stage consisting of a dose-escalation phase and an expansion phase; and a Phase II, randomized, placebo-controlled, double-blind, multicenter stage. The Phase Ib stage will assess the safety and tolerability, determine the maximum tolerated dose (MTD) and the recommended Phase II dose (RP2D), and evaluate the preliminary efficacy of trastuzumab emtansine in combination with venetoclax in participants with previously treated human epidermal growth factor receptor 2 (HER2) positive unresectable locally advanced breast cancer (LABC) or metastatic breast cancer (MBC). Additional patients may be enrolled in an expansion phase to evaluate the safety, tolerability, and efficacy of trastuzumab emtansine in combination with venetoclax at RP2D in patients with previously treated HER2-positive LABC or MBC who have previously received either trastuzumab emtansine or trastuzumab deruxtecan (DS-8201a). The Phase II randomized stage will evaluate the safety, efficacy, tolerability, and pharmacokinetics of trastuzumab emtansine in combination with venetoclax at RP2D compared with trastuzumab emtansine plus placebo in participants with previously treated HER2-positive LABC or MBC who have not received prior trastuzumab emtansine therapy, either alone or in combination with other anti-cancer therapies.

Hoffmann-La Roche
Sponsor

Phase 1/Phase 2
Phase

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Trial Identifiers

Eligibility Criteria:

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Gender	Age	Healthy Volunteers
All	**>=18 Years**	**No**