ForPatients
by Roche

Chronic Lymphocytic Leukemia

A study to look at the effects of Venetoclax in patients with Chronic Lymphocytic Leukemia who are on stable cBTKi therapy

A Study to Evaluate the Effect of Venetoclax on Participants Receiving a Covalent Bruton's Tyrosine Kinase Inhibitor (cBTKi) for First-Line Chronic Lymphocytic Leukemia (1L CLL) to Achieve Deep Durable Remissions to Allow Off-Treatment Period.

Trial Status	Trial Runs In	Trial Identifier
Recruiting	1 Countries	NCT06524375 ML45219

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

Trial Summary:

The main purpose of the study is to evaluate if adding venetoclax to participants receiving cBTKi for the 1L CLL can achieve deep durable remissions of undetectable measurable residual disease [uMRD < or 10^-4 in peripheral blood (PB)] by end of combination treatment (EOCT) to allow off-treatment period. The acronym BRAVE stands for Btki Responders to Achieve deep remission (or off-treatment periods) with VEnetoclax.

Genentech, Inc.
Sponsor

Phase 2
Phase

NCT06524375 ML45219
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>=18 Years	No

1. Why is this study needed?

This study is testing a medicine called Venetoclax and its effect when added to cBTKi to treat Chronic Lymphocytic Leukemia.

The combination of Venetoclax with cBTKi is experimental. This means health authorities (like the U.S. Food and Drug Administration and European Medicines Agency) have not

approved Venetoclax in combination with ibrutinib, acalabrutinib, or zanubrutinib for the treatment of Chronic Lymphocytic Leukemia.

This study aims to compare the effects of Venetoclax plus cBTKi therapy in people with Chronic Lymphocytic Leukemia.

2. Who can take part in the study?

People of (#18) years of age with Chronic Lymphocytic Leukemia (a type of cancer that starts from white blood cells in the bone marrow) can take part in the study if they are on a stable cBTKi therapy for at least 6 months.

People may not be able to take part in this study if they have previously received a Bcl-2 inhibitor therapy.

People who are pregnant, or currently breastfeeding cannot take part in the study.

3. How does this study work?

People will be screened to check if they are able to participate in the study. The screening period will take place from 14 days to 0 days before the start of treatment.

Everyone who joins this study will be given Venetoclax orally in pill form daily.

This is an open-label study. This means everyone involved, including the participant and the study doctor, will know the study treatment the participant has been given.

During this study, the study doctor will see participants every 28 days. They will see how well the treatment is working and any unwanted effects participants may have. Participants will have follow-up visits twice after 12 months of completing the study treatment. During the first follow-up visit, you will receive a phone call, and the second follow-up visit may require a clinic visit where the study doctor will check on the participant’s wellbeing. Total time of participation in the study will be about 2 years. Participants have the right to stop study treatment and leave the study at any time, if they wish to do so.

4. Are there any risks or benefits in taking part in this study?

Taking part in the study may or may not make participants feel better. But the information collected in the study can help other people with similar health conditions in the future.

It may not be fully known at the time of the study how safe and how well the study treatment works. The study involves some risks to the participant. But these risks are generally not greater than those related to routine medical care or the natural progression of the health condition. People interested in taking part will be informed about the risks

and benefits, as well as any additional procedures or tests they may need to undergo. All details of the study will be described in an informed consent document. This includes information about possible effects and other options of treatment.

Risks associated with the study drug Participants may have unwanted effects of the drug used in this study. These unwanted effects can be mild to severe, even life-threatening, and vary from person to person. During this study, participants will have regular check-ups to see if there are any unwanted effects.

Venentoclax Participants will be told about the known unwanted effects of Venetoclax, and possible unwanted effects based on human and laboratory studies or knowledge of similar medicines. Known unwanted effects include symptoms caused by fast breakdown of cancer cells (Tumor Lysis Syndrome), low white blood cell count (neutropenia), diarrhea, nausea, low red blood cell count, upper respiratory tract infection, low platelet count, and feeling tired.

Venetoclax will be given as an oral tablet (given by mouth).

The study medicine(s) may be harmful to an unborn baby. Women and men must take precautions to avoid exposing an unborn baby to the study treatment.