ForPatients
by Roche

Prostate Cancer

Study of Ipatasertib or Apitolisib With Abiraterone Acetate Versus Coralie in Participants With Castration-Resistant Prostate Cancer Previously Treated With Docetaxel Chemotherapy

Trial Status	Trial Runs In	Trial Identifier
Completed	9 Countries	NCT01485861 2011-004126-10 GO27983

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 Ib/II Study of Ipatasertib (GDC-0068) or Apitolisib (GDC-0980) With Abiraterone Acetate Versus Abiraterone Acetate in Patients With Castration-Resistant Prostate Cancer Previously Treated With Docetaxel-Based Chemotherapy

Trial Summary:

This multicenter, international, Phase Ib/II trial consists of three stages: a Phase Ib, open-label stage in which the recommended Phase II dose was determined for ipataseritib administrated in combination with abiraterone and of apitolisib administrated in combination with abiraterone (this phase is no longer active), a Phase II, 3-arm, double-blind, randomized comparison of ipatasertib with abiraterone and prednisone/prednisolone versus placebo with abiraterone and prednisone/prednisolone and a safety single-arm, open-label cohort of ipatasertib 400 mg daily alone or in combination with prednisone/prednisolone or prednisone/prednisolone plus abiraterone.

Genentech, Inc.
Sponsor

Phase 1/Phase 2
Phase

NCT01485861 2011-004126-10 GO27983
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
Male	#18 Years	No

Inclusion Criteria:

- Histologically confirmed metastatic or advanced prostate adenocarcinoma that has been previously treated with docetaxel-based therapy and has progressed during treatment of at least one hormonal therapy(prior docetaxel is not required for the safety cohort)
- Two rising PSA levels greater than or equal to (>/=) 2 ng/mL measured >/= 1 week apart or radiographic evidence of disease progression in soft tissue or bone
- Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 at screening
- Adequate hematologic and organ function
- Documented willingness to use an effective means of contraception
- Safety cohort only: agreement to use CGM for first cycle of treatment

Exclusion Criteria:

- History of Type I or Type II diabetes mellitus requiring insulin; safety cohort: patients who are receiving any pharmacologic treatment for diabetes are not eligible
- New York Heart Association Class III or IV heart failure or Left ventricular ejection fraction < 50% or ventricular arrhythmia requiring medication
- Significant atherosclerotic disease, as evidenced by: unstable angina, history of myocardial infarction within 6 months prior to Day 1, or cerebrovascular accident within 6 months prior to Day 1
- Active autoimmune disease that is not controlled by nonsteroidal anti-inflammatory drugs or active inflammatory disease which requires immunosuppressive therapy
- Clinically significant history of liver disease
- History of adrenal insufficiency or hyperaldosteronism
- Phase II only: Previous therapy for prostate cancer with 17 alpha-hydroxylase/C17,20-lyase inhibitors, including abiraterone
- Phase II only: Previous treatment for prostate cancer with Protein kinase B phosphatidylinositol 3 kinase and/or mammalian target of rapamycin inhibitors
- Need for chronic corticosteroid therapy of >/= 20 mg of prednisone per day or an equivalent dose of other anti inflammatory corticosteroids or immunosuppressant