ForPatients
by Roche

Colorectal Cancer (CRC)

A clinical trial to look at how well cibisatamab works in combination with another drug called atezolizumab after pre-treatment with obinutuzumab to treat advanced colorectal cancer (CRC) after chemotherapy has not worked

A phase Ib, multicenter, open-label study to evaluate the safety, efficacy, and pharmacokinetics of cibisatamab in combination with atezolizumab after pretreatment with obinutuzumab in patients with previously treated metastatic, microsatellite-stable colorectal adenocarcinoma with high CEACAM5 expression

Trial Status	Trial Runs In	Trial Identifier
Completed	4 Countries	NCT03866239 2018-003198-93 CO40939

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

Trial Summary:

CO40939 is a Phase Ib, open-label, multicenter, single-arm study designed to evaluate the safety, efficacy, pharmacokinetics, and immunogenicity of cibisatamab in combination with atezolizumab administered after pretreatment with obinutuzumab in patients with Stage IV microsatellite stable (MSS) metastatic colorectal cancer (mCRC) whose tumors have high carcinoembryonic antigen-related cell adhesion molecule 5 (CEACAM5) expression and who have progressed on two or more chemotherapy regimens. The study is composed of a safety run-in and an exploratory part.

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

NCT03866239 2018-003198-93 CO40939
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>=18 Years	No

How does the CO40939 clinical trial work? This clinical trial is recruiting people who have a particular type of colorectal cancer or CRC, which is cancer of the colon or rectum

(large intestine or large bowel). In order to take part, patients must have advanced CRC that has spread to other parts of the body (metastatic) and have already tried two or more types of chemotherapy that have not worked.

The purpose of this clinical trial is to test the safety and effectiveness of cibisatamab when given with another drug called atezolizumab after pre-treatment with obinutuzumab, and to understand the way your body processes these medicines.

How do I take part in this clinical trial? To be able to take part in this clinical trial, you must have been diagnosed with advanced CRC (showing high expression of a gene called *CEACAM5*) that has spread to other parts of your body. You must have also been previously treated for your metastatic disease with certain chemotherapy drugs including a fluoropyrimidine, irinotecan and oxaliplatin.

If you think this clinical trial may be suitable for you and would like to take part, please talk to your doctor. If your doctor thinks that you might be able to take part in this clinical trial, he/she may refer you to the closest clinical trial doctor. They will give you all the information you need to make your decision about taking part in the clinical trial. You can also find the clinical trial locations on this page.

You must have a very specific type of CRC for this trial so you may have some tests to make sure you will be able to join this clinical trial. Some of these tests or procedures may be part of your regular medical care. They may be done even if you do not take part in the clinical trial. If you have had some of the tests recently, they may not need to be done again.

Before starting the clinical trial, you will be told about any risks and benefits of taking part in the trial. You will also be told what other treatments are available so that you may decide if you still want to take part.

While taking part in the clinical trial, both men and women (if you are not currently pregnant but can become pregnant) will need to either not have heterosexual intercourse or take contraceptive medication for safety reasons.

What treatment will I be given if I join this clinical trial? Everyone who joins this clinical trial will be given:

- A pre-treatment called obinutuzumab, as an infusion (into the vein) as either a single dose or split doses across 2 days, approximately 2 weeks before you start the treatment with cibisatamab and atezolizumab
- On Day 1 of the trial, you will be given
    - atezolizumab as an infusion (into the vein), followed by
    - cibisatamab as an infusion (into the vein)

- You will be given atezolizumab and cibisatamab every 3 weeks until you no longer benefit from the treatment. If your clinical trial doctor thinks it is suitable, you may be allowed to continue treatment with atezolizumab and cibisatamab even after your cancer gets worse

While you are receiving treatment, the clinical trial doctors will check how you are responding to treatment and look for side effects. Patients who experience certain side effects may be treated with a drug called tocilizumab.

How often will I be seen in follow-up appointments, and for how long? You will be given the clinical trial treatment until you no longer benefit from the treatment. You will see the clinical trial doctor regularly throughout the study for a variety of tests and checks to assess how your body is coping with the treatment and ensure it is safe for you to continue. You will also have imaging assessments to see how your cancer is responding to treatment roughly 9 weeks after your first treatment with atezolizumab and cibisatamab and then roughly every 6 weeks after that. Please speak to your doctor if you would like more information on your scheduled visits.

You are free to stop this treatment at any time. After your last treatment, the clinical trial doctor will ask you to come back for a visit within 30 days. After that, your clinical trial doctor will follow up with you, either by phone or hospital visits, every 3 months for the rest of your life (as long as you agree to it). The hospital visits will include blood tests to check whether certain immune cells in your blood have returned to normal levels after stopping treatment.

What happens if I am unable to take part in this clinical trial? If this clinical trial is not suitable for you, you will not be able to take part. Your doctor will suggest other clinical trials that you may be able to take part in or other treatments that you can be given. You will not lose access to any of your regular care.

For more information about this clinical trial see the **For Expert** tab on the specific ForPatient page or follow this link to ClinicalTrials.gov https://clinicaltrials.gov/ct2/show/NCT03866239

Trial-identifier: NCT03866239