ARROS-1

ClinicalTrials.gov identifier: NCT05118789

Actively recruiting patients in the global Phase 2 ARROS-1 study

Cohort 2a: TKI-naïve patients with ROS1-positive non-small cell lung cancer (NSCLC)

Cohort 2e: Patients with ROS1-positive solid tumors, including adolescent patients 12 years old or older

Study Overview

Zidesamtinib (NVL-520) is an investigational therapy* that targets ROS1 and is specifically designed with the goal of addressing the combined medical needs of:

- Treating tumors that have developed resistance, such as those with the G2032R mutation,
- Treating brain metastases, and
- Avoidance of kinases such as TRK to minimize off-target adverse effects.

The Phase 2 portion of ARROS-1 is a global, single arm, open label, multi-cohort study designed to evaluate the clinical safety and efficacy of zidesamtinib in patients with advanced ROS1-positive NSCLC and other solid tumors.

Cohorts open and enrolling include:

Cohort	Tumor Type	Treatment Status	Prior ROS1 TKI	Prior Chemo/ Immunotherapy
2a	ROS1+ NSCLC	ROS1 TKI-naïve	None	Up to 1
Exploratory				
2e	Any ROS1+ solid tumor	Any Prior Therapy	Any	Any

Please refer to the current trial protocol for additional details.

Key Inclusion Criteria

- Age ≥ 12 years**
- Advanced non-small cell lung cancer (NSCLC) or other solid tumor
- Histologically or cytologically confirmed metastatic solid tumor with documented ROS1 rearrangement
- Measurable disease according to RECIST 1.1
- Adequate baseline organ function and bone marrow reserve
- For Cohort 2a only: Have not been previously treated with a ROS1 TKI for NSCLC
- For Cohort 2e only: Patients aged ≥ 18 years have any locally advanced or metastatic ROS1-positive solid tumor, excluding NSCLC***

Key Exclusion Criteria

- Patient's cancer has a known oncogenic driver alteration other than ROS1
- Major surgery within 4 weeks of study entry
- Actively receiving systemic treatment or direct medical intervention on another therapeutic clinical study

** Investigational therapies have not been approved by FDA or any other regulatory agency*

*** Patients aged 12 to 17 will only be enrolled in countries and sites where regulations allow*

**** Patients aged 12 to 17 are eligible for enrollment with any advanced ROS1-positive solid tumor, including NSCLC*

For a full list of inclusion/exclusion criteria, please visit **ClinicalTrials.gov (NCT05118789).**
For additional information, please contact **clinicaltrials@nuvalent.com**.

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