ForPatients
by Roche

Medullary Thyroid Cancer Thyroid Cancer

A clinical trial to compare pralsetinib with standard-of-care treatment (cabozantinib or vandetanib) in people with RET-mutated medullary thyroid cancer (RET-MTC)

A Study of Pralsetinib Versus Standard of Care (SOC) for Treatment of RET-Mutated Medullary Thyroid Cancer (MTC)

Trial Status	Trial Runs In	Trial Identifier
Withdrawn	1 Countries	NCT04760288 2020-005269-15 CO42865

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

Trial Summary:

A study to evaluate the efficacy and safety of pralsetinib compared with SOC treatment (cabozantinib or vandetanib) for participants with RET (rearranged during transfection)-mutant MTC who have not previously received a SOC MultiKinase Inhibitor (MKI) therapy. Participants will be randomized in a 1:1 ratio into one of two treatment arms: Arm A (pralsetinib) or Arm B (investigator's choice of either cabozantinib or vandetanib for adults and vandetanib for adolescents). Participants whose disease progresses during SOC treatment will be offered the option to cross over to receive pralsetinib after confirmation of progressive disease by blinded independent central review (BICR).

Hoffmann-La Roche
Sponsor

Phase 3
Phase

NCT04760288 2020-005269-15 CO42865
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>=12 Years	No

How does the AcceleRET-MTC clinical trial work?

This clinical trial is recruiting people who have a type of disease called medullary thyroid cancer (MTC), a rare type of cancer that affects the thyroid gland near the base of the

throat. In order to take part, patients must also have changes in a gene called *RET,* leading to *RET*-mutated MTC (*RET*-MTC).

The purpose of this clinical trial is to compare the effects, good or bad, of pralsetinib against standard-of-care treatment in patients with *RET*-MTC. If you take part in this clinical trial, you will receive either pralsetinib or the clinical trial doctor's choice of standard-of-care treatment (cabozantinib or vandetanib).

How do I take part in this clinical trial? To be able to take part in this clinical trial, you must be at least 18 years old (or at least 12 years old, depending on local rules and guardian consent). You must have been diagnosed with MTC that cannot be removed with surgery and/or has spread to other parts of the body. Your cancer must also have changes in a gene called *RET,* detected by a genetic test. In the last 14 months, you must have been confirmed as having progressive disease (your disease is getting worse).

You must not have received any previous treatment with a specific kind of anti-cancer drug called a kinase inhibitor, and must not have received any radiation therapy in the 14 days before you start this trial. If you are taking certain other medications or have certain other medical conditions, you may not be able to take part in this trial. If you are pregnant or breastfeeding, or intend to become pregnant soon after taking part in this trial, you will not be able to take part.

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 remain abstinent (refrain from heterosexual intercourse) or use appropriate contraception for safety reasons.

What treatment will I be given if I join this clinical trial? Everyone who joins this clinical trial will be split into two groups randomly (like flipping a coin) and given either:

- Pralsetinib, as capsules to be swallowed once every day
- OR clinical trial doctor's choice of cabozantinib (as capsules) **or** vandetanib (as tablets), to be swallowed once every day

You will have an equal chance of being placed in either group.

How often will I be seen in follow-up appointments and for how long?
You will be given the clinical trial treatment (pralsetinib, cabozantinib or vandetanib) for as long as it can help you. If your cancer gets worse while taking cabozantinib or vandetanib, you may be able to receive pralsetinib if you meet certain criteria.

You are free to stop treatment at any time. While being given treatment, you will have clinic visits every 28 days (one cycle). After Cycle 12 is completed (after roughly one year), you will have clinic visits every 12 weeks (three months) until Cycle 24 (roughly the second year) and every 16 weeks (four months) after that. These visits will include checks to see how you are responding to the treatment and any side effects that you may be having. In some areas and if you agree to it, a nurse may come to your home to conduct these checks instead.

Your clinical trial doctor will see you roughly 30 days after your last treatment dose. After this, you will continue to be seen roughly every three months so that the clinical trial doctor can check how you are and whether you have started any new treatments. These visits (or telephone calls) will continue for as long as you agree.

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/record/NCT04760288

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