LIBTAYO® (cemiplimab-rwlc)

FDA APPROVED IN ADVANCED NON-SMALL CELL LUNG CANCER (NSCLC)

LIBTAYO® is indicated for the first-line treatment of patients with non-small cell lung cancer (NSCLC) whose tumors have high PD-L1 expression (tumor proportion score [TPS] ≥50%) as determined by an FDA-approved test, with no EGFR, ALK, or ROS1 aberrations, and is:

- Locally advanced where patients are not candidates for surgical resection or definitive chemoradiation, or
- Metastatic

To see additional Important Safety Information throughout and accompanying full Prescribing Information.

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PROGRAM AGENDA
11/10/2022
6:30 PM Eastern
Please dial in 15 minutes before the program. You will be required to register upon logging in to the web conference.

LOCATION
Joe Muer Seafood
400 Renaissance Center Suite 1404
Detroit, Michigan 48243

PRESENTED BY
Faisal Musa, MD
Beaumont Hematology Oncology Center
Bloomfield Hills, MI

HOSTED BY
Cindy Johnston
cindy.johnston@regeneron.com
248-727-9007
RGN0021907
You may RSVP to your program host.

DURING THIS PRESENTATION, WE WILL DISCUSS:
- Existing challenges and unmet needs in treatment of advanced NSCLC
- The clinical data from EMPOWER LUNG-1 in patients with advanced NSCLC and Important Safety Information
- Support and resources for eligible patients receiving LIBTAYO
- Hypothetical patient profiles consistent with the EMPOWER-LUNG 1 Trial

Important Safety Information

Warnings and Precautions
Severe and Fatal Immune-Mediated Adverse Reactions

Immune-mediated adverse reactions, which may be severe or fatal, can occur in any organ system or tissue at any time after starting treatment. While immune-mediated adverse reactions usually occur during treatment, they can also occur after discontinuation. Immune-mediated adverse reactions affecting more than one body system can occur simultaneously.

Early identification and management are essential to ensuring safe use of PD-1/PD-L1–blocking antibodies. The definition of immune-mediated adverse reactions included the required use of systemic corticosteroids or other immunosuppressants and the absence of a clear alternate etiology. Monitor closely for symptoms and signs that may be clinical manifestations of underlying immuno-mediated adverse reactions. Evaluate liver enzymes, creatinine, and thyroid function at baseline and periodically during treatment. In cases of suspected immuno-mediated adverse reactions, initiate appropriate workup to exclude alternative etiologies, including infection. Institute medical management promptly, including specialty consultation as appropriate.

No dose reduction for LIBTAYO is recommended. In general, withhold LIBTAYO for severe (Grade 3) immune-mediated adverse reactions. Permanently discontinue LIBTAYO for life-threatening (Grade 4) immune-mediated adverse reactions, recurrent severe (Grade 3) immune-mediated adverse reactions that require systemic immunosuppressive treatment, or an inability to reduce corticosteroid dose to 10 mg or less of prednisone equivalent per day within 12 weeks of initiating steroids.

Withhold or permanently discontinue LIBTAYO depending on severity. In general, if LIBTAYO requires interruption or discontinuation, administer systemic corticosteroid therapy (1 to 2 mg/kg/day prednisone or equivalent) until improvement to Grade 1 or less. Upon improvement to Grade 1 or less, 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 corticosteroids.

Immune-mediated pneumonitis: LIBTAYO can cause immune-mediated pneumonitis. In patients treated with other PD-1/PD-L1–blocking antibodies, the incidence of pneumonitis is higher in patients who have received prior thoracic radiation. Immune-mediated pneumonitis occurred in 3.2% (25/610) of patients receiving LIBTAYO, including Grade 4 (0.5%).
Important Safety Information (cont'd)

Warnings and Precautions (cont'd)

Immun-mediated pneumonitis (cont'd):

Grade 3 (0.5%), and Grade 2 (2.1%). Pneumonitis led to permanent discontinuation in 1.4% of patients and withholding of LIBUTYO in 2.1% of patients. Systemic corticosteroids were required in all patients with pneumonitis. Pneumonitis resolved in 85% of the 26 patients. Of the 17 patients in whom LIBUTYO was withheld, 9 reinitiated after symptom improvement; of these, 3/9 (33%) had recurrence of pneumonitis. Withhold LIBUTYO for Grade 2, and permanently discontinue for Grade 3 or 4.

