## Transcript Details

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Reevaluating Outlooks for Small Cell Lung Cancer

**Announcer:**
Welcome to ReachMD.

This medical industry feature, titled “Reevaluating Outlooks for Small Cell Lung Cancer” is presented on behalf of Genentech, and the information presented is intended for physicians and consistent with FDA guidelines.

**Dr. Evans:**
Hello, my name is Dr. Tracey Evans. This program is presented on behalf of Genentech, and the information presented is consistent with FDA guidelines. I have been compensated by Genentech to serve as speaker for this program. This program is intended to provide general information about TECENTRIQ®, or atezolizumab, and not medical advice for any particular patient. Any adverse events included in this presentation today have already been reported to Genentech drug safety and no action is required by any member of the audience. This program may be monitored by Genentech for adherence to program requirements. All materials are the property of Genentech, and may not be recorded, photographed, copied or reproduced.

**Dr. Caudle:**
This is ReachMD, and I'm your host, Dr. Jennifer Caudle. On today's program, we'll be discussing a significant therapeutic advancement in the extensive stage small cell lung cancer treatment landscape. Joining me today is Dr. Tracey Evans. She's the Director of Thoracic Oncology Research at Lankenau Institute for Medical Research. She's also the Co-director of the Thoracic Oncology Program at Mainline health in Wynwood, Pennsylvania. Dr. Evans, thank you so much for being here today.

**Dr. Evans:**
Thank you for having me!

**Dr. Caudle:**
Of course. So Dr. Evans, can you give us a better understanding of small cell lung cancer and its impact on patients suffering from this disease?

**Dr. Evans:**
Absolutely. Small cell lung cancer is a highly aggressive, lethal, and widely metastatic lung cancer. Based on small cell lung cancer having a 15% global lung cancer incidence and an approximate 7% five-year survival for all stages combined, small cell lung cancer kills an estimated quarter of a million people worldwide yearly. Most cases of small cell lung cancer occur in individuals aged 60 to 80 years.

Small cell lung cancer also has a low survival rate with 60 to 70% of patients presenting with extensive stage disease at diagnosis. Stage IV small cell lung cancer has a relative five-year survival rate of about 3%.

**Dr. Caudle:**
Thanks for that overview, Dr. Evans. Now continuing on that track, can you walk us through the signs and symptoms of patients with small cell lung cancer?

**Dr. Evans:**
Sure. Patients with small cell lung cancer commonly present with the following signs and symptoms. A cough that does not go away or that gets worse, coughing up blood or rust-colored sputum, chest pain that is often worse with deep breathing, coughing, or laughing, hoarseness, weight loss and loss of appetite, shortness of breath, feeling tired or weak, infections such as a bronchitis or pneumonia

that doesn't go away or that keeps coming back, or new-onset wheezing.

Now with lung cancer metastasizes, patients tend to become multisymptomatic, and commonly experience signs and symptoms like bone pain, which can be pain felt in the back or hips, nervous system changes including headaches or seizures, yellowing of the skin and eyes or jaundice, lumps near the surface of the body.

**Dr. Caudle:**
And what are some risk factors to keep in mind when identifying patients with small cell lung cancer?

**Dr. Evans:**
Some risk factors for small cell lung cancer include smoking. This is a major risk factor, with 98% of patients having a history of smoking and/or are current smokers. Secondhand smoke is also a risk factor as well as radon exposure, air pollution, workplace carcinogens, and a personal or family history of lung cancer.

**Dr. Caudle:**
So with those considerations in mind, Dr. Evans, let's talk about the diagnostic workup for these patients. What should we keep top of mind?

**Dr. Evans:**
Patients usually come to medical attention for diagnostic workups due to their symptoms. The diagnostic workup steps include x-ray, diagnostic CT, biopsy and staging ideally with a PET/CT if possible and available, and an MRI of the brain with contrast.

