ForPatients
by Roche

Hepatocellular Carcinoma (HCC)

A Study of Hypoxia-inducible Factor 1a (HIF1A) Messenger Ribonucleic Acid (mRNA) Antagonist (RO7070179), to Demonstrate Proof-of-mechanism in Adult Participants With Hepatocellular Carcinoma (HCC)

Trial Status	Trial Runs In	Trial Identifier
Completed	1 Country	NCT02564614 NP29700

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 1b, Proof of Mechanism, Open-label Study of RO7070179, a Hypoxia-inducible Factor 1a (HIF1A) mRNA Antagonist in Adult Subjects With Hepatocellular Carcinoma (HCC)

Trial Summary:

This open-label study will demonstrate proof-of-mechanism of HIF1A inhibition by a decrease of HIF1A mRNA after intravenous (IV) infusion of RO7070179 in participants with hepatocellular carcinoma (HCC) who have failed at least one line of systemic therapy. This will be a single arm study and all participants will receive RO7070179, 13 milligram per kilogram per week (mg/kg/week), 2-hour IV infusion on Days 1 and 4 during Week 1 of Cycle 1, followed by once weekly in 6 week cycle. Treatment with RO7070179 will be continued until disease progression or unacceptable toxicity.

Hoffmann-La Roche Sponsor	**Phase 1** Phase

NCT02564614 NP29700
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

- Male or female of >=18 years of age with the Eastern Cooperative Oncology Group (ECOG) performance status 0-1, Child-Pugh score of 5-7, and Life expectancy of 3 months or greater.
- Confirmed to have HCC as described by the American Association for the Study of Liver Disease (AASLD).
- Participants who have failed at least one line of systemic therapy for advanced stage HCC or participants who are ineligible or unable to tolerate the standard of care treatment.
- Have measurable or evaluable disease.
- Participants with normal major organ functions as defined by hemoglobin (HgB) >= 8.5 gram/decilitre (dL), absolute neutrophil count (ANC) >= 1000/microliter (mcL), platelet >= 60,000/micL, aspartate aminotransferase/alanine transaminase (AST/ALT) <= 3 x Upper Limit of Normal (ULN), total Bilirubin <= 2 x ULN, creatinine <= 2 x ULN.
- Willingness to undergo two tumor biopsies: before and after administration of RO7070179.

Exclusion Criteria:

- Concurrent serious medical illness that could potentially interfere with protocol compliance (such medical illness will not include hepatitis or cirrhosis, as the degree of liver impairment caused by these diseases are covered by other exclusion criteria).
- Active hepatitis B or C, but participants on stable medications for hepatitis B or C.
- Bleeding esophageal or gastric varices within 2 months before enrollment.
- Participants who need to take therapeutic anti-coagulation or anti-platelet therapy.
- Presence of ascites that preclude biopsy of liver lesions.
- History of unstable angina or myocardial infarction within 12 months prior to Day 1 or ischemic heart disease.
- Known HIV positive and positive screening pregnancy test or is breast-feeding.
- Female or male of reproductive capacity unwilling to use methods of contraception to prevent pregnancy during this study. Participants unwilling to use methods of contraception to prevent pregnancy for 6 months after the last dose of RO7070179 due to the potential for prolonged half-life of RO7070179 in the liver.
- Known, clinically suspected, or history of CNS tumor involvement.
- Prior chemotherapy, immunotherapy, investigational therapeutic agent, or other therapy used to treat HCC within 4 weeks before the first scheduled administration of RO7070179.
- Participants who have not recovered from any reversible side effects (except alopecia) to Grade 0 or 1 toxicity attributed to the administration of an investigational therapeutic agent, chemotherapy, immunotherapy, radiotherapy, or other agents previously used to treat the cancer.
- Any condition that, in the opinion of the investigator or the Sponsor, makes the patients unsuitable for the study.
- Inability to comply with the study protocol.