ALKove-1

A Phase 1/2 Study of NVL-655 in Patients With Advanced NSCLC and Other Solid Tumors Harboring ALK Rearrangement or Activating ALK Mutation

ClinicalTrials.gov identifier: NCT05384626

Actively recruiting patients in Phase 1

Study Overview

NVL-655 is an investigational therapy that targets ALK and is specifically designed to potentially overcome some of the challenges that can limit currently available treatments. These challenges include treatment-emergent resistance mutations such as G1202R and its compound variants, brain penetrance to address brain metastases, and avoidance of similar kinases such as TRKB to minimize off-target adverse effects.

The ongoing Phase 1 portion of the ALKOVE-1 study is designed to evaluate the safety and tolerability of NVL-655, determine the recommended Phase 2 dose (RP2D), and evaluate the antitumor activity in patients.

Key Eligibility Criteria

Inclusion Criteria

- Age ≥ 18 years (*for Phase 1 portion only*)
- Histologically or cytologically confirmed locally advanced or metastatic solid tumor with documented ALK rearrangement or activating ALK mutation
- Prior anticancer treatment
- Measurable disease
- Adequate baseline organ function and bone marrow reserve

Exclusion Criteria

- Patient's cancer has a known primary driver alteration other than ALK
- Major surgery within 4 weeks of study entry
- Ongoing or recent anticancer therapy
- Actively receiving systemic treatment or direct medical intervention on another therapeutic clinical study

For a full list of inclusion/exclusion criteria, please visit **ClinicalTrials.gov** (**NCT05384626**)
For additional information, please contact medical@nuvalent.com

NUVL-02-002-01