ForPatients
by Roche

Breast Cancer Solid Tumors Breast Cancer Er-Positive Breast Cancer HER-2 Negative

To Evaluate the Safety, Tolerability, and Pharmacokinetics of GDC-0077 Single Agent in Participants With Solid Tumors and in Combination With Endocrine and Targeted Therapies in Participants With Breast Cancer

Trial Status	Trial Runs In	Trial Identifier
Active, not recruiting	5 Countries	NCT03006172 2016-003022-17 GO39374

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 is an open-label, multicenter, Phase I study designed to evaluate the safety, tolerability, and pharmacokinetics of inavolisib administered orally as a single agent in patients with locally advanced or metastatic PIK3CA-mutant solid tumors, including breast cancer, and in combination with standard-of-care endocrine and/or targeted therapies for the treatment of locally advanced or metastatic PIK3CA-mutant breast cancer. Participants will be enrolled in two stages: a dose-escalation stage (Stage I) and an expansion stage (Stage II). Participants will be assigned to one of seven regimens: inavolisib as a single agent (Arm A), inavolisib in combination with palbociclib and letrozole (Arm B), inavolisib in combination with letrozole (Arm C), inavolisib in combination with fulvestrant (Arm D), inavolisib in combination with palbociclib and fulvestrant (Arm E), inavolisib in combination with palbociclib, fulvestrant, and metformin (Arm F), and inavolisib in combination with trastuzumab and pertuzumab (and letrozole or fulvestrant, if applicable (Arm G)).

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

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Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>= 18 Years	No