SUMMARY OF PRODUCT CHARACTERISTICS

▼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.

1 NAME OF THE MEDICINAL PRODUCT

Eqjubi 600 mg concentrate for solution for infusion.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One vial of 20 mL of concentrate for solution for infusion contains 600 mg of sugemalimab.

Each mL of concentrate contains 30 mg of sugemalimab.

Sugemalimab is a fully human anti-programmed death-ligand 1 (PD-L1) monoclonal antibody (IgG4 isotype) produced in Chinese hamster ovary cells by recombinant DNA technology.

Excipient with known effect

Each vial contains 25.8 mg of sodium.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Concentrate for solution for infusion.

Clear to opalescent, colourless to slight yellow solution, essentially free from visible particles, pH 5.3 to 5.7.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Eqjubi in combination with platinum-based chemotherapy is indicated for the first-line treatment of adults with metastatic non-small-cell lung cancer (NSCLC) with no sensitising EGFR mutations, or ALK, ROS1 or RET genomic tumour aberrations.

4.2 Posology and method of administration

Therapy must be initiated and supervised by physicians experienced in the use of anticancer medicinal products.

Posology

The use of systemic corticosteroids or immunosuppressants before starting sugemalimab should be avoided (see section 4.5).

Recommended dose

The Recommended dose of sugemalimab is 1200 mg every 3 weeks for patients weighing less

than 115 kg, or 1500 mg every 3 weeks for those weighing more than 115 kg administered as

an intravenous infusion over 60 minutes.

Duration of treatment

Treatment with sugemalimab should be continued until disease progression, or unacceptable toxicity.

When given in combination on day 1 of each cycle of platinum-based chemotherapy, sugemalimab should be administered first, followed by chemotherapy. Refer to the full prescribing information for the combination products (see also section 5.1).

Treatment modification

The dose of sugemalimab should not be increased or reduced. Treatment

should be withheld or discontinued to manage adverse reactions. Recommended treatment modifications are provided in Table 1.

Table 1. Recommended treatment modifications of Eqjubi

Adverse reaction	Severity*	Treatment modification
Immune-related pneumonitis	Grade 2	Withhold until the adverse reaction recovers to Grade 0 to 1.
	Grade 3 or 4, or recurrent Grade 2	Permanently discontinue.
Immune-related colitis	Grade 2 or 3	Withhold until the adverse reaction recovers to Grade 0 to 1.
	Grade 4 or recurrent Grade 3	Permanently discontinue.
Immune-related nephritis	Grade 2 blood creatinine increased	Withhold until the adverse reaction recovers to Grade 0 to 1.
	Grade 3 or 4 blood creatinine increased	Permanently discontinue.
Immune-related ocular toxicities	Grade 2 ocular toxicities	Withhold until the adverse reaction recovers to Grade 0 to 1.
	Grade 3 or 4 ocular toxicities	Permanently discontinue.
Immune-related endocrine disorders	Symptomatic Grade 2 or 3 hypothyroidism Grade 2 or 3 hyperthyroidism Grade 2 or 3 symptomatic hypophysitis Grade 2 adrenal insufficiency Type-1 diabetes mellitus associated with Grade 3 hyperglycaemia	Withhold until the adverse reaction recovers to Grade 0 to 1.
	Grade 4 hypothyroidism Grade 4 hyperthyroidism Grade 4 symptomatic hypophysitis Grade 3 or 4 adrenal insufficiency Type-1 diabetes mellitus associated with Grade 4 hyperglycaemia	Permanently discontinue.
Immune-related hepatitis	Grade 2, aspartate aminotransferase (AST) or alanine aminotransferase (ALT) at > 3 to 5 times the upper limit of normal (ULN) or total bilirubin (TBIL) at > 1.5 to 3 times the ULN	Withhold until the adverse reaction recovers to Grade 0 to 1.
	Grade 3 or 4, AST or ALT > 5 times the ULN, or TBIL > 3 times the ULN	Permanently discontinue.
Immune-related skin reactions	Grade 3	Withhold until the adverse

