Cancer Research Consortium of West Michigan
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FAST FACTS

EA5221: A Randomized Phase III Trial of Chemo-Immunotherapy vs Immunotherapy Alone for the Vulnerable older adult with Advanced Non-Small Cell Lung Cancer: The ACHIEVE Study

Eligibility Criteria

Eligibility Criteria (Step 1 Registration)

_____ 3.1.1 Patient must be ≥ 70 years of age.

_____ 3.1.2 Patient must have histologically or cytologically confirmed non-small cell lung cancer (NSCLC) with PD-L1 TPS range of 1-49%.

_____ 3.1.3 Patient must have Stage IIIB, IIIC or IV disease and not be candidates for combined chemo-radiation. NOTE: Prior chemo-RT for stage III with recurrence is allowed.

_____ 3.1.4 Patient must have a tumor that is negative for EGFR mutation/ALK translocations or other actionable first line mutations in which patients would receive first-line oral tyrosine kinase inhibitors.

_____ 3.1.5 Patient must have an ECOG Performance Status of 2.

_____ 3.1.6 Patient must agree not to father children while on study and for 6 months after the last dose of protocol treatment.

_____ 3.1.7 Patient must have the ability to understand and the willingness to sign a written informed consent document. Patients with impaired decision-making capacity (IDMC) who have a legally authorized representative (LAR) or caregiver and/or family member available will also be considered eligible

_____ 3.1.8 Patient must have adequate organ and marrow function as defined below (these labs must be obtained within 14 days prior to Step 1 registration):

_____ Absolute neutrophil count (ANC) ≥ 1,500/ µL

ANC:_____Date of Test:_____

_____ Platelets ≥ 75,000/ µL

Platelets:_____Date of Test:_____

_____ Hemoglobin (Hgb) ≥ 8.0 g/dL

Hgb _____Date of Test _____

_____ Total bilirubin ≤ 1.5 x institutional upper limit of normal (ULN)

Total bilirubin:_____Institutional ULN:_____ Date of Test:_____

_____ AST(SGOT) and ALT(SGPT) ≤ 3.0 × institutional ULN

AST:_____Institutional ULN:_____

Date of Test:_____

ALT: _____Institutional ULN:_____

_____ Creatinine clearance (CrCL) ≥ 45 mL/min (estimated using Cockcroft- Gault method with actual body weight or measured)

Creatinine clearance _____Date of Test:_____

_____ 3.1.9 Human immunodeficiency virus (HIV)-infected patients on effective antiretroviral therapy with undetectable viral load within 6 months of Step 1 registration are eligible for this trial.

_____3.1.10 For patients with evidence of chronic hepatitis B virus (HBV) infection, the HBV viral load must be undetectable on suppressive therapy, if indicated.

_____3.1.11 Patients with a history of hepatitis C virus (HCV) infection must have been treated and cured. For patients with HCV infection who are currently on treatment, they are eligible if they have undetectable HCV viral.

_____3.1.12 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.

_____3.1.13 Patient must be English or Spanish speaking to be eligible for the QOL component of the study.

NOTE: Sites cannot translate the associated GA or QOL forms.

_____3.1.14 Patient must not have symptomatic central nervous system disease (CNS) metastases. Patients with a clinical history of CNS metastases or cord compression are eligible if they have been definitively treated and are clinically stable for at least 14 days prior to Step 1 registration and off all steroids for at least 24 hours prior to Step 1 registration. Patients with asympotmatic CNS metastases are eligible.

_____3.1.15 Patient must not have had any prior cytotoxic chemotherapy regimen for metastatic disease. Chemotherapy given in the setting of adjuvant therapy or locally advanced disease is allowed as long as treatment was completed, and they have fully recovered from treatment related adverse events prior to Step 1 registration.

_____3 . 1.16 Patient must not have had any prior immunotherapy for metastatic disease. Immunotherapy given in the setting of adjuvant therapy or locally advanced disease is allowed as long as treatment was completed greater than 6 months prior to Step 1 registration.

