▼This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See section 4.8 for how to report adverse reactions. **NAME OF THE MEDICINAL PRODUCT** LIBTAYO 350 mg concentrate for solution for infusion. **QUALITATIVE AND QUANTITATIVE COMPOSITION** One ml of concentrate contains 50 mg of cemiplimab. Each vial contains 350 mg of cemiplimab in 7 ml of solution. Cemiplimab is produced by recombinant DNA technology in Chinese hamster ovary (CHO) cell suspension culture. For the full list of excipients, see section 6.1. **PHARMACEUTICAL FORM** Concentrate for solution for infusion (sterile concentrate). Clear to slightly opalescent, colourless to pale yellow solution with a pH of 6.0 and osmolality between 300 and 360 mmol/kg. The solution may contain trace amounts of translucent to white particles in a single-use vial. **THERAPEUTIC INDICATIONS** Cutaneous Squamous Cell Carcinoma 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. Basal Cell Carcinoma 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). Non-Small Cell Lung Cancer 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. **POSOLOGY AND METHOD OF ADMINISTRATION** Treatment must be initiated and supervised by physicians experienced in the treatment of cancer. PD-L1 testing for patients with NSCLC For treatment with cemiplimab as monotherapy, patients should be selected based on PD-L1 tumour expression using a validated test (see section 5.1). Posology *Recommended dose* The recommended dose is 350 mg cemiplimab every 3 weeks (Q3W) administered as an intravenous infusion over 30 minutes. Treatment may be continued until disease progression or unacceptable toxicity. *Dose modifications* No dose reductions are recommended. Dosing delay or discontinuation may be required based on individual safety and tolerability. Recommended modifications to manage adverse reactions are provided in Table 1. Detailed guidelines for the management of immune-related adverse reactions are described in Table 1 (see also sections 4.4 and 4.8).

Table 1: Recommended treatment modifications

Adverse reaction[a]	Severity[b]	Dose modification	Additional intervention
Immune-related adverse reactions			
Pneumonitis	Grade 2	Withhold LIBTAYO	Initial dose of 1 to 2 mg/kg/day prednisone or equivalent followed by a taper
		Resume LIBTAYO if pneumonitis improves and remains at Grade 0 to 1 after corticosteroid taper to ≤10 mg/day prednisone or equivalent	
	Grade 3 or 4 or recurrent Grade 2	Permanently discontinue	Initial dose of 2 to 4 mg/kg/day prednisone or equivalent followed by a taper
Colitis	Grade 2 or 3	Withhold LIBTAYO	Initial dose of 1 to 2 mg/kg/day prednisone or equivalent followed by a taper
		Resume LIBTAYO if colitis or diarrhoea improves and remains at Grade 0 to 1 after corticosteroid taper to ≤10 mg/day prednisone or equivalent	
	Grade 4 or recurrent Grade 3	Permanently discontinue	Initial dose of 1 to 2 mg/kg/day prednisone or equivalent followed by a taper
Hepatitis	Grade 2 with AST or ALT >3 and ≤5×ULN or total bilirubin >1.5 and ≤3×ULN	Withhold LIBTAYO	Initial dose of 1 to 2 mg/kg/day prednisone or equivalent followed by a taper
		Resume LIBTAYO if hepatitis improves and remains at Grade 0 to 1 after corticosteroid taper to ≤10 mg/day prednisone or equivalent or returns to baseline AST or ALT after completion of corticosteroid taper	
	Grade ≥3 with AST or ALT >5×ULN or total bilirubin >3×ULN	Permanently discontinue	Initial dose of 1 to 2 mg/kg/day prednisone or equivalent followed by a taper
Hypothyroidism	Grade 3 or 4	Withhold LIBTAYO	Initiate thyroid hormone replacement as clinically indicated
		Resume LIBTAYO when hypothyroidism returns to Grade 0 to 1 or is otherwise clinically stable	
Hyperthyroidism	Grade 3 or 4	Withhold LIBTAYO	Initiate symptomatic management
		Resume LIBTAYO when hyperthyroidism returns to Grade 0 to 1 or is otherwise clinically stable	