Adverse reaction	Severity*	Treatment modification
	Suspected Stevens-Johnson syndrome (SJS) or toxic epidermal necrolysis (TEN)	reaction recovers to Grade 0 to 1.
	Grade 4 Confirmed SJS or TEN	Permanently discontinue.
Other immune-related adverse reactions	Grade 2 pancreatitis† First occurrence of other Grade 2 or Grade 3 immune-related adverse reactions depending on the reaction severity and type	Withhold until the adverse reaction recovers to Grade 0 to 1.
	Grade 2 or greater conjunctivitis Grade 3 or 4 pancreatitis Grade 2, 3 or 4 myocarditis Grade 3 or 4 encephalitis Grade 4 myositis First occurrence of other Grade 4 immune-related adverse reactions	Permanently discontinue.
Recurrent adverse reactions	Recurrent Grade 3 or 4 (except for endocrine disorders)	Permanently discontinue.
Infusion-related reactions	Grade 2	Infusion should be interrupted and may be resumed at 50% of previous rate once infusion related reactions have resolved or decreased to Grade ≤1, with close observation ensured.
	Grade 3 or 4	Permanently discontinue.

* Toxicity Grades are in accordance with the National Cancer Institute's Common Terminology Criteria for Adverse Events, Version 4.03 (NCI CTCAE V4.03).

† Continued clinical monitoring is recommended for asymptomatic pancreatitis or increase in pancreatic enzyme / lipase, but no temporary medicine discontinuation is required.

Special populations

Elderly

No treatment modification of sugemalimab is required for patients ≥ 65 years of age (see section 5.1).

Renal impairment

No treatment modification of sugemalimab is required in patients with mild or moderate renal impairment (see section 5.2). Sugemalimab has not been studied in patients with severe renal impairment.

Hepatic impairment

No treatment modification of sugemalimab is recommended for patients with mild hepatic impairment (see section 5.2). Sugemalimab has not been studied in patients with moderate or severe hepatic impairment.

Paediatric population

The safety and efficacy of sugemalimab in children below the age of 18 years have not been established. No data are available.

Method of administration

Sugemalimab is for intravenous use. After dilution, it is administered by infusion over 60 minutes.

Sugemalimab must not be administered as an intravenous push or bolus injection. For the management of infusion-related reactions see Table 1.

When administering sugemalimab in a regimen with chemotherapy, sugemalimab is administered first, followed by chemotherapy. Chemotherapy may be started 30 minutes after completion of sugemalimab administration.

For instructions on dilution of the medicinal product before administration, see section 6.6.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Traceability

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

Immune-related adverse reactions

Immune-related adverse reactions, including serious and fatal cases, have occurred in patients receiving sugemalimab. Immune-related adverse reactions can occur after discontinuation of treatment. In clinical studies, most immune-related adverse reactions were reversible and managed with interruptions of sugemalimab, administration of corticosteroids and/or supportive care. Immune-related adverse reactions affecting more than one body system can occur simultaneously.

For suspected immune-related adverse reactions, ensure adequate evaluation to confirm aetiology or exclude other causes. Based on the severity of the adverse reaction, withhold, or permanently discontinue sugemalimab and consider administration of corticosteroids. Upon improvement to Grade 1 or 0, initiate corticosteroid taper and continue to taper for at least 1 month. Restart sugemalimab if the adverse reaction remains at Grade 1 or 0 following corticosteroid dose reduction. If another episode of the severe adverse reaction occurs, permanently discontinue sugemalimab. (See section 4.2 and 4.4)

Immune-related pneumonitis

Immune-related pneumonitis has been reported in patients receiving sugemalimab (see section 4.8). Patients should be monitored for signs and symptoms of pneumonitis. Suspected pneumonitis should be confirmed with radiographic imaging to exclude other causes. For Grade 2 pneumonitis, treatment with sugemalimab should be withheld, and 1 to 2 mg/kg /day prednisone or equivalent should be administered. If symptoms improve to Grade 0 or 1, corticosteroids should be tapered for at least 1 month. Treatment with sugemalimab may be resumed if the event improves to Grade 0 to 1 following corticosteroid dose reduction. Sugemalimab should be permanently discontinued for severe (Grade 3), life-threatening (Grade 4) or recurrent moderate (Grade 2) pneumonitis (see section 4.2) and 1 to 2 mg/kg /day of methylprednisolone or equivalent should be administered.

