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UK Oncology Forum 2026

LIBTAYO® (cemiplimab)

Rethinking First-Line Treatment in Advanced NSCLC: Why the Choice of IO + Chemotherapy in PD-L1–Positive Disease Matters

Thursday 11th June 2026 | 17:30-18:15 | Lung Breakout Room

We look forward to seeing you at this interactive and engaging session, exploring how first-line treatment choice impacts outcomes in advanced NSCLC (aNSCLC).

For **UK LIBTAYO prescribing information**, please see the next page.

Agenda

Welcome and introduction - Dr Sean Dulloo (Chair)
Advancing First-Line aNSCLC: Introducing a New Option Following NICE Approval

Five Year Outcomes with LIBTAYO + Chemotherapy in Advanced PD-L1 positive NSCLC

Prof. Samreen Ahmed

Consultant Medical Oncologist, University Hospitals of Leicester NHS Trust

The Evolving Treatment Landscape: Why Your Choice of IO + CT Matters

Dr Shobhit Baijal

Consultant Medical Oncologist, The University Hospitals Birmingham NHS Trust

From Approval to Practice: What This Means for Treating Patients Today

Dr Sean Dulloo

Consultant Medical Oncologist, University Hospitals of Leicester NHS Trust

Panel discussion and Q&A - All

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UK Prescribing Information: LIBTAYO (cemiplimab)
350 mg concentrate for solution for infusion

Please refer to Summary of Product Characteristics (SmPC) prior to use.

Treatment must be initiated and supervised by physicians experienced in the treatment of cancer

Presentation: Each vial contains 350 mg of cemiplimab in 7 ml. **Indications:** LIBTAYO as monotherapy is indicated for the treatment of adult patients with metastatic or locally advanced cutaneous squamous cell carcinoma (mCSCC or laCSCC) who are not candidates for curative surgery or curative radiation. LIBTAYO as monotherapy is indicated for the adjuvant treatment of adult patients with CSCC at high risk of recurrence after surgery and radiation. LIBTAYO as monotherapy is indicated for the treatment of adult patients with locally advanced or metastatic basal cell carcinoma (laBCC or mBCC) who have progressed on or are intolerant to a hedgehog pathway inhibitor (HHI). LIBTAYO as monotherapy is indicated for the first-line treatment of adult patients with non-small cell lung cancer (NSCLC) expressing PD-L1 (in ≥ 50% tumour cells), with no EGFR, ALK or ROS1 aberrations, who have: locally advanced NSCLC who are not candidates for definitive chemoradiation, or metastatic NSCLC. LIBTAYO in combination with platinum-based chemotherapy is indicated for the first-line treatment of adult patients with NSCLC expressing PD-L1 (in ≥ 1% of tumour cells), with no EGFR, ALK or ROS1 aberrations, who have: locally advanced NSCLC who are not candidates for definitive chemoradiation, or metastatic NSCLC. LIBTAYO as monotherapy is indicated for the treatment of adult patients with recurrent or metastatic cervical cancer and disease progression on or after platinum-based chemotherapy.

Dosage and Administration: LIBTAYO is administered by intravenous infusion over 30 minutes through an intravenous line containing a sterile, non-pyrogenic, low-protein binding, in-line or add-on filter (0.2 micron to 5 micron pore size). Other medicinal products should not be co-administered through the same infusion line. *Recommended dose:* Locally advanced or metastatic CSCC, NSCLC, BCC and recurrent or metastatic cervical cancer, the recommended dose of LIBTAYO is 350 mg every 3 weeks (Q3W). Treatment may be continued until disease progression or unacceptable toxicity. Adjuvant treatment of high-risk CSCC, the recommended dose of cemiplimab administered as an intravenous infusion over 30 minutes is 350 mg every 3 weeks for 12 weeks followed by 700 mg every 6 weeks, or 350 mg every 3 weeks. Treatment may be continued until disease recurrence, unacceptable toxicity, or up to 48 weeks of total therapy. *Dose modifications:* No dose reductions are recommended. Dosing delay or discontinuation may be required based on individual safety and tolerability. For full details on the recommended treatment modifications to manage adverse reactions, please refer to Table 1 of the SmPC.

Special Populations: *Paediatric population (<18 years):* Safety and efficacy has not been established. *Elderly:* No dose adjustment is recommended. Data are limited in patients ≥75 years on cemiplimab monotherapy. *Renal impairment:* No dose adjustment is recommended. There are limited data for cemiplimab in patients with severe renal impairment (CL cr15-29 ml/min). *Hepatic impairment:* No dose adjustment is recommended for patients with mild or moderate hepatic impairment. Cemiplimab has not been studied in patients with severe hepatic impairment.

Contraindications: Hypersensitivity to the active substance or to any of the excipients.