Thyroiditis	Grade 3 to 4	Withhold LIBTAYO	Initiate symptomatic management
		Resume LIBTAYO when thyroiditis returns to Grade 0 to 1 or is otherwise clinically stable	
Hypophysitis	Grade 2 to 4	Withhold LIBTAYO	Initial dose of 1 to 2 mg/kg/day prednisone or equivalent followed by a taper and hormone replacement as clinically indicated
		Resume LIBTAYO if hypophysitis improves and remains at Grade 0 to 1 after corticosteroid taper to ≤10 mg/day prednisone or equivalent or is otherwise clinically stable	
Adrenal insufficiency	Grade 2 to 4	Withhold LIBTAYO	Initial dose of 1 to 2 mg/kg/day prednisone or equivalent followed by a taper and hormone replacement as clinically indicated
		Resume LIBTAYO if adrenal insufficiency improves and remains at Grade 0 to 1 after corticosteroid taper to ≤10 mg/day prednisone or equivalent or is otherwise clinically stable	
Type 1 diabetes mellitus	Grade 3 or 4 (hyperglycaemia)	Withhold LIBTAYO	Initiate treatment with anti-hyperglycaemics as clinically indicated
		Resume LIBTAYO when diabetes mellitus returns to Grade 0 to 1 or is otherwise clinically stable	
Skin adverse reactions	Grade 2 lasting longer than 1 week, Grade 3 or suspected Stevens-Johnson syndrome (SJS) or toxic epidermal necrolysis (TEN)	Withhold LIBTAYO	Initial dose of 1 to 2 mg/kg/day prednisone or equivalent followed by a taper
		Resume LIBTAYO if skin reaction improves and remains at Grade 0 to 1 after corticosteroid taper to ≤10 mg/day prednisone or equivalent	
	Grade 4 or confirmed SJS or TEN	Permanently discontinue	Initial dose of 1 to 2 mg/kg/day prednisone or equivalent followed by a taper
Immune-related skin reaction or other immune-related adverse reactions in patients with prior treatment with idelalisib[b]	Grade 2	Withhold LIBTAYO	Initiate management immediately, including initial dose of 1 to 2 mg/kg/day prednisone or equivalent followed by a taper
		Resume LIBTAYO if skin reaction or other immune-related adverse reaction improves and remains at Grade 0 to 1 after corticosteroid taper to ≤10 mg/day prednisone or equivalent	
	Grade 3 or 4 (excluding endocrinopathies) or recurrent Grade 2	Permanently discontinue	Initiate management immediately, including initial dose of 1 to 2 mg/kg/day prednisone or equivalent followed by a taper
Nephritis with renal dysfunction	Grade 2 creatinine increased	Withhold LIBTAYO	Initial dose of 1 to 2 mg/kg/day prednisone or equivalent followed by a taper
		Resume LIBTAYO if nephritis improves and remains at Grade 0 to 1 after corticosteroid taper to ≤10 mg/day prednisone or equivalent	
	Grade 3 or 4 creatinine increased	Permanently discontinue	Initial dose of 1 to 2 mg/kg/day prednisone or equivalent followed by a taper
Other immune-related adverse reactions (including but not limited to paraneoplastic encephalomyelitis, meningitis, myositis, solid organ transplant rejection, graft-vs-host disease, Guillain-Barre syndrome, central nervous system inflammation, chronic inflammatory demyelinating polyradiculoneuropathy, encephalitis, myasthenia gravis, neuropathy peripheral, myocarditis, pericarditis, immune thrombocytopenic purpura, vasculitis, arthralgia, arthritis, muscular weakness, myalgia, polymyalgia rheumatica, Sjogren's syndrome, keratitis, stomatitis, thyroiditis)	Grade 2 or 3 based on type of reaction	Withhold LIBTAYO	Initiate symptomatic management including initial dose of 1 to 2 mg/kg/day prednisone or equivalent as clinically indicated followed by a taper
		Resume LIBTAYO if other immune-related adverse reaction improves and remains at Grade 0 to 1 after corticosteroid taper to ≤10 mg/day prednisone or equivalent	