Immune-related skin reactions

Immune-related severe skin reactions have been reported in patients receiving sugemalimab (see section 4.8). Patients should be monitored for suspected severe skin reactions and other causes should be excluded. For Grade 3 skin reactions, sugemalimab should be withheld until recovery to Grade 0 to 1 and 1 to 2 mg/kg/day of prednisone or equivalent should be administered. Sugemalimab should be permanently discontinued for Grade 4 skin reactions, and corticosteroids should be administered.

Cases of Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) have been reported in patients receiving PD-1/PD-L1 immune checkpoint inhibitors. For suspected SJS or TEN, sugemalimab should be withheld and the patient should be referred to a specialised unit for assessment and treatment. For confirmed SJS or TEN, sugemalimab should be permanently discontinued (see section 4.2).

Caution should be used when considering the use of sugemalimab in a patient who has previously experienced a severe or life-threatening skin adverse reaction on prior treatment with other immune-stimulatory anti-cancer agents.

Immune-related colitis

Immune-related colitis has been reported in patients receiving sugemalimab monotherapy (see section 4.8). Patients should be monitored for signs and symptoms of colitis and other causes should be excluded. For Grade 2 colitis, treatment with sugemalimab should be withheld, and 1 to 2 mg/kg /day prednisone or equivalent should be administered. For Grade 3 colitis, treatment with sugemalimab should be withheld, and 1 to 2 mg methylprednisolone or equivalent should be administered. Treatment with sugemalimab may be resumed if the event improves to Grade 0 to 1 following corticosteroid dose reduction. Sugemalimab should be permanently discontinued for life-threatening (Grade 4) or recurrent Grade 3 colitis (see section 4.2), and 1 to 2 mg/kg /day methylprednisolone or equivalent should be administered.

Immune-related hepatitis

Immune-related hepatitis has occurred in patients receiving sugemalimab (see section 4.8). Patients should be monitored for abnormal liver tests prior to and as clinically indicated during treatment with sugemalimab. For Grade 2 hepatitis, treatment with sugemalimab should be withheld, and 1 to 2 mg/kg/day prednisone or equivalent should be administered. Treatment with sugemalimab may be resumed if the event improves to Grade 0 or 1. Sugemalimab should be permanently discontinued for severe (Grade 3) or life-threatening (Grade 4) hepatitis (see section 4.2), and 1 to 2 mg/kg/day methylprednisolone or equivalent should be administered.

Immune-related nephritis

Immune-related nephritis has been reported in patients receiving sugemalimab (see section 4.8). Patients should be monitored for abnormal renal function tests prior to and periodically during treatment with sugemalimab and managed as recommended. For Grade 2 nephritis, treatment with sugemalimab should be withheld, and 1 to 2 mg/kg/day prednisone or equivalent should be administered. For Grade 2 nephritis, treatment with sugemalimab may be resumed if the event improves to Grade 0 to 1. Sugemalimab should be permanently discontinued for severe (Grade 3) or life-threatening (Grade 4) nephritis (see section 4.2) and 1 to 2 mg/kg/day methylprednisolone or equivalent should be administered.

Immune-related endocrinopathies

Immune-related endocrinopathies including hyperthyroidism, hypothyroidism, thyroiditis, diabetes mellitus, adrenal insufficiency and hypophysitis have been reported in patients receiving sugemalimab treatment (see section 4.8).

Thyroid disorders have been reported in patients receiving sugemalimab, including hyperthyroidism, hypothyroidism and thyroiditis. These can occur at any time during treatment; therefore, patients should be monitored for changes in thyroid function and clinical signs and symptoms of thyroid disorders (at the start of treatment, periodically during treatment, and as indicated based on clinical evaluation).

For symptomatic hypothyroidism, sugemalimab should be withheld and thyroxine replacement therapy should be initiated as needed. For symptomatic hyperthyroidism sugemalimab should be withheld and an anti-thyroid medication should be initiated as needed. Treatment with sugemalimab may be resumed when symptoms are controlled, and thyroid function is improving. Sugemalimab should be permanently discontinued for life-threatening (Grade 4) hypothyroidism and hyperthyroidism (see section 4.2).

Type-1 diabetes mellitus has been reported in patients receiving sugemalimab. Patients should be monitored for hyperglycaemia or other signs and symptoms of diabetes and managed with insulin as clinically indicated. For type-1 diabetes mellitus associated with Grade 3 hyperglycaemia, sugemalimab should be withheld. Treatment with sugemalimab may be resumed if metabolic control is achieved on insulin replacement therapy. Sugemalimab should be permanently discontinued for type-1 diabetes mellitus associated with life-threatening (Grade 4) hyperglycaemia (see section 4.2).

