ForPatients
by Roche

Breast Cancer

A Dose-Finding Study of Pertuzumab (Perjeta) in Combination With Trastuzumab (Herceptin) in Healthy Male Participants and Women With Early Breast Cancer (EBC)

Trial Status	Trial Runs In	Trial Identifier
Completed	1 Countries	NCT02738970 BO30185

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 study involves a two-part design. Part 1 is designed to determine the optimal dose of subcutaneous (SC) Perjeta, injected alone or mixed with Herceptin, that results in comparable exposure to intravenous (IV) Perjeta. Exposure between SC Perjeta and IV Perjeta will be compared using a compilation of pharmacokinetic (PK) parameters such as area under the concentration-time curve (AUC), maximum serum concentration (Cmax), time of maximum concentration (Tmax), and serum trough concentration (Ctrough). Part 2 is designed to confirm the dosing regimen in women with EBC on the basis of safety, tolerability, and PK assessments.

Hoffmann-La Roche Sponsor	**Phase 1** Phase

NCT02738970 BO30185
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>= 18 Years & <= 45 Years	Accepts Healthy Volunteers