Resume in patients with complete or partial resolution (Grade 0 to 1) after corticosteroid taper. Permanently discontinue if no complete or partial resolution within 12 weeks of initiating steroids or inability to reduce prednisone to less than 10 mg per day (or equivalent) within 12 weeks of initiating steroids.

Immun-mediated colitis: LIBUTYO can cause immune-mediated colitis. The primary component of immune-mediated colitis was diarrhea. Cytomegalovirus (CMV) infection/reactivation has been reported in patients with corticosteroid-refractory immune-mediated colitis treated with PD-1/PD-L1-blocking antibodies. In cases of corticosteroid-refractory immune-mediated colitis, consider repeating infectious workup to exclude alternative etiologies. Immune-mediated colitis occurred in 2.2% (18/810) of patients receiving LIBUTYO, including Grade 3 (0.9%) and Grade 2 (1.1%). Colitis led to permanent discontinuation in 0.4% of patients and withholding of LIBUTYO in 1.5% of patients. Systemic corticosteroids were required in all patients with colitis. Colitis resolved in 39% of the 18 patients. Of the 12 patients in whom LIBUTYO was withheld, 4 reinitiated LIBUTYO after symptom improvement; of these, 3/4 (75%) had recurrence. Withhold LIBUTYO for Grade 2 or 3, and permanently discontinue for Grade 4. Resume in patients with complete or partial resolution (Grade 0 to 1) after corticosteroid taper. Permanently discontinue if no complete or partial resolution within 12 weeks of initiating steroids or inability to reduce prednisone to less than 10 mg per day (or equivalent) within 12 weeks of initiating steroids.

Immun-mediated hepatitis: LIBUTYO can cause immune-mediated hepatitis. Immune-mediated hepatitis occurred in 2% (15/810) of patients receiving LIBUTYO, including fatal (0.1%), Grade 4 (0.1%), Grade 3 (1.4%), and Grade 2 (0.2%). Hepatitis led to permanent discontinuation of LIBUTYO in 1.2% of patients and withholding of LIBUTYO in 0.5% of patients. Systemic corticosteroids were required in all patients with hepatitis. Additional immunosuppression with mycophenolate was required in 19% (3/16) of these patients. Hepatitis resolved in 50% of the 16 patients. Of the 5 patients in whom LIBUTYO was withheld, 3 reinitiated LIBUTYO after symptom improvement; of these, none had recurrence.

For hepatitis with no tumor involvement of the liver: Withhold LIBUTYO if AST or ALT increases to more than 3 and up to 8 times the upper limit of normal (ULN) or if total bilirubin increases to more than 1.5 and up to 3 times the ULN. Permanently discontinue LIBUTYO if AST or ALT increases to more than 8 times the ULN or total bilirubin increases to more than 3 times the ULN.

For hepatitis with tumor involvement of the liver: Withhold LIBUTYO if baseline AST or ALT is more than 1 and up to 3 times ULN and increases to more than 5 and up to 10 times ULN. Also, withhold LIBUTYO if baseline AST or ALT is more than 3 and up to 5 times ULN and increases to more than 8 and up to 10 times ULN. Permanently discontinue LIBUTYO if AST or ALT increases to more than 10 times ULN or if total bilirubin increases to more than 3 times ULN. If AST and ALT are less than or equal to ULN at baseline, withhold or permanently discontinue LIBUTYO based on recommendations for hepatitis with no liver involvement.

