ForPatients
by Roche

Breast CancerType 2 Diabetes Mellitus

A Study Evaluating the Safety of Inavolisib and Fulvestrant With or Without Palbociclib in Participants With Advanced Breast Cancer (ABC) and Type 2 Diabetes

Trial Status	Trial Runs In	Trial Identifier
Not yet recruiting		NCT07748208 GO45322

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 II Prospective, Open-Label Safety Study of Inavolisib and Fulvestrant With or Without Palbociclib in Participants With PIK3CA-Mutated Hormone Receptor-Positive, HER2-Negative Advanced Breast Cancer and Type 2 Diabetes

Trial Summary:

This study will evaluate the safety of inavolisib in combination with fulvestrant, with or without palbociclib, in participants with PIK3CA-mutated, HR+, HER2-negative ABC and type 2 diabetes.

Hoffmann-La Roche
Sponsor

Phase 2
Phase

NCT07748208 GO45322
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

- Type 2 diabetes with laboratory fasting blood glucose < 185 milligrams per deciliter (mg/dL) and HbA1c <= 8% on any stable anti-hyperglycemic regimen excluding insulin short-term insulin dosing
- Eligible for triplet of inavolisib, fulvestrant and palbociclib: no prior systemic therapy for locally advanced unresectable or metastatic disease
- Confirmed diagnosis of HR+/HER2- breast cancer

- Confirmation of biomarker eligibility (detection of specified mutation(s) of PIK3CA via specified test)
- Measurable disease per Response Evaluation Criteria in Solid Tumors, Version 1.1 (RECIST v1.1)
- Eastern Cooperative Oncology Group (ECOG) Performance Status of 0-1
- Adequate hematologic and organ function within 14 days prior to initiation of study treatment

Exclusion Criteria:

- Pregnant or breastfeeding, or intention of becoming pregnant during the study or within the time frame in which contraception is required
- Metaplastic breast cancer
- Any history of Type 1 diabetes
- Severe hyper- or hypoglycemia event within 6 months of initiation of study treatment
- Any history of leptomeningeal disease or carcinomatous meningitis
- Known and untreated, or active central nervous system (CNS) metastases Participants with a history of treated CNS metastases are eligible
- Active inflammatory or conditions in either eye or history of idiopathic or autoimmune-associated uveitis in either eye
- Symptomatic active lung disease
- History of active bowel inflammation or active inflammatory bowel disease