	– Grade 3 based on type of reaction or Grade 4 (excluding endocrinopathies) – Grade 3 or 4 neurologic toxicity – Grade 3 or 4 myocarditis or pericarditis – Recurrent Grade 3 immune-related adverse reaction – Persistent Grade 2 or 3 immune-related adverse reactions lasting 12 weeks or longer (excluding endocrinopathies) – Inability to reduce corticosteroid dose to 10 mg or less of prednisone or equivalent per day within 12 weeks	Permanently discontinue	Initial dose of 1 to 2 mg/kg/day prednisone or equivalent as clinically indicated followed by a taper
Infusion-related reactions[a]			
Infusion-related reaction	Grade 1 or 2	Interrupt or slow rate of infusion	Initiate symptomatic management
	Grade 3 or 4	Permanently discontinue	

ALT: alanine aminotransferase; AST: aspartate aminotransferase; ULN: upper limit of normal. [a] See also sections 4.4 and 4.8 [b] Toxicity should be graded with the current version of National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE). Patient Alert Card All prescribers of LIBTAYO should be familiar with the educational materials and inform the patients about the Patient Alert Card explaining what to do should they experience any symptom of immune-related adverse reactions and infusion-related reactions. The physician will provide the Patient Alert Card to each patient. *Special populations Paediatric population* The safety and efficacy of LIBTAYO in children and adolescents below the age of 18 years have not been established. No data are available. *Elderly* No dose adjustment is recommended for elderly patients. Cemiplimab exposure is similar across all age groups (see sections 5.1 and 5.2). Data are limited in patients ≥75 years on cemiplimab monotherapy. *Renal impairment* No dose adjustment of LIBTAYO is recommended for patients with renal impairment. There are limited data for LIBTAYO in patients with severe renal impairment CLcr 15 to 29 ml/min (see section 5.2). *Hepatic impairment* No dose adjustment is recommended for patients with mild or moderate hepatic impairment. LIBTAYO has not been studied in patients with severe hepatic impairment. There are insufficient data in patients with severe hepatic impairment for dosing recommendations (see section 5.2). *Method of administration* LIBTAYO is for intravenous use. It 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. For instructions on dilution of the medicinal product before administration, see section 6.6. CONTRAINDICATIONS Hypersensitivity to the active substance or to any of the excipients listed in section 6.1. **UNDESIRABLE EFFECTS** Summary of the safety profile Immune-related adverse reactions can occur with cemiplimab. Most of these, including severe reactions, resolved following initiation of appropriate medical therapy or withdrawal of cemiplimab (see "Description of selected adverse reactions" below). The safety of cemiplimab has been evaluated in 816 patients with advanced solid malignancies who received cemiplimab monotherapy in 4 clinical studies. The median duration of exposure to cemiplimab was 30.8 weeks (range: 2 days to 144 weeks). Immune-related adverse reactions occurred in 22.1% of patients treated with cemiplimab in clinical trials including Grade 5 (0.4%), Grade 4 (0.7%), Grade 3 (5.4%), and Grade 2 (11.8%). Immune-related adverse reactions led to permanent discontinuation of cemiplimab in 4.0% of patients. The most common immune-related adverse reactions were hypothyroidism (7.5%), hyperthyroidism (3.3%), pneumonitis (3.2%), hepatitis (2.0%), colitis (2.2%) and immune-related skin adverse reactions (1.6%) (see "Description of selected adverse reactions" below, Special warnings and precautions for use in section 4.4 and Recommended treatment modifications in section 4.2). Adverse events were serious in 30.1% of patients. Adverse events led to permanent discontinuation of cemiplimab in 8.1% of patients. Severe cutaneous adverse reactions (SCARs), including Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) have been reported in association with cemiplimab treatment (see section 4.4). **Tabulated list of adverse reactions** Adverse reactions