ForPatients
by Roche

Solid Tumors

Screening Study for Participants With Malignant Tumors

Trial Status	Trial Runs In	Trial Identifier
Recruiting	28 Countries	NCT05419375 BX43361

The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

Official Title:

Master Screening Study to Determine Biomarker Status and Potential Trial Eligibility for Patients With Malignant Tumors

Trial Summary:

The study objective is to determine the biomarker status of a participant's tumor tissue and use that status to determine eligibility for a linked Roche clinical trial.

Hoffmann-La Roche Sponsor	**Phase 2** Phase

NCT05419375 BX43361
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

General Inclusion Criteria:

- Confirmed availability of a representative formalin-fixed, paraffin-embedded (FFPE) tumor specimen meeting criteria defined in the protocol
- Considered by principal investigator (PI) to be a candidate for a linked clinical trial with an investigational medicinal product, and that the participant has the awareness and willingness to participate in said trial

Inclusion Criteria for Participants with Stage III NSCLC

- Locally advanced, unresectable Stage III NSCLC of either squamous or non-squamous histology based on 8th edition of the American Joint Committee on Cancer (AJCC) and Union for International Cancer Control (UICC) cancer staging system
- Eastern Cooperative Oncology Group (ECOG) performance status of 0, 1, or 2

Inclusion Criteria for Participants with Stage II, IIIA, or Select IIIB (T3N2 only) NSCLC Requiring Adjuvant Treatment

- Stage II, IIIA, or select IIIB (T3N2 only) NSCLC based on the 8th edition of the AJCC and UICC cancer staging system (Amin et al. 2017)
- Considered eligible for curative intent surgery (complete resection with all surgical margins testing negative for tumor)
- Screening within Study BX43361, using a pretreatment biopsy, is encouraged to be performed as early in the participant treatment pathway as possible to ensure the participant is potentially eligible for all cohorts, and should meet guidelines as defined by the protocol
- Representative FFPE tumor specimen obtained prior to the start of any treatment
- ECOG Performance Status of 0 or 1

Exclusion Criteria:

General Exclusion Criteria:

- History of malignancy other than NSCLC within 5 years prior to screening, except for malignancies with a negligible risk of metastasis or death
- Any condition that may affect the interpretation of study results
- Significant liver or cardiovascular disease
- Prior allogenic stem-cell or solid-organ transplantation