ForPatients
by Roche

Tumore al seno

Studio volto a valutare la sicurezza, la farmacocinetica e l'attività terapeutica di RO6874281 somministrato in monoterapia (Parte A) o in associazione a trastuzumab o cetuximab (Parte B o C)

Trial Status	Trial Runs In	Trial Identifier
Completata	9 Countries	NCT02627274 2015-002251-97 BP29842

Le informazioni sono reperite direttamente dai siti web di registri pubblici come ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com ecc. e non sono state modificate.

Official Title:

Studio di fase IA/IB, in aperto, multicentrico, con incremento progressivo della dose, volto a valutare la sicurezza, la farmacocinetica e l'attività terapeutica di RO6874281, un'immunocitochina costituita da una variante dell'interleuchina 2 (IL-2v) che agisce selettivamente sulla proteina alfa di attivazione fibroblastica (FAP #), somministrato in monoterapia (Parte A) o in associazione a trastuzumab o cetuximab (Parte B o C)

Trial Summary:

Questo studio di fase Ia/Ib, *prima sperimentazione clinica sull'uomo*, in aperto, multicentrico, adattivo e con dosi multiple crescenti valuterà la sicurezza, la tollerabilità, la farmacocinetica, la farmacodinamica e l'attività antitumorale preliminare di RO6874281 in monoterapia (Parte A) o in combinazione con trastuzumab o cetuximab (Parte B o C).

Hoffmann-La Roche
Sponsor

Fase I
Phase

NCT02627274 2015-002251-97 BP29842
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	# 18 Years	No

How does the BP29842 clinical trial work?

The first two parts of this trial to test RO6874281 either on its own or in combination with trastuzumab in people with solid tumours or breast cancer are no longer recruiting patients.

The third part of the clinical trial is still recruiting people who have head and neck cancer, that has either advanced or spread to other parts of the body.

The purpose of this part of the clinical trial is to test the safety of RO6874281 in combination with cetuximab, at different doses and to understand the way the body processes RO6874281.

How do I take part in this clinical trial?

Everyone who joins this part of the trial must have a type of head and neck cancer called ‘squamous cell carcinoma’. The cancer must be inoperable, or have spread to other parts of the body, or have previously gone away after treatment but has now come back.

You must not have cancer that is quickly getting worse or cancer that has spread to the brain or spinal cord that is untreated or causing symptoms.

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 will have some further tests to make sure you will be able to take the treatments given in 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? You will receive RO6874281 every week (the dose will depend on the stage of the study when you enrol) and standard doses of cetuximab every week.

How often will I be seen in follow-up appointments and for how long?

You will be given the clinical trial treatment for as long as it can help you. You are free to stop this treatment at any time. While being given treatment, you will be seen regularly by the clinical trial doctors. These hospital visits will include checks to see how you are responding to the treatment and any side effects that you may be having. After being given treatment, you will be seen by the clinical trial doctor after 1 month and then contacted every 3 months after that.

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/NCT02627274

Trial-identifier: NCT02627274

Inclusion Criteria:

Per ulteriori informazioni riguardanti lo studio e i criteri di inclusione, clicca sul seguente codice: NCT02627274

Exclusion Criteria:

Per ulteriori informazioni riguardanti lo studio e i criteri di esclusione, clicca sul seguente codice: NCT02627274