**Dr. Caudle:**
So, Dr. Evans, let's shift to therapeutic considerations and take a look at the history of treating this disease. You know, it seems there hasn't been a lot of progress made in the small cell lung cancer field over the years, is that correct?

**Dr. Evans:**
Unfortunately, that is true. Between 1970 and 2010, there were limited therapeutic advancements made in extensive stage small cell lung cancer. Radiotherapy plus platinum-based chemotherapy was the standard treatment for most small cell lung cancer cases for 30 years. But outcomes haven't changed dramatically, as the majority of patients develop chemo resistance. Patients show a dramatic initial response to chemotherapy only to have their cancer subsequently recur.

In 2012, the U.S. Cancer Institute designated small cell lung cancer a recalcitrant cancer due to slow rates of advancement or research breakthroughs and due to low survival rates.

**Dr. Caudle:**
Well, I understand that the emergence of immunotherapy has significantly advanced treatment in the space for the first time in decades. What can you tell us about that?

**Dr. Evans:**
Immunotherapy has indeed made some meaningful advances in the treatment landscape for extensive stage small cell lung cancer. In fact, the first FDA approval we've seen in 20 years for extensive stage small cell lung cancer was granted in 2019. And that was for the treatment option of TECENTRIQ.

TECENTRIQ, or atezolizumab, is a programmed death ligand-1, or PDL-1 blocking antibody that is indicated in combination with carboplatin and etoposide for the first-line treatment of adult patients with extensive stage small cell lung cancer.

**Dr. Caudle:**
Those are some great thoughts for us to carry into our practices when treating these patients and, with that, I'd like to thank my guest Dr. Tracey Evans. Thank you so much for giving us a better understanding of extensive stage small cell lung cancer and discussing TECENTRIQ + carbo and etoposide as a first-line combination treatment. Dr. Evans, it was great to have you with us today

**Dr. Evans:**
Thank you so much for having me!

**Dr. Caudle:**
For ReachMD, I'm your host, Dr. Jennifer Caudle. And now before we close, let's review some important safety information.

**Announcer:**

**Serious Adverse Reactions**

Please refer to the full Prescribing Information for important dose management information specific to adverse reactions.

**Severe and Fatal Immune-Mediated Adverse Reactions**

TECENTRIQ is a monoclonal antibody that belongs to a class of drugs that bind to either the programmed death-receptor 1 (PD-1) or the PD-ligand 1 (PD-L1), blocking the PD-1/PD-L1 pathway, thereby removing inhibition of the immune response, potentially breaking peripheral tolerance and inducing immune-mediated adverse reactions. Important immune-mediated adverse reactions listed under Warnings and Precautions may not include all possible severe and fatal immune-mediated reactions.

Immune-mediated adverse reactions can occur in any organ system or tissue and at any time after starting a PD-1/PD-L1 blocking antibody. While immune-mediated adverse reactions usually manifest during treatment with PD-1/PD-L1 blocking antibodies, they can also manifest after discontinuation of treatment.

Early identification and management of immune-mediated adverse reactions are essential to ensure safe use of PD-1/PD-L1 blocking antibodies. Monitor patients closely for symptoms and signs that may be clinical manifestations of underlying immune-mediated adverse reactions.

In general, if TECENTRIQ requires interruption or discontinuation, administer systemic corticosteroid therapy (1 to 2 mg/kg/day prednisone or equivalent) until improvement to Grade 1 or less, then initiate corticosteroid taper and continue to taper over at least 1 month. Consider administration of other systemic immunosuppressants in patients whose immune-mediated adverse reactions are not controlled with corticosteroid therapy.

**Immune-Mediated Pneumonitis**

TECENTRIQ can cause immune-mediated pneumonitis. The incidence of pneumonitis is higher in patients who have received prior thoracic radiation.

Immune-mediated pneumonitis occurred in 3% (83/2616) of patients receiving TECENTRIQ as a single agent, including fatal (<0.1%), Grade 4 (0.2%), Grade 3 (0.8%), and Grade 2 (1.1%) adverse reactions.

