ForPatients
by Roche

Chronic Hepatitis B

A clinical trial to look at the safety and effectiveness of RO7565020 at different doses and how the body processes RO7565020 in healthy people and those with hepatitis B

A Study to Investigate Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of RO7565020 in Healthy Participants and in Participants With Chronic Hepatitis B Virus Infection

Trial Status	Trial Runs In	Trial Identifier
Terminated	8 Countries	NCT05763576 EU Trial Number BP44118

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 is a first in human (FIH), multi-center, dose-finding, and dose-escalation Phase I clinical study of RO7565020 to investigate the safety and tolerability and to characterize the pharmacokinetics and pharmacodynamics following single and/or multiple doses of RO7565020 in healthy participants and/or virologically suppressed participants with chronic hepatitis B (CHB).

Hoffmann-La Roche	Phase 1
Sponsor	Phase

NCT05763576 EU Trial Number BP44118
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>=18 Years & <= 65 Years	Accepts Healthy Volunteers

1. Why is the BP44118 clinical trial needed? Around 300 million people worldwide have long-term hepatitis B virus (HBV) infection. HBV causes inflammation of the liver (hepatitis) or long-term liver problems, including scarring (cirrhosis) and liver cancer. The two types of standard treatment for HBV infection are nucleoside/nucleotide analogues (NUCs, such as tenofovir, entecavir and adefovir) and interferon (IFN)-alpha preparations. These treatments can reduce HBV levels and the chance of liver problems. Less than 3

in 100 people are cured of HBV infection. Treatment with IFN-based medicines can cause unwanted effects, including flu-like symptoms, and NUCs often need to be taken for life. RO7565020 is a type of drug. It attaches to the HBV and neutralises it. RO7565020 may also help the body's immune system remove HBV from the body. Researchers hope that RO7565020 and the standard treatment may cure more people or shorten the treatment time. This clinical trial aims to test the safety of RO7565020 at different doses. It also aims to understand how the body processes RO7565020 in healthy people and in people with HBV infection who are also taking NUCs and how well RO7565020 works to reduce HBV levels.

2. How does the BP44118 clinical trial work? This clinical trial is recruiting healthy people and people with a health condition called HBV infection. People who take part in this clinical trial (participants) will be given either single or multiple doses of the clinical trial treatment RO7565020 OR placebo. The clinical trial doctor will see them regularly. These hospital visits will include checks to see how the participant responds to the treatment and any side effects they may have. The total time in the clinical trial will be around one to two years, depending on which part of the trial a participant is in (see Section 5). Participants can stop trial treatment and leave the clinical trial at any time.

3. What are the main endpoints of the BP44118 clinical trial? The main clinical trial endpoints (the main results measured in the trial to see how safe the drug is) are the number and seriousness of any side effects after treatment with a single dose or multiple doses of RO7565020. The other clinical trial endpoints include how the body processes RO7565020, the change in HBV levels in the blood and how RO7565020 affects the immune system.

4. Who can take part in this clinical trial? People can take part in this trial if they are aged 18 to 65 years and are a healthy weight according to their body mass index. Women (if they can become pregnant) will need to either not have heterosexual intercourse or take contraceptive medication for safety reasons. People may not be able to take part in this trial if they are pregnant, planning to become pregnant, are breastfeeding, or have a history of autoimmune disease, cancer, or diseases affecting the heart, kidneys, lungs, or liver (other than HBV) etc., hepatitis A, C, D, E or HIV infection, or a history (or are suspected) of alcohol/drug abuse. People must also not have, within three months of the start of the trial, had blood loss over 500 mL (including blood donation), received any blood product, or taken part in any other clinical trial. Additionally, healthy people must not be an active smoker and not have HBV infection, and people with HBV must have taken standard NUC treatment entecavir, tenofovir alafenamide or tenofovir disoproxil fumarate for at least a year and the same NUC treatment for at least 3 months before the trial starts. People with HBV infection must also have normal blood and urine tests results or judged not clinically significant by the investigator and must not have antibodies against HBV, liver scarring (fibrosis or cirrhosis) or mental health problems.

5. What treatment will participants be given in this clinical trial? The clinical trial is in 3 parts. Part 1 will involve healthy participants only and is in two separate parts (Part 1a and Part 1b). Both parts are 'placebo-controlled', which means that some people will be given a substance with no active ingredients (also known as a 'placebo'); it looks like the drug being tested but does not contain any real medicine. Comparing results with placebo helps the researchers know whether any changes seen result from the drug or occur by chance. Participants will have a 3 in 4 chance of being given **RO7565020** and a 1 in 4 chance of being given **placebo**. In Part 1 neither the participant nor the clinical trial doctor can choose or know the group the participant is in, until the trial is over. This approach helps to prevent bias and expectations about what will happen. However, the participant's clinical trial doctor can find out which group the participant is in if their safety is at risk. Everyone in Part 1a will be split into groups randomly (like flipping a coin) and given a single dose of **RO7565020** or **placebo** given as an injection (under the skin) **or** as an infusion (into the vein). Each group will receive a different dose. Part 1b will be started if researchers want to learn more about how safe **RO7565020** is and how the body processes it. Everyone in Part 1b will be given multiple doses of **RO7565020** or **placebo** as an injection (under the skin). The dose and how often it is given will depend on the results of Part 1a. Parts 2 and 3 will involve participants with HBV only. Parts 2 and 3 are 'open-label', which means everyone involved, including the participant and the clinical trial doctor, will know the treatment the participant has been given. Everyone in Part 2 will be split into groups and given **NUC** (continued standard treatment) and a single dose of **RO7565020** as an injection (under the skin); each group will receive a different dose. Part 3 will be started if researchers want to learn more about how safe **RO7565020** is and how the body processes it. Everyone in Part 3 will be given **NUC,** and multiple doses of **RO7565020** as an injection (under the skin) - dose and how often it is given will depend on the results of Parts 1 and 2.

6. Are there any risks or benefits in taking part in this clinical trial? The safety or effectiveness of the experimental treatment or use may not be fully known at the time of the trial. Most trials involve some risks to the participant. However, it may not be greater than the risks related to routine medical care or the natural progression of the health condition. People who would like to participate will be told about any risks and benefits of taking part in the clinical trial, as well as any additional procedures, tests, or assessments they will be asked to undergo. All of these will be described in an informed consent document (a document that provides people with the information they need to decide to volunteer for the clinical trial).

Risks associated with the clinical trial drugs Participants may have side effects (an unwanted effect of a drug or medical treatment) from the drugs used in this clinical trial. Side effects can be mild to severe, even life-threatening, and vary from person to person. **RO7565020** has not yet been tested in humans. For this reason, this drug's side effects are not known now. Participants will be told about the possible side effects based on laboratory studies or knowledge of similar drugs. **RO7565020** and **placebo** will be given as injections under the skin (subcutaneous injection) or as infusions into

a vein (intravenous infusion). Participants will be told about any known side effects of subcutaneous injections and intravenous infusions.

Potential benefits associated with the clinical trial Participants' health may or may not improve from participation in the clinical trial. Still, the information collected may help other people with similar medical conditions in the future.

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/NCT05763576

Trial-identifier: NCT05763576