#3346: Phase 3 trial ResQ201A of NAI plus tislelizumab and docetaxel vs. docetaxel monotherapy for advanced or metastatic NSCLC resistant to ICI therapy (*Plain Language*)

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BACKGROUND

- This is a description of the phase 3 clinical trial ResQ201A-NSCLC (USA: NCT06745908 and EU: 2025-521221-32-00) for people with advanced or metastatic non-small cell lung cancer (NSCLC).[1]
- A phase 3 clinical trial looks at how well a possible new treatment works, as well as its side effects, in many people.
- The participants in this trial have NSCLC and have previously received a type of immunotherapy called an 'immune checkpoint inhibitor' (or ICI) for which the therapy stopped working over time.
- ICIs block proteins that prevent immune cells from actively killing tumor cells.
- In this study, an ICI called tislelizumab will be used with a new treatment called nogapendekin alfa inbakicept (NAI) that is very good at activating immune cells called natural killer and T cells.[2,3]
- It is thought these two treatments together with docetaxel - a standard chemotherapy used for NSCLC - will be more effective than docetaxel alone.
- Tislelizumab has already been approved by the U.S.A. FDA for two types of esophageal cancer[2] and NAI has already been shown to be effective for a particular type of bladder cancer, for which it was approved by the FDA in 2024.[3]

TRIAL DESIGN

Randomized, Open-label, Phase III Clinical Trial of N-803/NAI Plus Tislelizumab and Docetaxel versus Docetaxel Monotherapy in Participants with Advanced or Metastatic Non-Small Cell Lung Cancer who have Acquired Resistance to Immune Checkpoint Inhibitor Therapy[1]

N=462

Key Inclusion Criteria:

- Participants must be at least 18 years of age
- Be able to understand what will happen on the study (informed consent)
- Have stage 4 NSCLC that was previously treated with an ICI that either was not effective or that became less effective over time
- Need to be relatively healthy (ECOG score of 0 to 2)
- Have measurable tumors

Key Exclusion Criteria:
People who have immune diseases, are receiving treatment after an organ transplant, or who have a genetic alteration termed '*ALK*' cannot participate.

Stratification:

- **Histology** *Squamous or non-squamous NSCLC*
- **Geographical Region** *North America, Europe, Asia, Other*
- **Actionable Genomic Alteration** *EGFR, ROS, Other, None*

2:1 Randomization

n=308

Experimental Arm:

- Induction: 3-week cycles NAI [SC 1.2 mg], tislelizumab [IV 200 mg] plus docetaxel [IV 75 mg/m^2]
- Maintenance: Repeated 3-week cycles of NAI [SC 1.2 mg] and tislelizumab [IV 200 mg] without docetaxel

Control Arm:

- Repeated 3-week cycles with docetaxel [IV 75 mg/m^2]

n=154

Key Terms:
- An **open label trial** means the people running the trial and the participants receiving treatment in the study will know the treatment received.
- Tumors will be scanned by CT or MRI and measured using systems called **RECIST v1.1** and **immune RECIST.**

STUDY OBJECTIVES

- An important objective is the time a participant survives, called '**overall survival**'. This will be analyzed using a statistical method called Kaplan Meier.
- Important assessments are **changes in the tumor size**, if any, and **how long it lasts**, referred to as the disease control rate, the objective response rate, and progression-free survival.
- **Determination of safety** is very important, therefore vital signs and changes in laboratory tests will be recorded, as well as adverse events (AEs) of all severity using the NCI CTCAE v5.0 system.

REFERENCES

1. ResQ201A: Clinical Trial Of N-803 Plus tislelizumab and Docetaxel Versus Docetaxel Monotherapy In Participants With Advanced Or Metastatic Non-Small Cell Lung Cancer (ClinicalTrials.gov identifier: NCT06745908)
2. TEVIMBRA® (tislelizumab-jsgr) Package Insert, FDA March 2024
3. ANKTIVA® (nogapendekin alfa inbakicept-pmln) Package Insert, FDA April 2024

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