Nuvalent to Present Patient-Reported Outcomes Data from ARROS-1 Trial of ROS1-Selective Inhibitor, Zidesamtinib, at 2025 IASLC ASCO North America Conference on Lung Cancer

Encore pivotal efficacy and safety data from the ARROS-1 trial also to be presented during

poster session

CAMBRIDGE, Mass., Nov. 4, 2025 /PRNewswire/ -- Nuvalent, Inc. (Nasdaq: NUVL), a clinical-stage biopharmaceutical company focused on creating *precisely* targeted therapies for clinically proven kinase targets in cancer, today announced the first presentation of patient-reported outcomes data from the Phase 2 portion of the ARROS-1 Phase 1/2 clinical trial of zidesamtinib, an investigational ROS1 inhibitor, as well as encore pivotal efficacy and safety data from the ARROS-1 trial, during two poster presentations at the 2025 IASLC ASCO North America Conference on Lung Cancer being held December 5-7, 2025 in Chicago.

Details of the poster presentations are as follows:

Title: Patient-Reported Outcomes and Health-Related Quality of Life of TKI Pre-Treated and TKI-naïve Patients with Advanced ROS1-Positive NSCLC Treated with Zidesamtinib: Examination of ARROS-1 Phase 2 Trial Data
Abstract Number: PP01.41
Presenting Author: Melissa Laurie, Pharm.D., M.S., M.B.A.[1]
Session Date and Time: Saturday, December 6, 2025, 4:00-5:30 p.m. ET

Title: Zidesamtinib in Patients With Advanced Metastatic ROS1-Positive (ROS1+) Non-Small Cell Lung Cancer (NSCLC) Previously Treated With Tyrosine Kinase Inhibitors (TKI): Pivotal Efficacy and Safety Data From the Phase 1/2 ARROS-1 Trial
Abstract Number: PP01.32
Presenting Author: Stephen V. Liu, M.D.[2]
Session Date and Time: Saturday, December 6, 2025, 4:00-5:30 p.m. ET

[1]Nuvalent, Inc., Cambridge, MA, USA;[2]Georgetown University, Washington, DC, USA

About Zidesamtinib and the ARROS-1 Phase 1/2 Clinical Trial

Zidesamtinib is an investigational, novel brain-penetrant ROS1-selective inhibitor created with the aim to overcome limitations observed with currently available ROS1 inhibitors. Zidesamtinib is designed to remain active in tumors that have developed resistance to currently available ROS1 inhibitors, including tumors with treatment-emergent ROS1 mutations such as G2032R. In addition, zidesamtinib is designed for central nervous system (CNS) penetrance to improve treatment options for patients with brain metastases, and to avoid inhibition of the structurally related tropomyosin receptor kinase (TRK) family. Together, these characteristics have the potential to avoid TRK-related CNS adverse events seen with dual TRK/ROS1 inhibitors and to drive deep, durable responses for patients across all lines of therapy. Zidesamtinib has received breakthrough therapy designation for the treatment of patients with ROS1-positive metastatic non-small cell lung cancer (NSCLC) who have been previously treated with 2 or more ROS1 tyrosine kinase inhibitors and orphan drug designation for ROS1-positive NSCLC.

Zidesamtinib is currently being investigated in the ARROS-1 trial (NCT05118789), a first-in-human Phase 1/2 clinical trial for patients with advanced ROS1-positive NSCLC and other solid tumors. The completed Phase 1 portion enrolled ROS1-positive NSCLC patients who previously received at least one ROS1 TKI, or patients with other ROS1-positive solid tumors who had been previously treated. The Phase 1 portion of the trial was designed to evaluate the overall safety and tolerability of zidesamtinib, with additional objectives including determination of the recommended Phase 2 dose (RP2D), characterization of the pharmacokinetic profile, and evaluation of preliminary anti-tumor activity. The ongoing global, single arm, open label Phase 2 portion is designed with registrational intent for TKI-naïve and TKI pre-treated patients with advanced ROS1-positive NSCLC. Nuvalent completed its rolling NDA submission for zidesamtinib in TKI pre-treated patients with advanced ROS1-positive NSCLC in the third quarter of 2025 and continues to engage with the U.S. Food and Drug Administration (FDA) on potential opportunities for line-agnostic expansion.

About Nuvalent

Nuvalent, Inc. (Nasdaq: NUVL) is a clinical-stage biopharmaceutical company focused on creating *precisely* targeted therapies for patients with cancer, designed to overcome the limitations of existing therapies for clinically proven kinase targets. Leveraging deep expertise in chemistry and structure-based drug design, we develop innovative small molecules that have the potential to overcome resistance, minimize adverse events, address brain metastases, and drive more durable responses. Nuvalent is advancing a robust pipeline with investigational candidates for ROS1-positive, ALK-positive, and HER2-altered non-small cell lung cancer, and multiple discovery-stage research programs.

SOURCE Nuvalent, Inc.

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