ForPatients
by Roche

Solid Tumors

Investigating side effects of a new medicine (migoprotafib) and whether it can be tolerated by people

RLY-1971 in Subjects With Advanced or Metastatic Solid Tumors

Trial Status	Trial Runs In	Trial Identifier
Completed	1 Country	NCT04252339 REFMAL 678 GO43242

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:

Phase 1, Open Label, Dose Escalation and Expansion Study of RLY-1971, a Highly Potent and Selective SHP2 Inhibitor, in Subjects With Advanced or Metastatic Solid Tumors

Trial Summary:

This clinical trial was done to study a new medicine (migoprotafib) that blocks (inhibits) the activity of a protein (SHP) in the body. Migoprotafib, belonging to the “SHP2 inhibitor” class of medicines, may prove beneficial for multiple cancer types that grow using the RAS/MAPK signaling pathway. This was a Phase 1, open-label, dose escalation and expansion study of migoprotafib, carried out in the USA. This study investigated side effects to find out if migoprotafib can be tolerated by people.

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

NCT04252339 REFMAL 678 GO43242
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

Subject is willing and able to provide written informed consent for the study prior to the performance of any study-specific procedures Subject is a male or female subject #18 years of age at the time of consent Subject must have an ECOG PS # 1 Subject must have histologically or cytologically confirmed advanced or metastatic solid tumor Subjects who are refractory to FDA-approved, standard therapy or for which standard or curative therapy does not exist or is not considered sufficient or appropriate by the patient or Investigator Subject must have radiographically measurable or evaluable disease Subject must have recovered from the reversible effects of prior anti-neoplastic therapy, except for alopecia and # grade 2 neuropathy.

Subject has adequate end organ function Subject is willing to comply with all protocol-required visits, assessments, and procedures Male and female subjects of child-bearing potential are willing to use medically acceptable methods of birth control from the screening visit through 30 days after the last dose of study medication

Exclusion Criteria:

Subjects with documented history of tumor mutations that may not be amenable to treatment with RLY-1971, including:

KRAS mutations: G12D, G12V, G13X, and Q61X BRAF V600E mutation MEK mutations Subjects with prior antineoplastic therapy within 3 weeks of Study Day 1, or 5 half-lives, whichever is shorter Subjects with prior palliative radiotherapy within 1 week of Study Day 1 Subjects who have had major surgery or trauma, or incomplete recovery from surgery or trauma, within 4 weeks of Study Day 1 Subjects with known central nervous system (CNS) metastases or primary CNS tumor that is associated with progressive neurologic symptoms or requires increasing doses of corticosteroids to control the CNS disease. If patient requires corticosteroids for management of CNS disease, the dose must have been stable for the 2 weeks preceding C1D1, or subject has new lesions appearing on follow up brain MRI that require CNS-directed intervention.

Subjects with a history or evidence of ophthalmic disease Subjects with a history or evidence of significant cardiac dysfunction Subjects with a history or evidence of significant gastrointestinal disease Subjects with other serious concurrent medical conditions Subject is pregnant, as documented by a serum beta human chorionic gonadotropin (#-hCG) pregnancy test consistent with pregnancy obtained within 7 days before the first dose of study treatment