Adrenal insufficiency has been reported in patients receiving sugemalimab. Hypophysitis has also been reported in patients receiving sugemalimab. Patients should be monitored for signs and symptoms of adrenal insufficiency or hypophysitis (including hypopituitarism) and other causes should be excluded. For Grade 2 adrenal insufficiency or for Grade 2 or 3 hypophysitis, treatment with sugemalimab should be withheld (see Section 4.2), and treatment with sugemalimab may be resumed if the event improves to Grade 0 to 1. Corticosteroids to treat adrenal insufficiency or hypophysitis and other hormone replacement therapy (such as thyroxine in patients with hypophystitis) should be administered as clinically indicated. Pituitary function and hormone levels should be monitored to ensure appropriate hormone replacement. Sugemalimab should be permanently discontinued for Grade 3 or 4 adrenal insufficiency and for Grade 4 hypophysitis.

Immune-related myositis

Immune-related myositis has been reported in patients receiving sugemalimab at very low frequency or with delayed onset of symptoms (see section 4.8). Patients should be monitored for potential myositis and other causes should be excluded. If a patient develops signs and symptoms of myositis, close monitoring should be implemented, and the patient referred to a specialist for assessment and treatment without delay. Based on the severity of the adverse reaction, withhold, or permanently discontinue sugemalimab (see section 4.2). For Grade 2 myositis, 1 to 2 mg/kg/day prednisone or equivalent should be administered. For Grade 3 or 4 myositis, methylprednisolone 1 to 2 mg/kg/day or equivalents should be administered.

Immune-related myocarditis

Immune-related myocarditis has been reported in patients receiving sugemalimab (see section 4.8). Monitor patients for suspected myocarditis and exclude other causes. If myocarditis is suspected, treatment with sugemalimab should be withheld, prompt initiation of systemic corticosteroids at a dose of 1 to 2 mg/kg/day of prednisone or equivalent should be started, and prompt cardiology consultation with diagnostic workup according to current clinical guidelines should be initiated. Once a diagnosis of myocarditis is established, sugemalimab should be permanently discontinued for Grade 2, 3 or 4 myocarditis (see section 4.2).

Immune-related pancreatitis

Immune-related pancreatitis has been reported in patients receiving sugemalimab (see section 4.8). Patients should be closely monitored for signs of symptoms suggestive of acute pancreatitis and for increases in serum amylase or lipase. For Grade 2 pancreatitis, treatment with sugemalimab should be withheld, and 1 to 2 mg/kg/day prednisone or equivalent should be administered. For Grade 2 pancreatitis, treatment with sugemalimab may be resumed if the event remains at Grade 0 to 1 following corticosteroid dose reduction. Sugemalimab should be permanently discontinued for severe (Grade 3) or life-threatening (Grade 4) pancreatitis (see section 4.2) and 1 to 2 mg/kg/day methylprednisolone or equivalent should be administered.

Immune-related ocular toxicities

Immune-related ocular toxicities have been reported in patients receiving sugemalimab (see section 4.8). For Grade 2 ocular toxicities, treatment with sugemalimab should be withheld, and 1 to 2 mg/kg/day prednisone or equivalent should be administered. For Grade 2 ocular toxicities, treatment with sugemalimab may be resumed if the event remains at Grade 0 to 1 following corticosteroid dose reduction. Sugemalimab should be permanently discontinued for severe (Grade 3) or life-threatening (Grade 4) ocular toxicities (see section 4.2) and 1 to 2 mg/kg/day methylprednisolone or equivalent should be administered.

Other immune-related adverse reactions

Other immune-related adverse reactions including immune-related upper gastrointestinal disorders, immune-related arthritis, immune-related pancytopenia/bicytopenia, immune-related meningoencephalitis/encephalitis, immune-related Guillain-Barre syndrome/demyelination, and immune-related rhabdomyolysis/myopathy were reported in patients receiving sugemalimab (see section 4.8).

