Testing the Addition of Radiation Therapy to the Usual Immune Therapy Treatment (Atezolizumab) for Extensive Stage Small Cell Lung Cancer, The RAPTOR Trial

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Any confirmation (cytologic, histologic, or pathologic) of extensive stage small cell lung cancer at any site, either primary or metastases * Partial response (PR) or stable disease (SD) after 4-6 cycles of etoposide/platinum (E/P) doublet plus atezolizumab by re-staging scans (positron emission tomography \[PET\]/computed tomography \[CT\] scan, diagnostic CT scan, magnetic resonance imaging \[MRI\] optional per treating physician); atezolizumab should continue through randomization. Patients must be randomized within 9 weeks of last dose of etoposide/platinum (if not receiving PCI) or 6 weeks from completion of prophylactic cranial irradiation (PCI) * NOTE: Patients must have at least 3 cycles of E/P plus atezolizumab. They can have one cycle of induction E/P without concurrent atezolizumab if unable to receive concurrent E/P combined with atezolizumab for all cycles of induction therapy * Patients must have measurable disease (per Response Evaluation Criteria in Solid Tumors \[RECIST\]) and 3 or fewer observable liver metastases and no evidence of progressive disease (per RECIST) at time of enrollment * At time of enrollment after induction E/P chemotherapy and atezolizumab, if there is a pleural effusion, patients will be eligible if thoracentesis is cytologically negative or if pleural fluid is too small a volume to effectively sample by thoracentesis and does not show increased metabolic activity on CT/PET imaging * Appropriate stage for study entry based on the following diagnostic workup: * History/physical examination within 14 days prior to registration; * Imaging within 42 days prior to registration to include: * MRI brain with contrast or CT brain with contrast * CT chest, abdomen and pelvis or whole body PET/CT scan any time after the fourth cycle of chemotherapy and prior to registration * Eastern Cooperative Oncology Group (ECOG) performance status of 0-2 within 14 days prior to registration * Absolute neutrophil count (ANC) \>= 1,000/cells/mm\^3 (within 14 days prior to registration) * Platelets \>= 75,000 cells/mm\^3 (within 14 days prior to registration) * Hemoglobin \>= 8 g/dL (within 14 days prior to registration) * Total bilirubin =\< 1.5 x upper limit of normal (ULN) (within 14 days prior to registration) * Aspartate aminotransferase (AST) (serum glutamic-oxaloacetic transaminase \[SGOT\]) and alanine aminotransferase (ALT) (serum glutamate pyruvate transaminase \[SGPT\]) =\< 3.0 x ULN (AST and/or ALT =\< 5 ULN for patients with liver involvement) (within 14 days prior to registration) * Alkaline phosphatase =\< 2.5 x ULN (=\< 5 ULN for patients with documented liver involvement or bone metastases) (within 14 days prior to registration) * Adequate renal function = Creatinine clearance \>=40 mL/min by the Cockcroft-Gault (C-G) equation: (within 14 days prior to registration) * Upfront radiation therapy of symptomatic metastatic site is permissible if causing symptoms such as pain or impending fracture * Patients with brain metastases are eligible after receiving whole brain radiation before enrollment (anytime during induction systemic therapy). Whole brain radiation can be delivered with hippocampal sparing or 3-D conformal technique. Patients with irradiated brain metastases are eligible if they are clinically stable from a neurological standpoint after completing radiotherapy (e.g. not having uncontrolled seizures) and do not require use of steroids above a dose of 10 mg of prednisone daily * For women of childbearing potential, a negative serum or urine pregnancy test within 14 days prior to registration. * Note: Women will be considered post-menopausal if they have been amenorrheic for 12 months without an alternative medical cause. The following age-specific requirements apply: * Women \< 50 years of age would be considered post-menopausal if they have been amenorrheic for 12 months or more following cessation of exogenous hormonal treatments and if they have luteinizing hormone and follicle-stimulating hormone levels in the post-menopausal range for the institution or underwent surgical sterilization (bilateral oophorectomy or hysterectomy) * Women \>= 50 years of age would be considered post-menopausal if they have been amenorrheic for 12 months or more following cessation of all exogenous hormonal treatments, had radiation-induced menopause with last menses \> 1 year ago, had chemotherapy-induced menopause with last menses \> 1 year ago, or underwent surgical sterilization (bilateral oophorectomy, bilateral salpingectomy or hysterectomy) * Patients positive for human immunodeficiency virus (HIV) on effective anti-retroviral therapy with undetectable viral load within 6 months and a stable regimen of highly active anti-retroviral (HAART) HIV-positive patients must have no requirement for concurrent antibiotics or antifungal agents for the prevention of opportunistic infections * The patient or a legally authorized representative must provide study-specific informed consent prior to study entry