observed in clinical studies of cemiplimab as monotherapy (N=816) or reported from post-marketing use of cemiplimab are listed in Table 2. Adverse reactions are presented by system organ class and by frequency. Frequencies are defined as: very common (≥ 1/10); common (≥ 1/100 to < 1/10); uncommon (≥ 1/1,000 to < 1/100); rare (≥ 1/10,000 to < 1/1,000); very rare (< 1/10,000); not known (cannot be estimated from available data). Version 4.03 of NCI CTCAE was used to grade toxicity. a Upper respiratory tract infection includes upper respiratory tract infection, respiratory tract infection, nasopharyngitis, sinusitis, pharyngitis, rhinitis, and viral upper respiratory tract infection. b Post-marketing event. c Hypothyroidism includes hypothyroidism and immune-related hypothyroidism. d Thyroiditis includes autoimmune thyroiditis and thyroiditis. e Type 1 diabetes mellitus includes diabetic ketoacidosis and type 1 diabetes mellitus. f Peripheral neuropathy includes peripheral neuropathy, peripheral sensory neuropathy, polyneuropathy, neuritis, paraesthesia, and peripheral motor neuropathy. g Meningitis includes aseptic meningitis. h Myocarditis includes autoimmune myocarditis, immune-related myocarditis, and myocarditis. i Pericarditis includes autoimmune pericarditis and pericarditis. j Hypertension includes hypertension and hypertensive crisis. k Cough includes cough, productive cough, and upper-airway cough syndrome. l Dyspnoea includes dyspnoea and dyspnoea exertional. m Pneumonitis includes pneumonitis, immune-related pneumonitis, interstitial lung disease. n Abdominal pain includes abdominal pain, upper abdominal pain, abdominal discomfort, lower abdominal pain, and gastrointestinal pain. o Colitis includes colitis, enterocolitis, immune-related enterocolitis, and autoimmune colitis. p Hepatitis includes autoimmune hepatitis, hepatocellular injury, immune-related hepatitis, hepatic failure, hepatitis, and hepatotoxicity. q Rash includes rash, dermatitis, urticaria, rash maculo-papular, erythema, rash erythematous, rash pruritic, psoriasis, autoimmune dermatitis, dermatitis acneiform, dermatitis allergic, atopic dermatitis, dermatitis bullous, drug eruption, dyshidrotic eczema, lichen planus, skin reaction, dermatitis exfoliative, parapsoriasis, pemphigoid, rash macular, and rash papular. r Pruritus includes pruritus and allergic pruritus. s Musculoskeletal pain includes back pain, arthralgia, pain in extremity, musculoskeletal pain, musculoskeletal chest pain, bone pain, myalgia, neck pain, spinal pain, musculoskeletal stiffness, and musculoskeletal discomfort. t Arthritis includes arthritis and polyarthritis. u Nephritis includes nephritis, toxic nephropathy, acute kidney injury, and renal failure. v Fatigue includes fatigue, asthenia, and malaise. Description of selected adverse reactions The selected adverse reactions described below are based on safety of cemiplimab in 816 patients in clinical studies in monotherapy. *Immune-related adverse reactions (see section 4.2 and section 4.4)* Immune-related pneumonitis Immune-related pneumonitis occurred in 26 (3.2%) of 816 patients receiving cemiplimab, including 4 (0.5%) patients with Grade 4, 4 (0.5%) patients with Grade 3 pneumonitis. Immune-related pneumonitis led to permanent discontinuation of cemiplimab in 11 (1.3%) of 816 patients. Among the 26 patients with immune-related pneumonitis, the median time to onset was 2.5 months (range: 7 days to 18 months) and the median duration of pneumonitis was 22 days (range: 5 days to 16.9 months). Twenty-two of the 26 patients (84.6%) received high-dose corticosteroids for a median of 11 days (range: 1 day to 5.9 months). Resolution of pneumonitis had occurred in 15 (57.7%) of the 26 patients at the time of data cutoff. *mmune-related colitis* Immune-related diarrhoea or colitis occurred in 18 (2.2%) of 816 patients receiving