Patients should be monitored for suspected immune-related adverse reactions, adequate evaluation should be performed to confirm aetiology or exclude other causes. Based on the severity of the adverse reaction, withhold, or permanently discontinue sugemalimab (see section 4.2). For Grade 2 immune-mediated adverse reactions, 1 to 2 mg/kg/day prednisone or equivalent should be administered. For Grade 3 or 4 adverse reactions, methylprednisolone 1 to 2 mg/kg/day or equivalents should be administered.

<u>Infusion -related reactions</u>

Infusion-related reactions including anaphylactic reaction, hyperhidrosis, pyrexia, chills, erythema and rash, have been reported in patients receiving sugemalimab (see section 4.8). Patients should be closely monitored for clinical signs and symptoms of an infusion reaction and managed as recommended in section 4.2.

<u>Patients excluded from clinical studies</u>

Patients with the following conditions were excluded from clinical study: active autoimmune disease; receiving immunosuppressive treatment; live-virus vaccine administration within 28 days of the study treatment start; HIV infection, hepatitis B or hepatitis C infection; active or untreated CNS metastases; a history of interstitial lung disease or idiopathic pulmonary fibrosis.

Sodium

This medicinal product contains 51.6 mg sodium per 1200 mg dose and 64.5 mg sodium per 1500 mg dose. The equivalent of 2.58% and 3.23% of the WHO recommended maximum daily intake of 2 grams for an adult.

Patient alert card

All physicians administering sugemalimab must be familiar with the Physician Information and Management Guidelines. The physician must discuss the risks of sugemalimab therapy with the patient. The patient will be provided with the patient alert card and instructed by physician to carry the card at all times.

4.5 Interaction with other medicinal products and other forms of interaction

No formal pharmacokinetic (PK) interaction studies have been conducted with sugemalimab. Since sugemalimab is cleared from the circulation through catabolism, no metabolic interactions with other medicinal products are expected.

The use of systemic corticosteroids or immunosuppressants before starting sugemalimab should be avoided because of their potential interference with the pharmacodynamic activity and efficacy of sugemalimab. However, systemic corticosteroids or other immunosuppressants can be used after starting sugemalimab to treat immune -related adverse reactions (see section 4.4).

4.6 Fertility, pregnancy and lactation

Women of childbearing potential/Contraception in males and females

Women of childbearing potential must be advised to avoid pregnancy during treatment with sugemalimab. Female patients of childbearing potential receiving sugemalimab or male patients receiving sugemalimab and their female partners of childbearing potential should use effective contraception methods during treatment and for at least 4 months after the last dose of sugemalimab (see below and section 5.3).

Pregnancy

There are no data on the use of sugemalimab in pregnant women. Animal reproduction and developmental toxicity studies have not been conducted with sugemalimab. However, blockade of PD-L1 signalling in murine models of pregnancy has been shown to disrupt tolerance to the foetus and to increase foetal loss (see section 5.3).

Sugemalimab is not recommended during pregnancy and in women of childbearing potential not using contraception.

Breast-feeding

It is unknown whether sugemalimab is secreted in human milk. Since it is known that antibodies can be secreted in human milk, a risk to the newborns/infants cannot be excluded. A decision should be made whether to discontinue breast-feeding or to discontinue sugemalimab treatment, taking into account the benefit of breast-feeding for the child and the benefit of sugemalimab therapy for the woman.

Fertility

No clinical data are available on the possible effects of sugemalimab on fertility. Animal data did not show notable effects on the male and female reproductive organs (see section 5.3).

4.7 Effects on ability to drive and use machines

Sugemalimab may have an influence on the ability to drive and use machines. In some patients, fatigue has been reported following administration of sugemalimab (see section 4.8). Patients experiencing fatigue should be advised not to drive and use machines until the symptoms resolved.

4.8 Undesirable effects

Summary of the safety profile

The safety of sugemalimab in combination with chemotherapy has been evaluated in 435 patients receiving 1200mg every 3 weeks in clinical studies across tumour types.

The incidence of adverse reactions in this patient population was 95.6%. The most common adverse reactions (≥10%) were anaemia (77.5%), aspartate aminotransferase increased (34.0%), alanine aminotransferase increased (32.0%), rash (26.2%), hyperlipidaemia (21.6%), hyperglycaemia (18.4%), hyponatraemia (16.8%), hypokalaemia (15.6%), proteinuria (14.0%), abdominal pain (13.8%), fatigue (13.3%), arthralgia (12.2%), hypoaesthesia (11.5%), hypothyroidism (10.3%), and hypocalcaemia (10.1%).

