

Taking part in SENTINEL-1

Information for people thinking about joining the BX-101 study. Please read this before you decide.

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This information is for healthy people who are thinking about joining SENTINEL-1. It explains what the study involves, the possible risks, and your choices. Please read it before you decide. Ask the study team anything that is not clear.

Important: you will not be exposed to Nipah virus. No participant is exposed to Nipah virus or any infectious material at any point in this study.

What is this study for?

SENTINEL-1 is a Phase 1 study of BX-101, also called Nipavir. Phase 1 means that this is an early study. The main aims are to learn how the medicine moves through your body, how your body handles it, and what side effects it may cause. The study is not designed to test treatment of Nipah virus infection.

The study is being done in healthy adults. The information may help researchers decide whether more research is reasonable. It cannot show that BX-101 prevents or treats illness. BX-101 is investigational. It has not been approved by a regulatory authority in any country.

What is BX-101?

BX-101 is an oral capsule. It is a fusion inhibitor. In simple terms, it is designed to interfere with a step that a virus uses to join with a human cell. The study will show what happens when healthy people take the capsule. It is not a vaccine, and it is not a treatment you can get from a pharmacy.

What is Nipah virus and will I be exposed to it?

NO. You will not be exposed to Nipah virus, Nipah-infected cells, or any infectious material at any point. You take only the study capsule or placebo, and give samples such as blood. The study does not infect participants.

Nipah virus is a real virus that can cause a serious illness in people. It can affect the breathing system and the brain. People may catch it through contact with infected animals, infected people, or contaminated material. None of those things are used in SENTINEL-1. The study team will explain the safety measures and answer questions before you consent.

Why are you testing it on healthy people?

Early studies often start with healthy adults so that researchers can measure the medicine in a more controlled way. This can make it easier to see changes caused by the medicine rather than by an illness. You will be screened to check whether joining is suitable for you. Being healthy does not mean there is no risk.

Do I have to take part?

No. Taking part is your choice. You can take time to decide, talk with family or another person you trust, and ask for more information. Saying no will not affect your usual medical care, benefits, or relationship with your clinician. The study team must explain the consent form before you sign it. Signing it does not remove your rights.

What will happen to me?

You will have screening tests before enrolment. If you join, you will spend a planned residential period at the study site. Staff will check you often, record any symptoms, and take blood samples. You will be told when to take the capsule. Follow-up continues after you leave the site.

Study stage	What usually happens
Screening	Health questions, examination, heart tracing (ECG) if needed, and blood and other safety tests. The team checks the consent and eligibility requirements.
Residential period	You stay at the study site so staff can observe you and respond if you feel unwell.
Dosing days	You take BX-101 or placebo as directed. Staff record the time, food, symptoms, and medicines.
Blood samples	Samples are taken at planned times to measure the medicine and check safety. Some checks are weekly during follow-up.
30-day follow-up	The team contacts or sees you about 30 days after your last dose for a final safety review.

The consent form and site team will give you the exact dates, restrictions, and amount of blood taken. The schedule can change if the study doctor thinks this is needed for safety.

What is a placebo and might I get one?

A placebo looks like the study medicine but has no active BX-101. It is used as a comparison. You and the study team may not know which one you receive until the study allows this information to be shared. The study is designed to compare safety and medicine levels, not to promise a personal benefit. The team will tell you what happens if there is an urgent medical reason to know your assignment.

What are the possible side effects?

You may have no side effects, or you may have side effects that are not yet known. Common side effects seen with medicines of this type can include headache, nausea, or feeling tired. These symptoms can also happen for other reasons. Tell the study team about every symptom, even if it seems minor.

Blood tests may show changes in liver results. A blood test result is not the same as feeling ill, so you may not notice a change. The team will explain your results when appropriate. Weekly blood tests are used during the relevant follow-up period to look for changes early and to decide whether more checks, a pause, or other action is needed.

There may be risks that are not known yet because BX-101 is investigational. There are also risks from study procedures, such as pain, bruising, light-headedness, or infection at a needle site. The consent form lists the known and possible risks in more detail.

What is the optional lumbar puncture sub-study?

A lumbar puncture, sometimes called a spinal tap, uses a needle in the lower back to collect a small sample of the fluid around the brain and spinal cord. This optional sub-study asks whether BX-101 reaches that fluid. You can join SENTINEL-1 without joining this part. Choosing not to join will not affect the main study. Possible risks include temporary headache, back discomfort, bleeding, or infection. The study team will explain the procedure and its separate consent form.

What if I feel unwell?

Tell the study team straight away, even if you are unsure that the symptom is related to the study. Staff are available during the residential period. After you leave, use the contact number in your consent form. If you have a medical emergency, use local emergency services first and then tell the study team as soon as you can. Do not wait for a study visit.

Who pays, and will I be paid?

The study procedures are free to you. The study team will explain which reasonable travel costs can be reimbursed and what proof may be needed. Payment is for your time and travel. It is not payment for taking a health risk, and it does not mean that the medicine is safe or effective. Ask the site about the amount, timing, and tax treatment before you decide.

Can I stop?

Yes. You can stop taking part at any time, for any reason or for no reason. Stopping will not affect your usual care or your rights. Tell the study team if you can, so they can arrange a safe final check. The team may ask to keep information and samples already collected, as explained in the consent form.

What happens to my data and samples?

The study team records information such as your health history, test results, doses, symptoms, and contact during follow-up. Your study records use a code rather than your name in most study work. The sponsor, monitors, auditors, ethics reviewers, and health authorities may see coded records where the law allows. They must follow the rules that protect research participants.

Blood and other samples may be labelled with your study code and used for the purposes described in the consent form, including safety and medicine-level testing. The form should say how long samples may be kept, whether future research is optional, and what happens if you withdraw. Ask before signing if this is not clear.

Who has checked this study is ethical?

An independent ethics committee or institutional review board (a group that reviews research) must review and approve the study before it starts at a site. These groups look at the risks, possible benefits, consent process, privacy, payment, and protection for participants. The study is conducted under a cleared US Investigational New Drug application (the US permission route for testing a new medicine in people). This review does not mean that BX-101 is approved or that the study is risk-free.

Who do I contact?

The study site should give you the name and telephone number of the study doctor and an emergency contact. Use those details for questions about visits, symptoms, payment, or stopping. For questions about your rights as a research participant, ask for the independent ethics committee or institutional review board contact listed in the consent form.

For a general disclosure query about this public document, email disclosure@baxtra.pages.dev. This mailbox is not a substitute for emergency care or personal medical advice.

Questions you might want to ask the study team

- What will I need to do before I can join, and why?
- How many nights will I stay at the site, and what can I bring?
- How often will blood be taken, and how much will be taken?
- What are the known risks, and what risks are still unknown?
- Could I receive placebo? When would I learn my assignment?
- What payment and travel reimbursement will I receive, and when?
- What happens to my samples if I leave the study?
- Who do I call at night or after I leave the site?
- Who can I contact about my rights or a complaint?

A final reminder

Read the full consent form, not only this summary. Ask for a copy. Do not join until you understand what will happen and feel able to decide freely. Remember: no participant is exposed to Nipah virus or infectious material at any point in SENTINEL-1.

Important. Baxtra Research Labs develops investigational medicines and investigational medical devices. No Baxtra investigational medicine has been approved by any regulatory authority in any country, and the safety and efficacy of none of them has been established. This document is published for information. It is not medical advice, not biosafety or biosecurity guidance, not an offer to sell or a solicitation to buy securities, and not a forecast that any programme described in it will succeed. Forward-looking statements about timing, enrolment, regulatory interactions and intended indications are subject to change without notice.

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