_____ 3 . 1.17 Patient must not have a history of uncontrolled autoimmune conditions with the following exceptions, which are allowed: alopecia, vitiligo, rheumatoid

arthritis, psoriasis/psoriatic arthritis, Hashimoto's thyroiditis, lupus, inflammatory bowel disease.

_____ 3 . 1.18 Patient must not be on immunosuppressive medication, including steroids (if doses exceed the equivalent of prednisone 10 mg daily). Short courses of steroids which are discontinued prior to randomization are acceptable. Patients on inhaled, intranasal and/or topical steroids are eligible.

3.1.19 Patient must have baseline imaging done assessing all measurable or non-measurable sites of disease within 45 days prior to Step 1 registration.

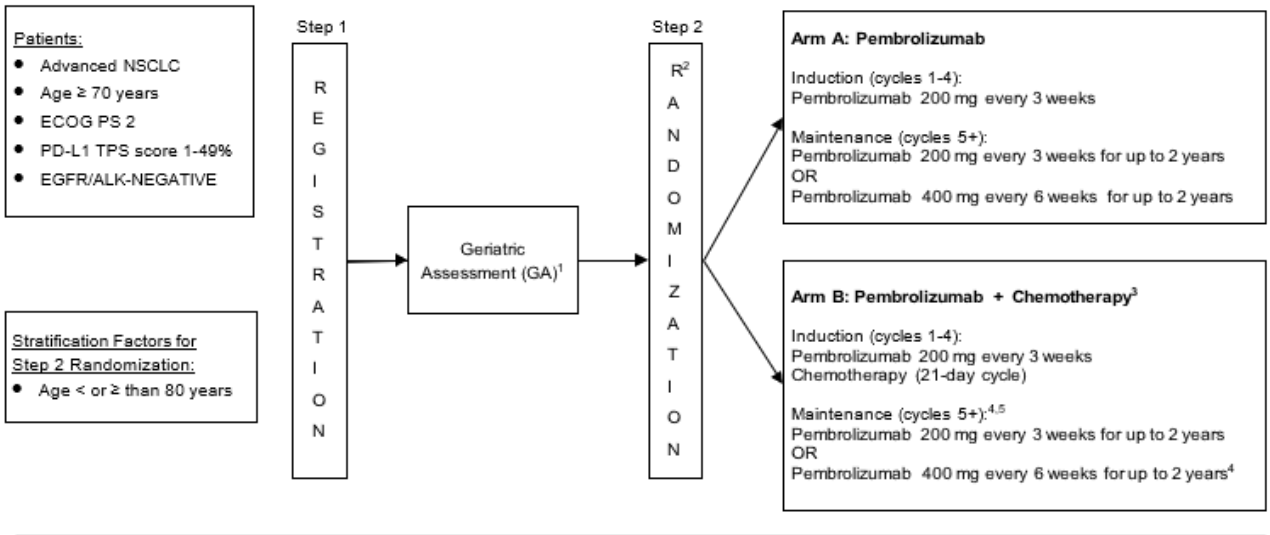
3.1.20 Investigator must declare their intended chemotherapy regimen should their patient be randomized to Arm B (doublet vs singlet) from the options outlined in Section 5.1.3.
Doublet?_____(Yes/No)

Singlet?_____(Yes/No)

Eligibility Criteria (Step 2 Randomization)

3.2.1 Patient must have completed the baseline Geriatric Assessment (GA) as outlined in Section 7.3, after Step 1 registration and prior to Step 2 randomization.

Schema



1. A baseline Geriatric Assessment (GA) will be completed following Step 1 registration and prior to Step 2 randomization. Refer to Section 7.3 and Appendix V for more information.
2. 1:1 Randomization
3. Investigator's choice of either platinum doublet or single agent chemotherapy regimen as outlined in Section 5.1.3 "Chemotherapy Regimen Options"
4. Arm B Cycle 5+: Patients will discontinue chemotherapy and continue Pembrolizumab alone.
5. Arm B: Patients who initiate treatment with pemetrexed may continue pemetrexed in the maintenance phase at the discretion of the treating investigator as outlined in Section 5.1.3.2.