Resume in patients with complete or partial resolution (Grade 0 to 1) after corticosteroid taper. Permanently discontinue if no complete or partial resolution within 12 weeks of initiating steroids or inability to reduce prednisone to less than 10 mg per day (or equivalent) within 12 weeks of initiating steroids.

Immun-mediated endocrinopathies: For Grade 3 or 4 endocrinopathies, withhold until clinically stable or permanently discontinue depending on severity.

- Adrenal insufficiency: LIBUTYO can cause primary or secondary adrenal insufficiency. For Grade 2 or higher adrenal insufficiency, initiate symptomatic treatment, including hormone replacement as clinically indicated. Withhold LIBUTYO depending on severity. Adrenal insufficiency occurred in 0.4% (3/810) of patients receiving LIBUTYO. Including Grade 3 (0.4%). Adrenal insufficiency led to permanent discontinuation of LIBUTYO in 1 (0.1%) patient. LIBUTYO was not withheld in any patient due to adrenal insufficiency. Systemic corticosteroids were required in all patients with adrenal insufficiency; of these, 67% (2/3) remained on systemic corticosteroids. Adrenal insufficiency had not resolved in any patient at the time of data cutoff.

- Hypophysis: LIBUTYO can cause immune-mediated hypophysitis. Hypophysitis can present with acute symptoms associated with mass effect such as headache, photophobia, or visual field defects. Hypophysitis can cause hypopituitarism. Initiate hormone replacement as clinically indicated. Withhold or permanently discontinue depending on severity. Hypophysitis occurred in 0.4% (3/810) of patients receiving LIBUTYO, including Grade 3 (0.2%) and Grade 2 (0.1%) adverse reactions. Hypophysitis led to permanent discontinuation of LIBUTYO in 1 (0.1%) patient and withholding of LIBUTYO in 1 (0.1%) patient. Systemic corticosteroids were required in 67% (2/3) of patients with hypophysitis. Hypophysitis had not resolved in any patient at the time of data cutoff.

- Thyroid disorders: LIBUTYO can cause immune-mediated thyroid disorders. Thyroiditis can present with or without endocrinopathy. Hypothyroidism can follow hyperthyroidism. Initiate hormone replacement or medical management of hyperthyroidism as clinically indicated. Withhold or permanently discontinue LIBUTYO depending on severity.

- Thyroidosis: Thyroidosis occurred in 0.6% (5/810) of patients receiving LIBUTYO, including Grade 2 (0.2%) adverse reactions. No patient discontinued LIBUTYO due to thyroidosis. Thyroidosis led to withholding of LIBUTYO in 1 patient. Systemic corticosteroids were not required in any patient with thyroiditis. Thyroiditis had not resolved in any patient at the time of data cutoff. Blood thyroid stimulating hormone increased and blood thyroid stimulating hormone decreased have also been reported.

- Hyperthyroidism: Hyperthyroidism occurred in 3.2% (26/810) of patients receiving LIBUTYO, including Grade 2 (0.9%). No patient discontinued treatment and LIBUTYO was withheld in 0.5% of patients due to hyperthyroidism. Systemic corticosteroids were required in 3.8% (1/26) of patients. Hyperthyroidism resolved in 50% of 26 patients. Of the 4 patients in whom LIBUTYO was withheld for hyperthyroidism, 2 patients reinitiated LIBUTYO after symptom improvement; of these, none had recurrence of hyperthyroidism.

- Hypothyroidism: Hypothyroidism occurred in 7% (60/810) of patients receiving LIBUTYO, including Grade 2 (6%). Hypothyroidism led to permanent discontinuation of LIBUTYO in 1 (0.1%) patient. Hypothyroidism led to withholding of LIBUTYO in 1.1% of patients. Systemic corticosteroids were not required in any patient with hypothyroidism. Hypothyroidism resolved in 8.3% of the 60 patients. Majority of the patients with hypothyroidism required long-term thyroid hormone replacement. Of the 9 patients in whom LIBUTYO was withheld for hypothyroidism, 1 reinitiated LIBUTYO after symptom improvement; 1 required ongoing hormone replacement therapy.

