ForPatients
by Roche

Biliary Tract CancerHepatocellular Carcinoma (HCC)

A Phase I Study Evaluating Safety, Pharmacokinetics, Pharmacodynamics, And Clinical Activity Of RO7119929 (TLR7 Agonist) In Participants With Unresectable Advanced Or Metastatic Hepatocellular Carcinoma, Biliary Tract Cancer, Or Solid Tumors With Hepatic Metastases

Trial Status	Trial Runs In	Trial Identifier
Completed	6 Countries	NCT04338685 WP41377

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 First In Human, Open Label, Dose Escalation Phase I Study Evaluating Safety, Pharmacokinetics, Pharmacodynamics, And Preliminary Clinical Activity Profile Of Single Agent RO7119929 (TLR7 Agonist) Administered Orally To Participants With Unresectable Advanced Or Metastatic Hepatocellular Carcinoma, Biliary Tract Cancer, Or Solid Tumors With Hepatic Metastases

Trial Summary:

Phase I study of RO7119929 given orally to participants with unresectable advanced or metastatic primary liver cancers and other solid tumors with predominant liver involvement. The primary objective of the study is to explore the safety and to determine the maximum tolerated dose (MTD) and/or optimal biologic dose (OBD) of RO7119929 as single agent.

Hoffmann-La Roche
Sponsor

Phase 1
Phase

NCT04338685 WP41377
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

- Histologically confirmed diagnosis of one of the following: unresectable advanced or metastatic HCC (including fibrolamellar HCC) not amenable to a curative treatment approach, unresectable advanced or metastatic intrahepatic or perihilar (Klatskin) BTC not amenable to a curative treatment approach, extrahepatic BTC or gallbladder cancer infiltrating the liver or metastasized into the liver with predominant liver disease, not amenable to a curative treatment approach, metastasized colorectal cancer (CRC), pancreatic ductal adenocarcinoma (PDAC), Gastric cancer (GC), renal cell carcinoma (RCC), triple negative breast cancer (TNBC), cutaneous melanoma, or ocular melanoma with predominant liver disease not amenable to a curative treatment approach. Participants with other solid tumors with predominant liver disease not amenable to a curative treatment approach might be enrolled after Sponsor approval
- Measurable disease with at least one measurable locally untreated liver lesion, as defined by RECIST v1.1
- Eastern Cooperative Oncology Group (ECOG) performance status 0 or 1
- Adequate hematologic and major organ functions
- Participants for which there is no available standard therapy likely to confer clinical benefit, or participants who are not candidates for such available therapy
- Life expectancy of #12 weeks, approximated with Royal Marsden Hospital score 0-1 or Gustave Roussy Immune (GRIm) score 0-1. Participants with a Royal Marsden Hospital or GRIm score of #2 and a life expectancy of #12 weeks according to the investigator's clinical judgement may be enrolled after Medical Monitor approval has been obtained.
- For participants with HCC: Child-Pugh score of A6 or better

Exclusion Criteria:

- History or clinical evidence of central nervous system (CNS) primary tumors or metastases including leptomeningeal metastases, unless they have been previously treated, are asymptomatic, and have had no requirement for steroids or enzyme-inducing anticonvulsants in the last 14 days prior to Screening
- Evidence of any extra-hepatic primary tumor or metastasis requiring prompt medical intervention
- Receipt of prior therapy with a TLR7/8/9 agonist and/or IFN-alpha
- Prior chemotherapy, antibody, or other registered or experimental cancer treatment within 3 weeks of study Cycle 1 Day 1. Specifically, no CPI antibody is allowed to be administered within 6 weeks of study Cycle 1 Day 1
- Receipt of investigational agent for any other indication within 3 weeks of dosing
- Treatment with systemic immunosuppressive medication (including, but not limited to, corticosteroids, cyclophosphamide, azathioprine, methotrexate, thalidomide, and anti-TNF-alpha agents) within 2 weeks prior to initiation of study treatment, or anticipation of need for systemic immunosuppressive medication during study treatment
- Local therapy to liver (e.g. radiofrequency ablation, percutaneuous ethanol or acetic acid injection, cryoablation, high-intensity focused ultrasound, transarterial chemoembolization, and transarterial embolization) within 3 weeks prior to initiation of study treatment, radioembolization within 3 months prior to initiation of study treatment, or non-recovery from side effects of such procedure
- Treatment-related toxicities from prior cancer therapy that have not resolved to </= Grade 1 CTC AE prior to study treatment with the exception of the following Grade 2 toxicities:

alopecia, peripheral neuropathy, any laboratory changes that still lie within the inclusion criteria defined above

- History of other malignancy within 2 years; exception for ductal carcinoma in situ not requiring chemotherapy, low grade cervical intraepithelial neoplasia (CIN), nonmelanoma skin cancer, low grade localized prostate cancer (Gleason score < Grade 7), or optimally treated Stage 1 uterine cancer.

- Active or history of immunologic-mediated disease, including but not limited to myasthenia gravis, myositis, autoimmune hepatitis, systemic lupus erythematosus, rheumatoid arthritis, multiple sclerosis, inflammatory bowel disease, antiphospholipid antibody syndrome, Wegener granulomatosis, Sjogren's syndrome or Guillain-Barré syndrome
- Known active or uncontrolled bacterial, viral, fungal, mycobacterial, parasitic, or other infection.
- Ascites, pleural effusion, or pericardial effusion requiring medical intervention within 12 months prior to study entry.
- History of human immunodeficiency virus (HIV) infection
- Active hepatitis B virus (HBV) infection
- Coinfection of HBV and hepatitis C virus (HCV).