cemiplimab including 7 (0.9%) with Grade 3 immune-related diarrhoea or colitis. Immune-related diarrhoea or colitis led to permanent discontinuation of cemiplimab in 3 (0.4%) of 816 patients. Among the 18 patients with immune-related diarrhoea or colitis, the median time to onset was 3.8 months (range: 21 days to 15.5 months) and the median duration of immune-related diarrhoea or colitis was 2.3 months (range: 6 days to 10.0 months). Thirteen of the 18 patients (72.2%) with immune-related diarrhoea or colitis received high-dose corticosteroids for a median of 20 days (range: 5 days to 5.2 months). Resolution of immune-related diarrhoea or colitis had occurred in 8 (44.4%) of the 18 patients at the time of data cutoff. *Immune-related hepatitis* Immune-related hepatitis occurred in 16 (2.0%) of 816 patients receiving cemiplimab including 1 (0.1%) patient with Grade 5, 1 (0.1%) patient with Grade 4, and 11 (1.3%) patients with Grade 3 immune-related hepatitis. Immune-related hepatitis led to permanent discontinuation of cemiplimab in 10 (1.2%) of 816 patients. Among the 16 patients with immune-related hepatitis, the median time to onset was 2.5 months (range: 7 days to 22.5 months) and the median duration of hepatitis was 27.5 days (range: 10 days to 7.6 months). Fourteen (87.5%) patients with immune-related hepatitis received high-dose corticosteroids for a median of 30 days (range: 6 days to 3.1 months). Resolution of hepatitis had occurred in 8 (50.0%) of the 16 patients at the time of data cutoff. *Immune-related endocrinopathies* Hypothyroidism occurred in 61 (7.5%) of 816 patients receiving cemiplimab. One (0.1%) of 816 patients discontinued cemiplimab due to hypothyroidism. Among the 61 patients with hypothyroidism, the median time to onset was 4.1 months (range: 15 days to 18.9 months) with a median duration of 7.9 months (range: 1 day to 23.3 months). Resolution of hypothyroidism had occurred in 5 (8.2%) of the 61 patients at the time of data cutoff. Hyperthyroidism occurred in 27 (3.3%) of 816 patients receiving cemiplimab including 7 (0.9%) patients with Grade 2 hyperthyroidism. No patient discontinued cemiplimab due to hyperthyroidism. Among the 27 patients with hyperthyroidism, the median time to onset was 2.1 months (range: 20 days to 23.8 months) and the median duration was 1.9 months (range: 1 day to 24.5 months). Resolution of hyperthyroidism had occurred in 13 (48.1%) of the 27 patients at the time of data cutoff. Thyroiditis occurred in 5 (0.6%) of 816 patients receiving cemiplimab including 2 (0.2%) patients with Grade 2 thyroiditis. No patient discontinued cemiplimab due to thyroiditis. Thyroiditis had not resolved in any patient at the time of data cutoff. Adrenal insufficiency occurred in 3 (0.4%) of 816 patients receiving cemiplimab including 3 (0.4%) patients with Grade 3 adrenal insufficiency. One (0.1%) of 816 patients discontinued cemiplimab due to adrenal insufficiency. Among the 3 patients with adrenal insufficiency, the median time to onset was 11.5 months (range: 4.2 months to 18.3 months) and the median duration was 5.1 months (range: 4.9 months to 6.1 months). One of the 3 patients (33.3%) received high-dose corticosteroids. Adrenal insufficiency had not resolved in any patient at the time of data cutoff. Immune-related hypophysitis occurred in 3 (0.4%) of 816 patients receiving cemiplimab, including 2 (0.2%) patients with Grade 3 hypophysitis. One (0.1%) of 816 patients discontinued cemiplimab due to hypophysitis. Among the 3 patients with hypophysitis, the median time to onset was 4.6 months (range: 2.6 months to 7.4 months) with a median duration of 23 days (range: 9 days to 1.5 months). One of the 3 patients (33.3%) received high-dose corticosteroids. Hypophysitis had not resolved in any patient at the time of data cutoff. Type 1 diabetes mellitus without an alternative