**Immune-Mediated Colitis**

TECENTRIQ can cause immune-mediated colitis. Colitis can present with diarrhea, abdominal pain, and lower gastrointestinal (GI) bleeding. Cytomegalovirus (CMV) infection/reactivation has been reported in patients with corticosteroid-refractory immune-mediated colitis. In cases of corticosteroid-refractory colitis, consider repeating infectious workup to exclude alternative etiologies

Immune-mediated colitis occurred in 1% (26/2616) of patients receiving TECENTRIQ as a single agent, including Grade 3 (0.5%) and Grade 2 (0.3%) adverse reactions.

**Immune-Mediated Hepatitis**

TECENTRIQ can cause immune-mediated hepatitis

Immune-mediated hepatitis occurred in 1.8% (48/2616) of patients receiving TECENTRIQ as a single agent, including fatal (<0.1%), Grade 4 (0.2%), Grade 3 (0.5%), and Grade 2 (0.5%) adverse reactions.

**Immune-Mediated Endocrinopathies (1 of 2)**

***Adrenal Insufficiency***

TECENTRIQ can cause primary or secondary adrenal insufficiency. For Grade 2 or higher adrenal insufficiency, initiate symptomatic treatment, including hormone replacement as clinically indicated.

Adrenal insufficiency occurred in 0.4% (11/2616) of patients receiving TECENTRIQ as a single agent, including Grade 3 (<0.1%) and Grade 2 (0.2%) adverse reactions.

***Hypophysitis***

TECENTRIQ can cause immune-mediated hypophysitis. Hypophysitis can present with acute symptoms associated with mass effect such as headache, photophobia, or visual field cuts. Hypophysitis can cause hypopituitarism. Initiate hormone replacement as clinically indicated.

Hypophysitis occurred in <0.1% (2/2616) of patients receiving TECENTRIQ as a single agent, including Grade 2 (1 patient, <0.1%) adverse reactions

**Immune-Mediated Endocrinopathies (2 of 2)**

*Thyroid Disorders*

TECENTRIQ can cause immune-mediated thyroid disorders. Thyroiditis can present with or without endocrinopathy. Hypothyroidism can follow hyperthyroidism. Initiate hormone replacement for hypothyroidism or medical management for hyperthyroidism as clinically indicated.

Thyroiditis occurred in 0.2% (4/2616) of patients receiving TECENTRIQ as a single agent, including Grade 2 (<0.1%) adverse reactions.

Hyperthyroidism occurred in 0.8% (21/2616) of patients receiving TECENTRIQ as a single agent, including Grade 2 (0.4%) adverse reactions.

Hypothyroidism occurred in 4.9% (128/2616) of patients receiving TECENTRIQ as a single agent, including Grade 3 (0.2%) and Grade 2 (3.4%) adverse reactions.

Hypothyroidism occurred in 11% (277/2421) of patients with NSCLC and SCLC receiving TECENTRIQ in combination with platinum-based chemotherapy, including Grade 4 (<0.1%), Grade 3 (0.3%), and Grade 2 (5.7%) adverse reactions.

*Type 1 Diabetes Mellitus, Which Can Present With Diabetic Ketoacidosis*

Initiate treatment with insulin as clinically indicated.

Type 1 diabetes mellitus occurred in 0.3% (7/2616) of patients receiving TECENTRIQ as a single agent, including Grade 3 (0.2%) and Grade 2 (<0.1%) adverse reactions.

**Immune-Mediated Nephritis with Renal Dysfunction**

TECENTRIQ can cause immune-mediated nephritis

Immune-mediated nephritis with renal dysfunction occurred in <0.1% (1/2616) of patients receiving TECENTRIQ as a single agent, and this adverse reaction was a Grade 3 (<0.1%) adverse reaction.