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Exclusion Criteria:

* Metastatic disease invading the liver (\> 3 metastases), heart or \> 10 metastatic sites detectable after induction systemic therapy. Each visible bone metastasis on radiographic scan counts as one site * Patients with a concurrent malignancy whose natural history or treatment has the potential to interfere with the safety or efficacy assessment of the investigational regimen with atezolizumab or radiation * Prior radiotherapy in the thorax that would result in overlapping RT fields, unless the overlapping fields meet acceptable dose constraints for normal tissue * Active autoimmune disease, including, but not limited to: systemic lupus erythematosus; rheumatoid arthritis; inflammatory bowel disease (e.g. Crohn's, ulcerative colitis); vascular thrombosis associated with antiphospholipid syndrome; Wegener's granulomatosis; Sjogren's syndrome; Guillain-Barre syndrome; multiple sclerosis; vasculitis; or glomerulonephritis. * If the autoimmune disease is not active for over 3 years and the patient is not receiving immunosuppressive treatment such as methotrexate or steroids above a dose equivalent to 10 mg prednisone daily, the patient is eligible. * Patients with a history of autoimmune hypothyroidism on a stable dose of thyroid replacement hormone are eligible * Patients with controlled type 1 diabetes mellitus on a stable insulin regimen are eligible * Patients with eczema, psoriasis, lichen simplex chronicus or vitiligo with dermatologic manifestations are excluded only if they have active disease with acute exacerbation and on immunosuppressive medications within the 12 months prior to enrollment. They are eligible otherwise. * Severe, active co-morbidity defined as follows: * Any other diseases, metabolic dysfunction, physical examination finding, or clinical laboratory finding giving reasonable suspicion of a disease or condition that contraindicates the use of an investigational drug or that may affect the interpretation of the results or render the patient at high risk from treatment complications; * Active tuberculosis; * Known clinically significant liver disease, including active viral, alcoholic, or other hepatitis; cirrhosis; fatty liver; and inherited liver disease * Patients with past or resolved hepatitis B infection (defined as having a negative hepatitis B surface antigen \[HBsAg\] test and a positive anti-HBc \[antibody to hepatitis B core antigen\] antibody test) are eligible * Patients positive for hepatitis C virus (HCV) antibody are eligible only if polymerase chain reaction (PCR) is negative for HCV ribonucleic acid (RNA). (The HCV RNA test must be performed for patients who have a positive HCV antibody test) * Known immunosuppressive disease, for example history of bone marrow transplant or chronic lymphocytic leukemia (CLL); * Chronic obstructive pulmonary disease (COPD) requiring chronic oral steroid therapy of \> 10 mg prednisone daily or equivalent at the time of registration. Inhaled corticosteroids are not exclusionary; * Unstable angina and/or congestive heart failure requiring hospitalization within the last 3 months; * History of recent myocardial infarction within 6 months prior to registration. * Clinically significant interstitial lung disease * Pregnancy: Administration of atezolizumab may have an adverse effect on pregnancy and poses a risk to the human fetus, including embryo-lethality. Women of child-bearing potential and men must agree to use adequate contraception (hormonal or barrier method of birth control; abstinence) prior to study entry, for the duration of study treatment, and for 5 months (150 days) after the last dose of study agent. Should a woman become pregnant or suspect she is pregnant while she or her partner is participating in this study, she should inform her treating physician immediately * Women who are breastfeeding and unwilling to discontinue * History of allogeneic organ transplant * Patients who have had immunotherapy-induced pneumonitis

Conditions & Interventions

Interventions:

DRUG: Atezolizumab PROCEDURE: Biospecimen Collection PROCEDURE: Computed Tomography PROCEDURE: Magnetic Resonance Imaging PROCEDURE:

DRUG: Atezolizumab, PROCEDURE: Biospecimen Collection, PROCEDURE: Computed Tomography, PROCEDURE: Magnetic Resonance Imaging, PROCEDURE: Positron Emission Tomography, RADIATION: Radiation Therapy

Conditions:

Extensive Stage Lung Small Cell Carcinoma

More Information

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