ForPatients

by Roche

Cancer

A Study of RO7172508 in Patients With Locally Advanced and/or Metastatic CEA-Positive Solid Tumors

Trial Status Trial Runs In Trial Identifier
Terminated 4 Countries NCT03539484 BP40092

The source of the below information is the publicly available website ClinicalTrials.gov. It has been summarised and edited into simpler language.

Trial Summary:

This study was to determine the maximum-tolerated dose (MTD) and/or the optimal biological dose (OBD) as well as the optimal schedule for intravenous (IV) and subcutaneous (SC) administrations of RO7172508 as monotherapy, with or without obinutuzumab pre-treatment, in participants with locally advanced and/or metastatic carcinoembryonic antigen (CEA)-positive solid tumors who have progressed on standard of care (SOC) treatment, are intolerant to SOC, and/or are non-amenable to SOC. This study was conducted in two parts. Part I of the study consisted of an IV single participant cohort/multiple-ascending dose-escalation to evaluate the safety of RO7172508. Part II was a multiple participant cohort/multiple-ascending dose-escalation to define the MTD and/or OBD of RO7172508 administered as single agent, IV and/or SC, in participants with tumors that are expressing high as well as moderate/low-CEA. The study switched from Part I to Part II when the maximum planned dose for Part I was reached or the occurrence of a RO7172508-related Grade >= 2 adverse event (AE) or dose-limiting toxicity (DLT) was observed, whichever comes first. The Sponsor may decide to switch from Part I to Part II in the absence of an observed RO7172508-related Grade >= 2 toxicity or prior to maximum planned dose for Part I.

Hoffmann-La Roche Sponsor		Phase 1 Phase	
NCT03539484 BP40092 Trial Identifiers			
Eligibility Criteria:			
Gender All	Age >= 18 Years	Healthy Volunteers No	