Precautions and Warnings: *Traceability:* To improve traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded. *Immune-mediated adverse reactions (IMARs):* Severe and fatal immune-mediated adverse reactions have been observed with cemiplimab. IMARs may involve any organ system. Most IMARs can manifest at any time during treatment, however they can also occur after discontinuation of cemiplimab. IMARs affecting more than one body system can occur simultaneously, such as myositis and myocarditis or myasthenia gravis, in patients treated with cemiplimab or other PD-1/PD-L1 inhibitors. Patients treated with cemiplimab should be monitored for signs and symptoms of IMARs. IMARs should be managed with cemiplimab treatment modifications, hormone replacement therapy (if clinically indicated), and corticosteroids. For suspected IMARs, patients should be evaluated to confirm an IMAR and to exclude other possible causes, including infection. Depending upon the severity of the adverse reaction, cemiplimab should be withheld or permanently discontinued. *Immune-mediated pneumonitis:* Defined as requiring use of corticosteroids with no clear alternate aetiology, including fatal cases, has been observed. Patients should be monitored for signs and symptoms of pneumonitis and causes other than immune related pneumonitis should be ruled out. Patients with suspected pneumonitis should be evaluated with radiographic imaging as indicated based on clinical evaluation and managed with cemiplimab treatment modifications and corticosteroids. *Immune-mediated diarrhoea or colitis:* Defined as requiring use of corticosteroids with no clear alternate aetiology, has been observed. Patients should be monitored for signs and symptoms of diarrhoea or colitis and managed with cemiplimab treatment modifications, anti-diarrhoeal agents, and corticosteroids. *Immune-mediated hepatitis:* Defined as requiring use of corticosteroids with no clear alternate aetiology, including fatal cases, have been observed. Patients should be monitored for abnormal liver tests prior to and periodically during treatment as indicated based on clinical evaluation and managed with cemiplimab treatment modifications and corticosteroids. *Immune-mediated endocrinopathies:* Defined as treatment-emergent endocrinopathies with no clear alternate aetiology, have been observed. *Thyroid disorders (Hypothyroidism/ Hyperthyroidism/Thyroiditis):* Thyroiditis can present with or without an alteration in thyroid function tests. Hypothyroidism can follow hyperthyroidism. Thyroid disorders can occur at any time during the treatment. Patients should be monitored for changes in thyroid function at the start of treatment and periodically during the treatment as indicated based on clinical evaluation. Patients should be managed with hormone replacement therapy (if indicated) and cemiplimab treatment modifications. Hyperthyroidism should be managed according to standard medical practice. *Hypophysitis:* Immune-mediated hypophysitis has been observed. Patients should be monitored for signs and symptoms of hypophysitis and managed with cemiplimab treatment modifications, corticosteroids and hormone replacement, as clinically indicated. *Adrenal insufficiency:* Patients should be monitored for signs and symptoms of adrenal insufficiency during and after treatment and managed with cemiplimab treatment modifications, corticosteroids and hormone replacement, as clinically indicated. *Type 1 diabetes mellitus:* Immune-mediated type 1 diabetes mellitus, including diabetic ketoacidosis, has been observed. Patients should be monitored for hyperglycaemia and signs and symptoms of diabetes as indicated based on clinical evaluation and managed with oral anti-hyperglycaemics or insulin and cemiplimab treatment modifications. *Immune-mediated skin adverse reactions:* Defined as requiring use of systemic corticosteroids with no clear alternate aetiology, including severe cutaneous adverse reactions (SCARs), such as Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) (some cases with fatal outcome), and other skin reactions such as rash, erythema multiforme, pemphigoid, have been reported in association with cemiplimab treatment. Patients should be monitored for evidence of suspected severe skin reactions and exclude other causes. Patients should be managed with cemiplimab treatment modifications and corticosteroids. For symptoms or signs of SJS or TEN, refer the patient for specialised care for assessment and treatment and manage patient with treatment modifications. Cases of SJS, fatal TEN and stomatitis occurred following 1 dose of cemiplimab in patients with prior exposure to idelalisib, who were participating in a clinical trial evaluating cemiplimab in Non-Hodgkins Lymphoma (NHL), and who had recent exposure to sulfa containing antibiotics. Patients should be managed with cemiplimab treatment modifications and corticosteroids as described above. *Immune-mediated nephritis:* Defined as requiring use of corticosteroids with no clear alternate aetiology, including a fatal case, has been observed in patients receiving cemiplimab. Monitor patients for changes in renal function. Patients should be managed with cemiplimab treatment modifications and corticosteroids. *Other IMARs:* Other fatal and life-threatening IMARs have been observed in patients receiving cemiplimab including paraneoplastic encephalomyelitis, meningitis, myositis, myocarditis and pancreatitis. Noninfective cystitis has been reported with other PD-1/PD-L1 inhibitors. Evaluate suspected IMARs to exclude other causes. Patients should be monitored for signs and symptoms of IMARs and managed with cemiplimab treatment modifications and corticosteroids as clinically indicated. Solid organ transplant rejection has been reported in the post-marketing setting in patients treated with PD-1 inhibitors. Treatment with cemiplimab may increase the risk of rejection in solid organ transplant recipients. The benefit of treatment with cemiplimab versus the risk of possible organ rejection should be considered in these patients. Cases of graft versus-host disease have been reported in the post-marketing setting in patients treated with other PD-1/PD-L1 inhibitors in association with allogeneic hematopoietic stem cell transplant. Haemophagocytic lymphohistiocytosis (HLH) has been reported in patients receiving cemiplimab. Patients should be monitored for clinical signs and symptoms of HLH. If HLH is confirmed, administration of cemiplimab should be discontinued and treatment for HLH initiated. Coeliac disease and pancreatic exocrine insufficiency have been reported with other PD-1/PD-L1 inhibitors and may also occur with cemiplimab. *Infusion-related reactions:* Cemiplimab can cause severe or life-threatening infusion-related reactions. Patients should be monitored for signs and symptoms of infusion-related reactions and managed with cemiplimab treatment modifications and corticosteroids. Cemiplimab should be interrupted, or the rate of infusion slowed for mild or moderate infusion-related reactions. The infusion should be stopped and cemiplimab should be permanently discontinued for severe (Grade 3) or life-threatening (Grade 4) infusion-related reactions. ***Fertility, Pregnancy and Breastfeeding:*** No clinical data available on the possible effects of cemiplimab on fertility. Women of childbearing potential should use effective contraception during treatment with cemiplimab and for at least 4 months after the last dose of cemiplimab. Cemiplimab, as an IgG4, has the potential to be transmitted across the placenta from the mother to the developing fetus. Cemiplimab is not recommended during pregnancy and in women of childbearing potential not using effective contraception unless the clinical benefit outweighs the potential risk. It is unknown whether cemiplimab is secreted in human milk. If a lactating woman chooses to be treated with cemiplimab, she should be instructed not to breastfeed while being treated with cemiplimab and for at least 4 months after the last dose. ***Interactions:*** No pharmacokinetic drug-drug interaction studies have been conducted with cemiplimab. The use of systemic corticosteroids or immunosuppressants before starting cemiplimab, except for physiological doses of systemic corticosteroid (≤10 mg/day prednisone or equivalent), should be avoided because of their potential interference with the pharmacodynamic activity and efficacy of cemiplimab. However, systemic corticosteroids or other immunosuppressants can be used after starting cemiplimab to treat IMARs.

