ResQ201A: Clinical Trial Of N-803 Plus TISLELIZUMAB And DOCETAXEL Versus DOCETAXEL Monotherapy In Participants With Advanced Or Metastatic Non-Small Cell Lung Cancer

Status: RECRUITING

Eligibility Criteria

Age: 18 years to 90 years old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria Participants must meet ALL of the following criteria for inclusion in the study: 1. Age ≥ 18 years old. 2. Able to understand and provide a signed informed consent that fulfills the relevant Institutional Review Board (IRB) or Independent Ethics Committee (IEC) guidelines. 3. Pathologically confirmed stage IV NSCLC disease. 4. Have acquired resistance to an immune checkpoint inhibitor, defined as disease progression immediately following an initial response or stable disease (≥ 6 months duration) to exactly 1 line of anti-PD-L1 or anti-CTLA-4 therapy (for Stage III, IV, or recurrent disease) that was given alone or in combination with chemotherapy. 5. Participants with AGA must have 1 or more documented AGA(s): EGFR, ROS1, neurotrophic tyrosine receptor kinase (NTRK), B rapidly accelerated fibrosarcoma (BRAF), mesenchymal epithelial transition (MET) exon 14 skipping, rearranged during transfection (RET), Kirsten RAt sarcoma (KRAS). 6. Participants with AGA must meet the following criteria for advanced or metastatic NSCLC. Participants who have been treated with 1 or 2 prior lines of applicable targeted therapy that is locally approved for the participant's genomic alteration at the time of screening: 1. Participants who have tumors with EGFR L858R or exon 19 deletion mutations must have received prior Osimertinib. 2. Participants who received a targeted agent as adjuvant therapy for early-stage disease must have relapsed or progressed while on the treatment or within 6 months of the last dose or received at least one additional course of targeted therapy for the same genomic alteration (which may or may not be same agent used in the adjuvant setting) for relapsed/progressive disease. 3. Participants who have been treated with a prior tyrosine kinase inhibitor (TKI) must receive additional approved targeted therapy, if locally available and clinically appropriate, for the applicable genomic alteration, or the participant will not be allowed in the study. 4. 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. (at Baseline day 1). 9. Ability to attend required study visits and return for adequate follow-up, as required by this protocol. 10. Agreement to practice effective contraception for female participants of child-bearing potential and non-sterile males. Female participants of child-bearing potential must agree to use effective contraception for up to 7 months after completion of therapy, and non-sterile male participants must agree to use a condom for up to 7 months after treatment. Effective contraception includes surgical sterilization (eg, vasectomy, tubal ligation), orals, injectables, 2 forms of barrier methods (eg, condom, diaphragm) used with spermicide, intrauterine devices (IUDs), and hormonal therapy. 11. 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. Exclusion Criteria Participants with ANY of the following criteria are excluded from participation in the study: 1. Systemic autoimmune disease currently requiring treatment (eg, lupus erythematosus, rheumatoid arthritis, Addison's disease, or autoimmune disease associated with lymphoma). The participant must have been off treatment for 180 days. 2. History of organ transplant requiring immunosuppression; or history of pneumonitis or interstitial lung disease requiring treatment with systemic steroids; or a history of receiving systemic steroid therapy or any other immunosuppressive medication ≤ 3 days prior to study initiation. Daily steroid replacement therapy (eg, prednisone or hydrocortisone) and corticosteroids used to manage AEs are permitted. 3. Participants with AGA of ALK. 4. History of 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. Participants with 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. Participants must have fully recovered from the effects of prior surgery in the opinion of the treating Investigator. 11. Inadequate organ function, evidenced by the following laboratory results: 1. Absolute lymphocyte count \< institutional upper limit of normal (ULN). 2. Absolute neutrophil count \< 1,500 cells/mm3. 3. Platelet count \< 100,000 cells/mm3. 4. Total bilirubin greater than the ULN; unless the participant has documented Gilbert's syndrome). 5. Aspartate aminotransferase (AST \[serum glutamic-oxaloacetic transaminase; SGOT\]) or alanine aminotransferase (ALT \[serum glutamic pyruvic transaminase; SGPT\]) \> 1.5 × ULN. 6. Alkaline phosphatase (ALP) levels \> 2.5 × ULN. 7. Hemoglobin \< 9.0 g/dL. 8. Serum creatinine \> 2.0 mg/dL or 177 µmol/L or creatinine clearance \< 40 mL/min (using the Cockcroft-Gault formula below): Female = \[(140

•age in years) × weight in kg × 0.85\] / \[72 × serum creatinine in mg/dL\] Male = \[(140

•age in years) × weight in kg × 1.00\] / \[72 × serum creatinine in mg/dL\] 12. Have any of following: 1. Cirrhosis at a level of Child-Pugh B (or worse); 2. Cirrhosis (any degree) and a history of hepatic encephalopathy; or 3. Clinically meaningful ascites resulting from cirrhosis. Clinically meaningful ascites is defined as ascites from cirrhosis requiring diuretics or paracentesis. 13. Participation in an investigational drug study or history of receiving any investigational treatment within 21 days prior to study entry, except for hormone-lowering therapy in participants with hormone-sensitive cancer. 14. Assessed by the Investigator to be unable or unwilling to comply with the requirements of the protocol. 15. Pregnant and nursing women. 16. History of allergic reactions to tislelizumab. 17. History of prior adverse reaction to immunotherapy that led to its permanent discontinuation.

Conditions & Interventions

Interventions:

DRUG: N-803, DRUG: Tislelizumab, DRUG: Docetaxel

Conditions:

NSCLC Stage IV

More Information

Contact(s): Phillip Trieu - Phillip.Trieu@immunitybio.com

Principal Investigator:

IRB

Number:

System ID: NCT06745908