

INFORMED CONSENT FORM

Study Title: A Phase III Study of NovaPlex-450 in Advanced NSCLC
Protocol Number: NVX-1218.22
Sponsor: NexaVance Therapeutics Inc.
Principal Investigator: Dr. James Harrison
Site: London Oncology Institute, London, United Kingdom
ICF Version: v2.1
Version Date: 2024-11-15

Purpose of the Study

You are being asked to take part in a research study. The purpose of this study is to evaluate the safety and effectiveness of NovaPlex-450, an investigational drug, compared to standard chemotherapy in patients with advanced non-small cell lung cancer (NSCLC) whose cancer has spread and who have not received prior chemotherapy for advanced disease.

Study Procedures

If you agree to take part, you will be randomly assigned to receive either NovaPlex-450 or standard chemotherapy. You will receive study treatment in 21-day cycles. You will attend clinic visits approximately every 3 weeks for the first 6 months, then every 6 weeks. Blood tests, tumour assessments (CT scans), and questionnaires will be performed at each visit.

Risks and Discomforts

NovaPlex-450 may cause side effects including: nausea, fatigue, decreased blood cell counts, immune-related reactions, and rarely, more serious effects on the heart, lungs, or liver. Blood draws may cause bruising. CT scans involve low-level radiation exposure.

Benefits

You may benefit from study participation if NovaPlex-450 is effective. However, there is no guarantee of benefit. Your participation will contribute to scientific knowledge that may benefit future patients.

Voluntary Participation

Your participation is completely voluntary. You may withdraw at any time without penalty or loss of benefits to which you are otherwise entitled. Your medical care will not be affected if you choose not to participate or if you withdraw.

Confidentiality

Your personal information will be kept strictly confidential. Study data will be identified only by a subject code. Your records may be inspected by regulatory authorities and the sponsor for verification purposes, but your identity will remain confidential.

Consent Signature

I have read and understood the information in this consent form. I have had the opportunity to ask questions and all my questions have been answered to my satisfaction. I voluntarily agree to participate in this study.

Subject Name (Print)

Subject Signature

Date

Witness Signature