NRG-LU005

Report Based on Data Through: 04/30/2019

Limited Stage Small Cell Lung Cancer (LS-SCLC): A Phase II/III Randomized Study of Chemoradiation Versus Chemoradiation Plus Atezolizumab

PATIENT POPULATION:
Limited stage (Tx, T1-T4, N0-3, M0) small cell lung cancer (LS-SCLC)

STRATIFICATION

- Radiation schedule, BID (3 weeks) vs daily (6.5 weeks)
- Chemotherapy (cisplatin vs carboplatin)
- Sex (male vs female)
- ECOG Performance Status (0/1 vs 2)

RANDOMIZE*

Arm 1	**Arm 2**
Platinum**/etoposide q3 weeks x 4 cycles + Thoracic RT 45 Gy bid or 66 Gy daily beginning with cycle 2 of chemotherapy***	Platinum**/etoposide q3 weeks x 4 cycles + Thoracic RT 45 Gy bid or 66 Gy daily beginning with cycle 2 of chemotherapy*** + Atezolizumab q3 weeks x 1 year, beginning with cycle 2 of chemotherapy

* Randomization is 1:1.

** First cycle of chemotherapy must be given prior to study entry for a total of 4 cycles, 3 given on study. Chemotherapy doublets delivered concurrently, cisplatin/etoposide or carboplatin/etoposide, is required. The site/investigator must declare the chemotherapy regimen that the patient will receive prior to the patient's randomization. Patients who develop a contraindication to cisplatin after beginning therapy may receive carboplatin in subsequent cycles. See Section 5.1 and 6 for details.

*** All patients with a complete or near complete response are strongly recommended to receive prophylactic cranial irradiation (PCI), planned within 4-6 weeks from completion of chemoradiotherapy**.** **Significant chemoradiotherapy toxicities should be resolved to grade 2 or less before beginning PCI.** Patients on Arm 2 who receive PCI will receive it concurrent with atezolizumab.

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To Be Activated: May/June 2019

- **Study Description**

  NRG-LU005 is a phase II/III trial to assess the efficacy of atezolizumab when combined with standard chemoradiation for patients with limited stage small cell lung cancer (LS-SCLC). The primary endpoint of the phase II portion of the trial is progression-free survival as assessed using RECIST 1.1. If the phase II portion of the trial demonstrates sufficient efficacy, accrual will continue into the phase III portion. The primary endpoint for the phase III portion of the trial is overall survival.