ForPatients
by Roche

Solid Tumors

A study of to find out if a new medicine (ipatasertib) behaves differently in people from China

A Study Of The Pharmacokinetics And Safety Of Ipatasertib In Chinese Participants With Locally Advanced Or Metastatic Solid Tumors.

Trial Status	Trial Runs In	Trial Identifier
Completed	1 Country	NCT04341259 YP40057

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 I Study Of The Pharmacokinetics And Safety Of Ipatasertib In Chinese Patients With Locally Advanced Or Metastatic Solid Tumors.

Trial Summary:

Treatments available for cancer do not work for everyone and can have serious side effects. This clinical trial was for a new medicine called, “ipatasertib.” It was a Phase 1, pharmacokinetic study, that looked at how fast the body takes in, uses, breaks down, and gets rid of ipatasertib. This study was done in people from China who had cancer. Ipatasertib is an experimental medicine. People in China were given the same dose that had been tested previously in people from other countries.

Genentech, Inc. (A part of F. Hoffmann-La Roche Ltd., Switzerland)	Phase 1
Sponsor	Phase

NCT04341259 YP40057
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

- Histologically documented locally advanced or metastatic solid tumor that has progressed or failed to respond to at least one prior regimen.
- Not a candidate for regimens known to provide clinical benefit.
- Evaluable or measurable disease according to RECIST, v1.1.
- Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 at screening.
- Life expectancy of >= 12 weeks.
- Adequate haematologic and organ function within 14 days prior to initiation of study treatment.
- Women of childbearing potential: agreement to remain abstinent (refrain from heterosexual intercourse) or use contraceptive measures and agreement to refrain from donating eggs.
- Men: agreement to remain abstinent (refrain from heterosexual intercourse) or use contraceptive measures, and agreement to refrain from donating sperm.
- Participants must reside in the People's Republic of China

Exclusion Criteria:

- Leptomeningeal disease as the only manifestation of the current tumor.
- Type 1 or 2 diabetes mellitus requiring insulin at study entry.
- Inability or unwillingness to swallow pills.
- Malabsorption syndrome or other condition that would interfere with enteral absorption.
- Known and untreated, or active CNS metastases (progressing or requiring anticonvulsants for symptomatic control).
- Congenital long QT syndrome or corrected QT interval (QTc) > 480 ms.
- Active congestive heart failure or ventricular arrhythmia requiring medication.
- Uncontrolled pleural effusion, pericardial effusion, or ascites requiring weekly paracentesis for 3 consecutive weeks prior to initiation of ipatasertib treatment.
- Severe infections within 4 weeks prior to screening including but not limited to, hospitalization for complications of infection, bacteremia, or severe pneumonia.
- Requirement for any daily supplemental oxygen.
- History of Inflammatory bowel disease or active bowel inflammation.
- Symptomatic hypercalcemia requiring continued use of bisphosphonate or denosumab therapy.
- Clinically significant history of liver disease, including viral disease or hepatitis,current alcohol abuse or cirrhosis.
- Known HIV infection.
- Active (chronic or acute) hepatitis C virus (HCV) at screening.
- Hepatitis B virus (HBV) infection (chronic or acute), defined as having a positive hepatitis B surface antigen (HBsAg) test or a positive quantitative HBV DNA test at screening
- Significant traumatic injury within 3 weeks prior to initiation of ipatasertib treatment.
- Major surgical procedure within 4 weeks prior to initiation of ipatasertib treatment.
- Treatment with chemotherapy, immunotherapy, or biologic therapy as cancer therapy within 3 weeks prior to initiation of ipatasertib treatment.
- Use of strong CYP3A4 inhibitors within 4 weeks prior to initiation of ipatasertib treatment.
- Oral endocrine therapy within 2 weeks prior to initiation of ipatasertib treatment.
- Prior treatment with a PI3-kinase inhibitor in which the patient experienced a Grade >= 3 drug-related adverse event or otherwise would be at increased risk for additional PI3K-related toxicity.
- Palliative radiation to bony metastases within 2 weeks prior to initiation of ipatasertib treatment.
- Radiotherapy (other than palliative radiation to bony metastases) as cancer therapy within 4 weeks prior to initiation of ipatasertib treatment.
- Treatment with an investigational agent within 4 weeks prior to initiation of ipatasertib treatment.
- Unresolved toxicity from prior therapy, except for alopecia and Grade 1 peripheral neuropathy.
- Pregnant or lactating.
- Inability to comply with study and follow-up procedures.