aetiology occurred in 1 (0.1%) of 816 patients including 1 (0.1%) patient with *Grade 4 type 1 diabetes mellitus*. Immune-related skin adverse reactions Immune-related skin adverse reactions occurred in 13 (1.6%) of 816 patients receiving cemiplimab including 7 (0.9%) patients with Grade 3 immune-related skin adverse reactions. Immune-related skin adverse reactions led to permanent discontinuation of cemiplimab in 1 (0.1%) of 816 patients. Among the 13 patients with immune-related skin adverse reactions, the median time to onset was 1.2 months (range: 2 days to 17.0 months) and the median duration was 2.7 months (range: 13 days to 12.5 months). Eight patients (61.5%) with immune-related skin adverse reactions received high-dose corticosteroids for a median of 15 days (range: 4 days to 2.6 months). Resolution of skin reaction had occurred in 9 (69.2%) of 13 patients at the time of data cutoff. *Immune-related nephritis* Immune-related nephritis occurred in 5 (0.6%) of 816 patients receiving cemiplimab including 1 (0.1%) patient with Grade 5, and 1 (0.1%) patients with Grade 3 immune-related nephritis. Immune-related nephritis led to permanent discontinuation of cemiplimab in 1 (0.1%) of 816 patients. Among the 5 patients with immune-related nephritis, the median time to onset was 1.8 months (range: 14 days to 5.6 months) and the median duration of nephritis was 26 days (range: 9 days to 1.6 months). Four (80%) patients with immune-related nephritis received high-dose corticosteroids for a median of 16 days (range: 3 days to 1.0 months). Resolution of nephritis had occurred in 4 (80%) of the 5 patients at the time of data cutoff. *Other immune-related adverse reactions* The following clinically significant, immune-related adverse reactions occurred at an incidence of less than 1% of 816 patients treated with cemiplimab monotherapy. The events were Grade 3 or less unless stated otherwise: **Nervous system disorders:** Meningitisa (Grade 4), paraneoplastic encephalomyelitis (Grade 5), chronic inflammatory demyelinating polyradiculoneuropathy, encephalitisb, myasthenia gravis, peripheral neuropathyc Cardiac Disorders: Myocarditisd, pericarditise **Immune system disorders:** Immune thrombocytopenic purpura **Musculoskeletal and connective tissue disorders:** Arthralgia, arthritisf, muscular weakness, myalgia, myositis, polymyalgia rheumatica, Sjogren's syndrome **Eye disorders:** Keratitis **Gastrointestinal disorders:** Stomatitis [a] includes meningitis and aseptic meningitis [b] includes encephalitis and noninfective encephalitis [c] includes neuritis and peripheral neuropathy [d] includes autoimmune myocarditis and myocarditis [e] includes autoimmune pericarditis and pericarditis [f] includes arthritis and polyarthritis The following additional immune-related adverse reactions were observed in patients receiving combination therapy in clinical trials: vasculitis, Guillain-Barre syndrome and central nervous system inflammation, each with the frequency of rare. *Infusion-related reactions* Infusion-related reactions occurred in 63 (7.7%) of 816 patients treated with cemiplimab including 1 (0.1%) patient with Grade 3 infusion-related reaction. Infusion-related reaction led to permanent discontinuation of cemiplimab in 1 (0.1%) patient. The most common symptoms of infusion-related reaction were pyrexia, nausea, and rash. All patients recovered from the infusion-related reaction. Immunogenicity As with all therapeutic proteins, there is a potential for immunogenicity with cemiplimab. In clinical studies with patients treated with cemiplimab, 2.2% of patients developed treatment-emergent antibodies, with approximately 0.4% exhibiting persistent antibody responses. No neutralizing antibodies have been observed. There was no evidence of an altered PK or safety profile with anti-cemiplimab antibody development. Reporting of