Cancer Research Consortium of West Michigan
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FAST FACTS

A081801 – Integration of Immunotherapy Into Adjuvant Therapy For Resected NSCLC: ALCHEMIST CHEMO-IO

Eligibility Criteria:

1. Previously registered to A151216
2. Central and/or local testing of EGFR with no EGFR exon 19 deletion of EGFR L858 R mutation (applicable to non-squamous patients only)
3. Central and/or local testing of ALK with no ALK rearrangement (failed testing is considered negative) (applicable to non-squamous patients only)
4. Central and/or local testing of PD-L1 IHC using one of the following assays: DAKO 22C3, DAKO 28-8, EIL3N or SP263

   Note: Central testing of EGFR was discontinued as of A081801 Update 10; central testing of ALK and PD-L1 will continue. Local testing results by a local CLIA certified laboratory is required for EGFR and acceptable for ALK.. The report must indicate the result as well as the CLIA number of the laboratory that performed the assay. Local result of PD-L1 by DAKO 22C3, Dako 28-8, EIL3N or SP263 are acceptable for enrollment on A081801. Patients with local results for EGFR, ALK and PD- L1 still need to be registered to A151216 and follow all the submissions requirements but do NOT need to wait for the results to proceed to A081801 registration.
5. Completely resected stage IIA, IIB IIA or IIIB (T3-4N2) NSCLC (squamous or non squamous) with negative margins (complete R0 resection). Patients will be staged according to the 8th edition of the AJCC Cancer Staging Manual, 2017.
   Note: Patients with pathologic N2 disease, completely resected, are eligible. However, patients known to have N2 disease prior to surgery are not eligible; guidelines do not recommend up-front surgery for this population.
6. Complete recovery from surgery. Registration to A081801 must be 30-77 days following surgery.
7. No prior neoadjuvant or adjuvant therapy for current lung cancer diagnosis.
8. No prior allogeneic tissue/solid organ transplant
9. Patients must NOT have uncontrolled intercurrent illness including, but not limited to, serious ongoing or active infection, symptomatic congestive heartfailure, uncontrolled cardiac arrhythmia, unstable angina pectoris, that would limit compliance with study requirements.
10. No current pneumonitis or history of (non-infectious) pneumonitis that required steroids.
11. HIV-infected patients on effective anti-retroviral therapy with undetectable viral load within 6 months are eligible for this trial.
12. Age ≥18 years
13. ECOG PS: 0-1
14. No active auto-immune disease that has required systemic treatment within the last 2 years (e.g., disease-modifying agents, corticosteroids, or immunosuppressive drugs). Replacement therapy (e.g., thyroxine, insulin, or physiologic corticosteroid release therapy for adrenal or pituitary insufficiency) is not considered a form of systemic treatment.

15. 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 pregnancy test done ≤ 7 days prior to registration is required.

16. No patients with a "currently active" second malignancy that is progressing or has required active treatment within the last 3 years. Participants with non-melanoma skin cancers or carcinoma in situ (e.g., breast carcinoma or cervical cancer in situ) that have undergone potentially curative therapy are eligible.

17. No hypersensitivity (≥ Grade 3) to pembrolizumab and/or any of its excipients

18. No live vaccine within 30 days prior to registration. Examples of live vaccines include, but are not limited to, the following: measles, mumps, rubella, varicella/zoster (chicken pox), yellow fever, rabies, Bacillus Calmette–Guérin (BCG), and typhoid vaccine. Seasonal influenza vaccines for injection are generally killed virus vaccines and are allowed; however, intranasal influenza vaccines (e.g., FluMist®) are live attenuated vaccines and are not allowed.

19. No known history of Hepatitis B (defined as HBsAg reactive) or known Hepatitis C virus (defined as HCV RNA [qualitative] is detected) infection.

20. Required Initial Laboratory Values
    - Absolute Neutrophil Count (ANC) ≥ 1,500/mm3
    - Platelet Count ≥100,000/mm3
    - Hemoglobin ≥8 gm/dl
    - Calc. Creatinine Clearance ≥ 45 mL/min
    - Total Bilirubin ≤ 1.5 x upper limit of normal (ULN)
    - AST / ALT ≤ 2.5 x upper limit of normal (ULN)

FOR PATIENTS CONSENTED ON/AFTER UPDATE #1 POSTING