The incidence of Grade ≥ 3 adverse reactions in these patients was 33.1%. The most common Grade ≥ 3 adverse reactions (> 1%) were anaemia (17.5%), hyponatraemia (4.4%), hypokalaemia (3.0%), hyperlipidaemia (2.3%), amylase increased (2.1%), hepatic function abnormal (1.8%), hyperglycaemia (1.6%), fatigue (1.4%), rash (1.4%), blood alkaline phosphatase increased (1.1%), and pneumonitis (1.1%).

Tabulated list of adverse reactions

Adverse drug reactions observed in clinical studies of sugemalimab in combination with chemotherapy or sugemalimab monotherapy are listed in Table 2. These 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); and very rare (< 1/10 000). Within each frequency grouping, adverse reactions are presented in the order of decreasing frequency.

Table 2. Adverse reactions in patients treated with sugemalimab

Blood and lymphatic system disorders	
Very common	anaemia
Uncommon	haemolytic anaemia[#], immune-related pancytopenia/bicytopenia*
Immune system disorders	
Uncommon	anaphylactic reaction, anti-neutrophil cytoplasmic antibody positive vasculitis[#]
Injury, poisoning and procedural complications	
Common	infusion related reaction
Endocrine disorders	
Very common	hypothyroidism
Common	hyperthyroidism
Uncommon	immune-related hypophysitis*, adrenal insufficiency, immune-mediated thyroiditis
Metabolism and nutrition disorders	
Very common	hyperlipidaemia[a], hyperglycaemia[b], hyponatraemia hypokalaemia, hypocalcaemia[c]
Common	hyperuricaemia[d], hypochloraemia[e], hypomagnesaemia diabetes

	mellitus
Uncommon	dyslipidaemia
Nervous system disorders	
Very common	hypoaesthesia[f]
Common	neuropathy peripheral
Uncommon	immune-mediated encephalitis, immune-related Guillain-Barre syndrome/demyelination*
Cardiac disorders	
Common	tachycardia[g]
Uncommon	immune-mediated myocarditis
Eye disorders	
Common	conjunctivitis, dry eye
Respiratory, thoracic, and mediastinal disorders	
Common	pneumonitis[h]
Gastrointestinal disorders	
Very common	abdominal pain[i]
Common	stomatitis[j], dry mouth
Uncommon	pancreatitis, proctitis, colitis[#]
Hepatobiliary disorders	
Common	hepatic function abnormal, hepatitis[k]
Skin and subcutaneous tissue disorders	
Very common	rash[l]
Uncommon	skin hypopigmentation[m]
Musculoskeletal and connective tissue disorders	
Very common	arthralgia
Common	myalgia, bone pain
Uncommon	myositis[#], immune-mediated arthritis
Renal and urinary disorders	
Very common	proteinuria[n]
Common	nephritis[o]
General disorders and administration site conditions	
Very common	fatigue
Vascular disorders	
Common	hypertension
Investigations	
Very common	aspartate aminotransferase increased, alanine aminotransferase

	increased
Common	blood creatinine increased, blood alkaline phosphatase increased, amylase increased, blood bilirubin increased[p], blood thyroid stimulating hormone increased, blood thyroid stimulating hormone decreased, thyroxine increased[q], transaminases increased, blood creatine phosphokinase MB increased, thyroxine free decreased, tri-iodothyronine free increased, lipase increased
Uncommon	troponin T increased, cortisol decreased

#Frequency estimate based on incidence in sugemalimab monotherapy study.
*Grouped terms which refer to a class effect of immune-related adverse reaction. In clinical studies of sugemalimab in combination with chemotherapy, only myelosuppression, blood corticotrophin decreased, and neuritis were observed respectively under immune-related pancytopenia/bicytopenia, hypophysitis, and Guillain-Barre syndrome/demyelination.
The following terms represent a group of related events that describe a medical condition rather than a single event:

a. Hyperlipidaemia (hyperlipidaemia, hypercholesterolaemia, hypertriglyceridaemia, blood triglycerides increased)

b. Hyperglycaemia (hyperglycaemia, blood glucose increased)