suspected adverse reactions Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via : **Belgium:** Federal Agency for Medicines and Health Products – Afdeling Vigilantie – Postbus 97 – 1000 Brussel Madou – Website: www.eenbijwerkingmelden.be – E-mail: adr@fagg.be **Luxembourg:** Centre Régional de Pharmacovigilance de Nancy –crpv@chru-nancy.fr – Tél.: (+33) 383 656085/87 **or** Division de la Pharmacie et des Médicaments – Direction de la santé, Luxembourg – pharmacovigilance@ms.etat.lu – Tél.: (+352) 24785592 – Link naar het formulier: https://guichet.public.lu/fr/entreprises/sectoriel/sante/medecins/notification-effets-indesirables- medicaments.html **MARKETING AUTHORISATION HOLDER** Regeneron Ireland Designated Activity Company (DAC) One Warrington Place Dublin 2, D02 HH27 Ireland **MARKETING AUTHORISATION NUMBER(S)** EU/1/19/1376/001 **DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION** Date of first authorisation: 28 June 2019 Date of latest renewal: 10 May 2021 DATE OF REVISION OF THE TEXT 07/01/2022 Detailed information on this medicinal product is available on the website of the European Medicines Agency http://www.ema.europa.eu

Table 2: Tabulated list of adverse reactions in patients treated with cemiplimab monotherapy

System organ class preferred term	Grades 1-5 (Frequency category)	Grades 1-5 (%)	Grades 3-5 (%)
Infections and infestations			
Upper respiratory tract infection[a]	Very Common	10.8	0.4
Urinary tract infection	Common	5.4	1.0
Blood and lymphatic system disorders			
Anaemia	Very Common	13.0	3.3
Immune system disorders			
Infusion-related reaction	Common	3.2	0
Sjogren's syndrome	Uncommon	0.2	0
Immune thrombocytopenic purpura	Uncommon	0.1	0
Solid organ transplant rejection[b]	Not known	--	--
Endocrine disorders			
Hypothyroidism[c]	Common	7.5	0
Hyperthyroidism	Common	3.3	0
Adrenal insufficiency	Uncommon	0.4	0.4
Thyroiditis[d]	Uncommon	0.6	0
Type 1 diabetes mellitus[e]	Uncommon	0.1	0.1
Hypophysitis	Uncommon	0.4	0.2
Nervous system disorders			
Headache	Common	7.7	0.4
Peripheral neuropathy[f]	Common	1.5	0.1
Meningitis[g]	Uncommon	0.1	0.1
Encephalitis	Uncommon	0.1	0.1
Myasthenia gravis	Uncommon	0.1	0
Paraneoplastic encephalomyelitis	Uncommon	0.1	0.1
Chronic inflammatory demyelinating polyradiculoneuropathy	Uncommon	0.1	0
Eye disorders			
Keratitis	Uncommon	0.1	0
Cardiac disorders			
Myocarditis[h]	Uncommon	0.6	0.5
Pericarditis[i]	Uncommon	0.2	0.2
Vascular disorders			
Hypertension[j]	Common	6.1	2.5
Metabolism and nutrition disorders			
Decreased appetite	Very common	12.5	0.6
Respiratory, thoracic and mediastinal disorders			
Cough[k]	Very common	12.5	0.1
Dyspnoea[l]	Common	9.9	1.3
Pneumonitis[m]	Common	4.2	1.2
Gastrointestinal disorders			
Nausea	Very common	12.3	0.1
Diarrhoea	Very common	16.7	0.5
Constipation	Very common	10.8	0.2
Abdominal pain[n]	Common	9.7	0.6
Vomiting	Common	7.4	0.1
Stomatitis	Common	1.5	0
Colitis[o]	Common	2.2	1.0
Hepatobiliary disorders			
Hepatitis[p]	Common	2.2	1.3
Skin and subcutaneous skin disorders			
Rash[q]	Very common	22.7	1.6
Pruritus[r]	Very common	13.1	0.1
Musculoskeletal and connective tissue disorders			
Musculoskeletal pain[s]	Very Common	29.8	1.6
Arthritis[t]	Common	1.0	0.1
Muscular weakness	Uncommon	0.4	0
Myositis	Uncommon	0.1	0
Polymyalgia rheumatica	Uncommon	0.1	0
Renal and urinary disorders			
Nephritis[u]	Common	1.3	0.2
Noninfective cystitis	Not known	-	-
General disorders and administration site conditions			
Fatigue[v]	Very common	28.1	2.3
Investigations			
Aspartate aminotransferase increased	Common	4.8	0.9
Alanine aminotransferase increased	Common	4.7	0.6
Blood alkaline phosphatase increased	Common	2.3	0.2
Blood creatinine increased	Common	2.0	0
Blood thyroid stimulating hormone increased	Uncommon	0.7	0
Transaminases increased	Uncommon	0.6	0.1
Blood bilirubin increased	Uncommon	0.5	0.1
Blood thyroid stimulating hormone decreased	Uncommon	0.1	0