

FAST FACTS

A082302: EVALUATING ADJUVANT ATEZOLIZUMAB OR ATEZOLIZUMAB AND HYALURONIDASE-TQJS TO PREVENT RECURRENCE IN STAGE I NON-SMALL CELL LUNG CANCER (NSCLC): A RANDOMIZED PHASE III TRIAL (AASI-NSCLC)

3.2.1 Documentation of Disease

- Pathologically stage IA3 or IB NSCLC per AJCC Cancer Staging Manual, 9th edition.

Note: Tumors with any histology are allowed including both squamous and non-squamous subtypes, except those containing small-cell morphology. Nonsquamous histology includes adenocarcinoma, large cell neuroendocrine, poorly differentiated tumors and adenosquamous, etc.

3.2.2 Patient must have undergone complete surgical resection with negative margins (complete R0 resection). Surgical resection must be lobectomy or higher, unless the tumor measured no more than 2 cm based on clinical staging, where sublobar resection, e.g., wedge or segmentectomy, will be acceptable.

Note: For patients who underwent sub-lobar resection for clinical tumors size of ≤ 2.0 cm, must have CT Chest confirming tumor size within 60 days of surgical resection. Patients who received a lobectomy or higher do not require to fulfil this imaging criteria.

3.2.3 Patient must have undergone adequate nodal sampling as defined by Commission on Cancer, 2020 Standard. Adequate nodal sampling includes pathological evaluation of at least one (named and/or numbered) hilar station (level 10 or higher) and at least three distinct (named and or numbered) mediastinal stations (level 2-9).

3.2.4 PD-L1 immunohistochemistry showing Tumor Proportion Score (TPS) $\geq 50\%$, by an FDA-approved assay including but not limited to SP263, SP142, 22C3, 28-8, performed either on surgical specimen or biopsy specimen.

3.2.5 No EGFR Exon 19 del or L858R mutation or ALK fusion; molecular testing may have been performed either on surgical specimen or biopsy specimen. Tumors with purely squamous histology are not required to undergo EGFR or ALK gene testing

3.2.6 Prior Treatment

- Patient to be registered to A082302 no earlier than 21 days and no later than 77 days from surgical resection.
- Recovered from surgical resection as determined by the treating provider or the investigator.
- No prior neoadjuvant or adjuvant therapy for current lung cancer diagnosis.

- Patient must NOT have uncontrolled intercurrent illness, including but not limited to serious ongoing or active infection, symptomatic congestive heart failure (NYHA Class $\geq$ III), unstable angina, or unstable arrhythmia.
- No current pneumonitis or history of (non-infectious) pneumonitis that required steroids or history of interstitial lung disease (ILD).
- No active auto-immune disease that has required systemic treatment within the last 2 years (e.g., disease modifying agents, corticosteroids, or immunomodulatory agents). Replacement therapy (e.g., thyroid for history of autoimmune thyroiditis, insulin for type I or II diabetes, corticosteroids for adrenal or pituitary insufficiency) is not considered a form of systemic treatment.
- No known hypersensitivity ($\geq$ grade 3) to atezolizumab and/or any of its excipients.
- No live vaccine within 30 days prior to registration. Examples include but are not limited to: measles, mumps, rubella, varicella, yellow fever, Bacillus Calmette-Guerin (BCG), typhoid, nasally administered influenza.
- No history of prior allogeneic bone marrow, stem cell, or solid organ transplant.
- Patient has not received continuous systemic treatment with corticosteroids (>10 mg daily prednisone or equivalents) or other immunosuppressive medications within 14 days prior to registration, with the following exceptions:

Inhaled or topical steroids and adrenal replacement doses ≤ 10 mg daily prednisone equivalents are permitted in the absence of active autoimmune disease. Patients are permitted to use topical, ocular, intra-articular, intranasal, and inhalational corticosteroids (with minimal systemic absorption). Physiologic replacement doses of systemic corticosteroids are permitted, if < 10 mg/day prednisone equivalents. A brief course of corticosteroids for prophylaxis (e.g., contrast dye allergy) or for treatment of non-autoimmune conditions (e.g., delayed-type hypersensitivity reaction caused by contact allergen or COPD exacerbation) is permitted.

3.2.7 Age ≥ 18 years

3.2.8 ECOG Performance Status ≤ 2 (or Karnofsky $\geq 60\%$)

3.2.9 Required Initial Laboratory Values:

- Absolute Neutrophil Count (ANC) $\geq 1,500/\text{mm}^3$
- Platelet Count $\geq 100,000/\text{mm}^3$
- Total Bilirubin $\leq 1.5 \times$ upper limit of normal (ULN), except patients with Gilbert Syndrome who can have total bilirubin < 3.0 mg/dl
- AST (SGOT)/ALT (SGPT) $\leq 3 \times$ upper limit of normal (ULN)
- Creatinine Clearance ≥ 30 mL/min (using standard Cockcroft-Gault formula, unless measured CrCl is available and meet the specified threshold)

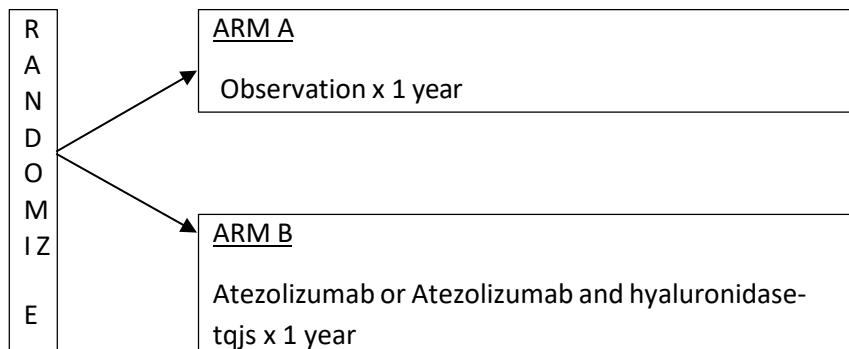
3.2.10 Not pregnant and not nursing, because this study involves an agent that has known genotoxic, mutagenic and teratogenic effects. Therefore, for women of childbearing potential only, a negative urine or serum pregnancy test done ≤ 7 days prior to registration is required.

3.2.11 Comorbid Conditions

- Patients with a prior or concurrent malignancy whose natural history or treatment does not have the potential to interfere with the safety or efficacy assessment of the investigational regimen are eligible for this trial.
- HIV: Patients with known HIV infection on effective anti-retroviral therapy with undetectable viral load within 6 months prior to registration are eligible for this trial. Patients with no known history of HIV do not require any testing.
- Hepatitis B and Hepatitis C: No active Hepatitis B (defined as negative for HepB DNA, and positive for HepB surface antibody) or Hepatitis C (defined as HCV RNA [qualitative] detected) infection. If there is a history of either infection, patient should be negative for active disease, for Hepatitis B negative for HBsAg, and for hepatitis C – negative for HCV RNA (qualitative). Patients with no known history of chronic hepatitis do not require any testing.
- No active infection requiring systemic therapy
- Cardiac function: Patients with known history or current symptoms of heart failure, or history of treatment with cardiotoxic agents, should have a clinical risk assessment of cardiac function using the New York Heart Association Functional Classification. To be eligible for this trial, patients should be class 2B or better.

Schema

1 Cycle = 21 Days



Treatment is to continue for up to one year, or until unacceptable adverse events, disease recurrence, or new lung primary, whichever occurs earlier. Patients will be followed for 10 years for recurrence or until death, whichever occurs earlier.