Adverse Reactions: *Very common:* Upper respiratory tract infection, anaemia, decreased appetite, cough, diarrhoea, nausea, constipation, abdominal pain, rash, pruritus, musculoskeletal pain and fatigue. *Common:* Urinary tract infection, infusion related reaction, hypothyroidism, hyperthyroidism, headache, peripheral neuropathy, hypertension, dyspnoea, pneumonitis, vomiting, colitis, stomatitis, hepatitis, actinic keratosis, nephritis, pyrexia, oedema, alanine aminotransferase increased, aspartate aminotransferase increased, blood alkaline phosphatase increased and blood creatinine increased. *Uncommon:* Thrombocytopaenia, Sjögren's syndrome, thyroiditis, hypophysitis, adrenal insufficiency, myocarditis, pericarditis, gastritis, pancreatitis, arthritis, myositis, muscular weakness, polymyalgia rheumatica, blood thyroid stimulating hormone increased, transaminases increased and blood bilirubin increased. *Rare:* Type 1 diabetes mellitus, meningitis, encephalitis, myasthenia gravis, paraneoplastic encephalomyelitis, chronic inflammatory demyelinating polyradiculoneuropathy, keratitis, uveitis and blood thyroid stimulating hormone decreased. *Not known:* Haemophagocytic lymphohistiocytosis, solid organ transplant rejection and noninfective cystitis. *Prescribers should consult the SmPC in relation to other adverse reactions and frequency, as incidence may vary according to whether cemiplimab is used as monotherapy or combined with chemotherapy.*

Special Precautions for Storage: *Unopened vial:* Store in a refrigerator (2°C to 8°C). Do not freeze. Store in the original carton in order to protect from light. For storage conditions after first opening or dilution of the medicinal product, consult pharmaceutical particulars section of SmPC.

Legal Category: POM.

List Price and Marketing Authorisation Number: PLGB 45232/0001 – £4,650 per vial.

Marketing Authorisation Holder: Regeneron UK Limited, The Charter Building, Vine Street, Uxbridge, Middlesex, UB8 1JG, United Kingdom

For more information, please contact Regeneron Medical Information by calling 0800 917 7120 or emailing **medical.information_Global@regeneron.com**

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