c. Hypocalcaemia (hypocalcaemia, blood calcium decreased)

d. Hyperuricaemia (hyperuricaemia, blood uric acid increased)

e. Hypochloraemia (hypochloraemia, blood chloride decreased)

f. Hypoaesthesia (hypoaesthesia, anaesthesia)

g. Tachycardia (tachycardia, sinus tachycardia, supraventricular tachycardia, atrial tachycardia, atrial fibrillation, ventricular fibrillation)

h. Pneumonitis (pneumonitis, immune-mediated lung disease, interstitial lung disease)

i. Abdominal pain (abdominal pain, abdominal discomfort, abdominal distension, abdominal pain upper)

j. Stomatitis (stomatitis, mouth ulceration)

k. Hepatitis (hepatitis, immune-mediated hepatic disorder, immune-mediated hepatitis, drug-induced liver injury, hepatic failure)

l. Rash (rash, rash maculo-papular, eczema, erythema, dermatitis, dermatitis acneiform, rash erythematous, rash pruritic, urticaria□pruritus□immune-mediated dermatitis)

m. Skin hypopigmentation (skin hypopigmentation, skin depigmentation□leukoderma)

n. Proteinuria (proteinuria, protein urine present)

o. Nephritis (nephritis, renal impairment, renal failure, acute kidney injury)

p. Blood bilirubin increased (blood bilirubin unconjugated increased, bilirubin conjugated increased)

q. Thyroxine increased (thyroxine increased, thyroxine free increased)

Description of selected adverse reactions

Data for the following immune-related adverse reactions are based on information from 435 patients treated with sugemalimab in combination with chemotherapy in

clinical studies. The management guidelines for these adverse reactions are described in section 4.4.

Immune-related adverse reactions

Immune related hypothyroidism

Immune-related hypothyroidism was reported in 14.3% of patients treated with sugemalimab in combination with chemotherapy. The majority of events were Grade 1 or 2 in severity reported in 9.2% and 4.8% of patients, respectively. Grade 3 hypothyroidism was reported in 0.2% of patients. No serious hypothyroidism was reported. Events leading to treatment interruption and discontinuation were reported in 0.9% and 0.2% of patients, respectively. The median time to onset was 112 days (range:16 to 607 days), and the median duration was 83 days (range:1+ to 857+ days).

Immune related hyperthyroidism

Immune-related hyperthyroidism was reported in 9.4% of patients treated with sugemalimab in combination with chemotherapy. All events were Grade 1 and 2 in severity reported in 8.7% and 0.7% of patients, respectively. There were no serious events, or events leading to treatment interruption or discontinuation. The median time to onset was 91.0 days (range: 20 to 620 days), and the median duration was 44 days (range: 10 to 484^{+} days).

Immune-related thyroiditis

Immune-related thyroiditis was reported in 0.5% of patients treated with sugemalimab in combination with chemotherapy. All events were Grade 1 in severity. There were no serious events, or events leading to treatment interruption or discontinuation. The median time to onset was 136 days (range: 105 to 167 days), and the median duration was not reached (range: 736+ to 835+ days).

Diabetes mellitus

Immune-related diabetes mellitus was reported in 2.8% of patients treated with sugemalimab in combination with chemotherapy. The majority of events were Grade 1 in severity reported in 2.3% of patients. Grade 2 and Grade 3 events were reported in 0.2% of patients, respectively. There were no serious events, or events leading to treatment interruption or discontinuation. The median time to onset was 154 days (range: 43 to 635 days), and the median duration was 41 days (range: 2 to 307^{+} days).

Immune-related hypophysitis

Immune-related hypophysitis was reported in 0.9% of patients treated with sugemalimab in combination with chemotherapy. All events were Grade 1 in severity. There were no serious events, or events leading to treatment interruption or discontinuation. The median time to onset was 240.5 days (range: 112 to 754 days), and the median duration was not reached (range: 13^{+} to 478^{+} days).

Immune-related adrenal insufficiency

Immune-related adrenal insufficiency was reported in 0.2% of patients treated with sugemalimab in combination with chemotherapy. The event occurred in a single

patient, was Grade 1 in severity, and did not lead to treatment interruption nor discontinuation.

