For Patients with Small Cell Lung Cancer

**EA5161 Available Through ECOG-ACRIN Cancer Research Group**

Randomized Phase II Clinical Trial of Cisplatin/Carboplatin and Etoposide (CE) Alone or in Combination with Nivolumab as Frontline Therapy for Extensive Stage Small Cell Lung Cancer (ED-SCLC)

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**Cycle = 3 weeks; Maintenance cycle = 6 weeks**

**Arm A:**
- Nivolumab 360 mg IV day 1 followed by carboplatin AUC 5 or 6 IV or cisplatin 75 mg/m² IV on day 1, then etoposide 100 mg/m² IV on days 1, 2, and 3
- After 4 cycles, nivolumab only will be continued as maintenance, administered at 240 mg IV every 2 weeks until progression, unacceptable toxicity, or up to 2 years/50 doses

**Arm B:**
- Carboplatin AUC 5 or 6 IV or cisplatin 75 mg/m² IV on day 1, followed by etoposide 100 mg/m² IV on days 1, 2, and 3
- After 4 cycles, patients will proceed to observation

**Radiation Therapy:**
- Patients with good clinical response after 4 cycles of first-line chemotherapy can receive prophylactic cranial radiation/whole brain radiation per protocol and local standard of care; in the investigational arm, nivolumab will not be administered during 1 week before and after brain radiation treatment
- Thoracic radiation with intent to eliminate residual disease is not allowed following completion of 4 cycles of first-line chemotherapy; palliative radiation is allowed in non-measurable sites of disease (a 1 week washout is permitted for palliative radiation to non-CNS disease)

**Notes:**
- Choice of cisplatin or carboplatin (5 or 6) is at the discretion of the treating physician; cisplatin/carboplatin and etoposide to be administered with SOC pre-medications and pre/post hydration
- Maximum 4 cycles of platinum and etoposide
- All treatment visits must occur +/-3 days from scheduled date (see protocol for details)

**Patient Enrollment**
All Sites: Oncology Patient Enrollment Network (OPEN) [https://open.ctsu.org](https://open.ctsu.org)

**Protocol Information**
ECOG-ACRIN Operations-Boston: 857-504-2900, [http://ecog-acrin.org](http://ecog-acrin.org) (Member Login)

Please Enroll Your Eligible Patients!
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Schema

Cycles 1-4

- Arm A
  - Cisplatin/Carboplatin Etoposide and Nivolumab
  - Nivolumab Maintenance

Cycles 5+

- Arm B
  - Cisplatin/Carboplatin Etoposide
  - Observation

Randomize

Stratification
1. Gender (M vs. F)
2. LDH ≤ upper limits of normal or > ULN

Cycle = 3 weeks during cycles 1-4 (21 days)
Cycle = 6 weeks during maintenance cycle 5+
Accrual goal = 150 patients

1. Refer to Section 5.1 for specific doses.
2. Until disease progression or unacceptable toxicity. Or up to 2 years (50 doses)
3. Until disease progression or non-protocol treatment regimen is initiated.
4. All patients will proceed to maintenance or observation after 4 cycles of chemotherapy.