- Type 1 diabetes mellitus, which can present with diabetic ketoacidosis: Monitor for hyperglycemia or other signs and symptoms of diabetes. Initiate treatment with insulin as clinically indicated. Withhold LIBUTYO depending on severity. Type 1 diabetes mellitus occurred in...
Ocular: Uveitis, iritis, and other ocular inflammatory toxicities. Some cases can be associated with retinal detachment. Various grades of visual impairment to include 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, stomatitis

Musculoskeletal and connective tissue: Myositis/polymyositis, rhabdomyolysis, and associated sequelae including renal failure, arthritis, polymyalgia rheumatica

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

Severe infusion-related reactions (Grade 3) occurred in 0.1% of patients receiving LIBUTAYO as a single agent. Monitor patients for signs and symptoms of infusion-related reactions. The most common symptoms of infusion-related reaction were nausea, pyrexia, rash, and dyspnea. Interrupt or slow the rate of infusion for Grade 1 or 2, and permanently discontinue for Grade 3 or 4.

Complications of allogeneic HSCT

Fetal and other serious complications can occur in patients who receive allogeneic hematopoietic stem cell transplantation (HSCT) before or after being treated with a PD-1/PD-L1–blocking antibody. Transplant-related complications include hyperacute graft-versus-host disease (GVHD), acute GVHD, chronic GVHD, hepatic veno-occlusive disease (VOD) after reduced intensity conditioning, and steroid-requiring febrile syndrome (without an identified infectious cause). These complications may occur despite intervening therapy between PD-1/PD-L1 blockade and allogeneic HSCT. Follow patients closely for evidence of transplant-related complications and intervene promptly. Consider the benefit versus risks of treatment with a PD-1/PD-L1–blocking antibody prior to or after an allogeneic HSCT.

Embryo-fetal toxicity

LIBUTAYO can cause fetal harm when administered to a pregnant woman due to an increased risk of immune-mediated rejection of the developing fetus resulting in fetal death. Advise women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with LIBUTAYO and for at least 4 months after the last dose.

Adverse Reactions

In the pooled safety analysis of 810 patients, the most common adverse reactions (≥15%) with LIBUTAYO were musculoskeletal pain, fatigue, rash, and diarrhea.

In the pooled safety analysis of 810 patients, the most common Grade 3-4 laboratory abnormalities (≥2%) with LIBUTAYO were lymphopenia, hyponatremia, hypophosphatemia, increased aspartate aminotransferase, anemia, and hyperkalemia.

Use in Specific Populations

Lactation: Because of the potential for serious adverse reactions in breastfed children, advise women not to breastfeed during treatment and for at least 4 months after the last dose of LIBUTAYO.

Females and males of reproductive potential: Verify pregnancy status in females of reproductive potential prior to initiating LIBUTAYO.
SPEAKER PROGRAM EXPECTATIONS – COVID-19

Regeneron Pharmaceuticals, Inc., and your local Regeneron Representative look forward to your attendance at the upcoming Speaker Program. Regeneron is committed to the health and safety of our employees, our valued healthcare professional customers, and their patients. As such, we observe all national, state, and local guidelines for COVID-19.

Out of an abundance of caution, we ask that you not attend a Speaker Program in person if any of the following apply:

- You are experiencing symptoms consistent with COVID-19. For the most up-to-date information and full list of COVID-19 symptoms, please visit the CDC website at https://www.cdc.gov/coronavirus/2019-ncov/index.html
- You are living with someone who tested positive for COVID-19 in the past 14 days, experienced symptoms of COVID-19, or is under self-quarantine due to COVID-19.
- You have traveled by air or live with someone who has returned from international travel within the past 14 days.

Additionally, please notify your Regeneron Representative if you test positive within 14 days after attending the Speaker Program.

Thank you