Immune checkpoint relapsed advanced NSCLC

2:1 Randomization

N-803/NAI
Tislelizumab
Docetaxel

Docetaxel

Study Protocol Summary

This is a randomized, open-label, phase 3 clinical trial to compare the efficacy and safety of N-803/NAI plus tislelizumab and docetaxel (experimental arm) versus docetaxel monotherapy (control arm). Approximately 460 enrolled participants will be randomized 2:1 to treatment in the experimental arm or the control arm. Participant randomization will be stratified by geographical region (North America vs Europe vs ASIA vs Other), NSCLC histology (squamous vs nonsquamous), and actionable genomic alteration (AGA); (*epidermal growth factor receptor [EGFR]* vs OTHER AGA vs No AGA).

About the Study

ANKTIVA - nogapendekin alfa inbakicept-pmln (N-803/NAI) is being studied in several clinical trials for other types of cancer including advanced or metastatic non-small cell lung cancer.

Visit: **https://clinicaltrials.gov/study/NCT06745908**

Become an Investigator in the ResQ201A study.

Your cancer prognosis may or may not improve by taking part in the ResQ201A study.

N-803/NAI is investigational for this indication. Safety and efficacy have not been established by any Health Authority or Health Agency, including the FDA, for this indication.

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Contact ImmunityBio to learn more at **844-696-5235** or visit **Immunitybio.com/open-a-trial**

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ResQ201A

NCT06745908

This is an investigational trial for advanced or metastatic non-small cell lung cancer

For healthcare provider use

Join ImmunityBio in Clinical Research

ANKTIVA - nogapendekin alfa inbakicept-pmln (N-803/NAI) is an IL-15 receptor agonist that activates and proliferates natural killer (NK) cells, and effector and memory T cells.

ResQ201A Clinical Trial

A study is enrolling patients who have been diagnosed with advanced or metastatic non-small cell lung cancer who have acquired resistance to immune checkpoint inhibitor therapy to evaluate the efficacy and safety of N-803/NAI in combination with tislelizumab and docetaxel versus docetaxel monotherapy.

Inclusion and Exclusion

INCLUSION CRITERIA: Participants must meet ALL of the following criteria for inclusion in the study:

1. Age ≥ 18 years old
2. Provide a signed informed consent
3. Pathologically confirmed stage IV NSCLC disease
4. Have acquired resistance to an immune checkpoint inhibitor
5. Participants with AGA must have 1 or more documented AGA(s): *EGFR, ROS1, NTRK, BRAF, MET, RET, KRAS*
6. Participants with AGA must have been treated with 1 or 2 prior lines of targeted therapy that is locally approved (and is standard of care) for the genomic alteration at the time of screening:
   a. Participants who have tumors with *EGFR* L858R or exon 19 deletion mutations must have received prior osimertinib
   b. Participants who received a targeted agent as adjuvant therapy for early-stage disease must have relapsed or progressed while on the treatment
   c. Participants who have been treated with a prior tyrosine kinase inhibitor (TKI) must receive additional approved targeted therapy, if locally available and clinically appropriate
   d. Participants must meet the inclusion criteria #4 listed above
7. ECOG performance status of 0 to 2
8. Measurable tumor lesions according to RECIST v1.1
9. Agreement to practice effective contraception
10. Participants with known HIV infection must be receiving anti-retroviral therapy and have an undetectable viral load at their most recent viral load test within 6 months prior to enrollment

NOTE: Additional criteria as defined in full study protocol. **https://clinicaltrials.gov/study/NCT06745908**

EXCLUSION CRITERIA: Participants with ANY of the following criteria are excluded from participation in the study:

1. Systemic autoimmune disease currently requiring treatment
2. History of allogeneic hematopoietic stem cell transplant or organ transplant requiring immunosuppression manage AEs are permitted
3. Participants with AGA of *ALK*
4. Known active hepatitis B or C infection
5. Active infection requiring antibiotic therapy
6. Active treatment with CYP3A4 inhibitors
7. Received a live vaccine ≤ 4 weeks prior to the first dose of study drug(s)
8. History of or active inflammatory bowel disease (eg, Crohn's disease, ulcerative colitis)
9. Known history of severe hypersensitive reactions to docetaxel or to other drugs formulated with polysorbate 80
10. Had major surgery within 28 days prior to study randomization
11. Inadequate organ function, evidenced by the following laboratory results:
    a. Absolute lymphocyte count < institutional lower limit of normal (LLN). (ie. Participant should have a normal lymphocyte count to enroll in the study)
    b. Absolute neutrophil count < 1,500 cells/mm3
    c. Platelet count < 100,000 cells/mm3
    d. Total bilirubin 1.5 times greater than the ULN
    e. AST or ALT > 1.5 × ULN
    f. Alkaline phosphatase (ALP) levels > 2.5 × ULN
    g. Hemoglobin < 9.0 g/dL
    h. Serum creatinine > 2.0 mg/dL or 177 µmol/L or creatinine clearance < 40 mL/min (using the Cockcroft-Gault formula below):
       i. Female = [(140 - age in years) × weight in kg × 0.85] / [72 × serum creatinine in mg/dL]
       ii. Male = [(140 - age in years) × weight in kg × 1.00] / [72 × serum creatinine in mg/dL]
12. Have any of following:
    a. Cirrhosis at a level of Child-Pugh B (or worse);
    b. Cirrhosis (any degree) and a history of hepatic encephalopathy; or
    c. Clinically meaningful ascites resulting from cirrhosis
    d. Participation in an investigational drug study within 21 days prior to study entry
13. Pregnant and nursing women
14. History of allergic reactions to tislelizumab
15. History of prior adverse reaction to immunotherapy that led to its permanent discontinuation

NOTE: Additional criteria as defined in full study protocol. **https://clinicaltrials.gov/study/NCT06745908**