**Immune-Mediated Dermatologic Adverse Reactions**

TECENTRIQ can cause immune-mediated rash or dermatitis. Exfoliative dermatitis, including Stevens-Johnson syndrome (SJS), DRESS, and toxic epidermal necrolysis (TEN), has occurred with PD-1/PD-L1 blocking antibodies. Topical emollients and/or topical corticosteroids may be adequate to treat mild to moderate non-exfoliative rashes.

Immune-mediated dermatologic adverse reactions occurred in 0.6% (15/2616) of patients receiving TECENTRIQ as a single agent, including Grade 3 (<0.1%) and Grade 2 (0.2%) adverse reactions.

**Other Immune-Mediated Adverse Reactions**

The following clinically significant immune-mediated adverse reactions occurred at an incidence of <1% (unless otherwise noted) in patients who received TECENTRIQ or were reported with the use of other PD-1/PD-L1 blocking antibodies.

- **Cardiac/Vascular**: Myocarditis, pericarditis, vasculitis
- **Nervous System**: Meningitis, encephalitis, myelitis and demyelination, myasthenic syndrome/myasthenia gravis (including exacerbation), Guillain-Barré syndrome, nerve paresis, autoimmune neuropathy
- **Ocular**: Uveitis, iritis, and other ocular inflammatory toxicities can occur. Some cases can be associated with retinal detachment. Various grades of visual impairment, including blindness, can occur. If uveitis occurs in combination with other immune-mediated adverse reactions, consider a Vogt-Koyanagi-Harada-like syndrome, as this may require treatment with systemic steroids to reduce the risk of permanent vision loss.
- **Gastrointestinal**: Pancreatitis to include increases in serum amylase and lipase levels, gastritis, duodenitis
- **Musculoskeletal and Connective Tissue**: Myositis/polymyositis, rhabdomyolysis and associated sequelae including renal failure, arthritis, polymyalgia rheumatic
- **Endocrine**: Hypoparathyroidism
- **Other (Hematologic/Immune)**: Hemolytic anemia, aplastic anemia, hemophagocytic lymphohistiocytosis, systemic inflammatory response syndrome, histiocytic necrotizing lymphadenitis (Kikuchi lymphadenitis), sarcoidosis, immune thrombocytopenic purpura, solid organ transplant rejection.

**Infusion-Related Reactions**

TECENTRIQ can cause severe or life-threatening infusion-related reactions. Interrupt, slow the rate of infusion, or permanently discontinue based on severity.

Infusion-related reactions occurred in 1.3% of patients, including Grade 3 (0.2%) reactions.

**Complications of Allogeneic HSCT After PD-1/PD-L1 Inhibitors**

Fatal and other serious complications can occur in patients who receive allogeneic HSCT before or after being treated with a PD-1/PD-L1 blocking antibody.

Follow patients closely for evidence of transplant-related complications and intervene promptly. Consider the benefits versus risks of treatment with a PD-1/PD-L1 blocking antibody prior to or after an allogeneic HSCT.

**Embryo-Fetal Toxicity**

TECENTRIQ can cause fetal harm when administered to a pregnant woman.

Verify pregnancy status of females of reproductive potential prior to initiating TECENTRIQ.

Advise females of reproductive potential of the potential risk to a fetus and to use effective contraception during treatment with TECENTRIQ and for at least 5 months after the last dose.

**Most Common Adverse Reactions**

The most common adverse reactions (rate ≥20%) in patients who received TECENTRIQ in combination with other antineoplastic drugs for NSCLC and SCLC were fatigue/asthenia (49%), nausea (38%), alopecia (35%), constipation (29%), diarrhea (28%), and decreased appetite (27%).

**Use in Specific Populations**

Advise female patients not to breastfeed during treatment and for at least 5 months after the last dose.

You may report side effects to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. You may also report side effects to Genentech at 1-888-835-2555.

Please see full prescribing information for additional important safety information.

**Announcer:**
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