Immune-related skin adverse reactions

Immune-related skin adverse reactions (excluding severe) were reported in 10.6% of patients treated with sugemalimab in combination with chemotherapy. All events were Grade 1 and 2 in severity and were reported in 7.1% and 3.4% of patients, respectively. Immune-related skin adverse reaction (excluding severe) leading to treatment interruption were reported in 0.9% of patients. There were no serious events or events leading to treatment discontinuation. The median time to onset was 158 days (range: 3 to 990 days), and the median duration was 31 days (range: 1 to 950^{+} days).

Immune-related severe skin adverse reaction was reported in 1.6% of patients treated with sugemalimab in combination with chemotherapy. Serious events were reported in 0.5% of patients, events leading to treatment interruption were reported in 0.9% of patients, and events leading to treatment discontinuation were reported in 0.5% of patients. The median time to onset was 312 days (range: 19 to 738 days), and the median duration was 95 days (range: 12 to 522^{+} days).

Immune-related hepatitis

Immune-related hepatitis was reported in 9.7% of patients treated with sugemalimab in combination with chemotherapy. Grade 1, 2, 3 and 4 events were reported in 5.7%, 1.4%, 2.3% and 0.2% of patients, respectively. Serious events were reported in 2.5% of patients. Events leading to treatment interruption and discontinuation were reported in 2.3% and 1.6% of patients, respectively. The median time to onset was 53 days (range: 1 to 717 days), and the median duration was 25 days (range: 2 to 777^{+} days).

Immune-related pancreatitis

Immune-related pancreatitis was reported in 3.4% of patients treated with sugemalimab in combination with chemotherapy. Grade 1, 2, 3 and 4 events were reported in 1.6%, 0.7%, 0.9% and 0.2% of patients, respectively. Serious events were reported in 0.2% of patients. Events leading to treatment interruption were reported in 0.5% of patients. No events leading to treatment discontinuation were reported. The median time to onset was 42 days (range: 20 to 629 days), and the median duration was 53 days (range: 2 to 958^{+} days).

Immune-related pneumonitis

Immune-related pneumonitis was reported in 3.0% of patients treated with sugemalimab in combination with chemotherapy. Grade 1, 2, 3 and 5 events were reported in 0.2%, 1.6%, 0.9% and 0.2% of patients, respectively. Serious events were reported in 2.1% of patients. Events led to treatment interruption and discontinuation were reported in 1.1% and 1.8% of patients, respectively. The median time to onset was 165 days (range: 6 to 903 days), and the median duration was 229 days (range: 18 to 558^{+} days).

Immune-related myositis

Immune-related myositis was reported in 2.5% of patients treated with sugemalimab in combination with chemotherapy. All events were Grade 1 and 2 in severity and were reported in 0.9% and 1.6% of patients, respectively. Events leading to treatment interruption were reported in 0.2% of patients. There were no serious events or events leading to treatment discontinuation. The median time to onset was 135 days (range: 3 to 649 days), and the median duration was 42 days (range: 2 to 655^{+} days).

Immune-related colitis

Immune-related colitis disorder was reported in 2.5% of patients treated with sugemalimab in combination with chemotherapy. All events were Grade 1 and 2 in severity and were reported in 1.1% and 1.4% of patients, respectively. Events leading to treatment interruption were reported in 0.2% of patients. No serious events or events leading to treatment discontinuation were reported. The median time to onset was 103 days (range: 1 to 682 days), and the median duration was 9 days (range: 2 to 445^{+} days).

Immune-related myocarditis

Immune-related myocarditis was reported in 2.1% of patients treated with sugemalimab in combination with chemotherapy. All events were Grade 1 and 2 in severity and were reported in 1.1% and 0.9% of patients, respectively. Serious events were reported in 0.7% of patients. Events leading to treatment interruption and discontinuation were reported in 1.1% and 0.2% of patients, respectively. The median time to onset was 221 days (range: 41 to 442 days), and the median duration was 23 days (range: 1 to 429^{+} days).

Immune-related nephritis

Immune-related nephritis (including renal failure) was reported in 1.8% of patients treated with sugemalimab in combination with chemotherapy. Grade 1, 2 and 3 events were reported in 0.9%, 0.2% and 0.7% of patients, respectively. Serious events were reported in 0.9% of patients. Events leading to treatment interruption and discontinuation were reported in 0.5% and 0.2% of patients, respectively. The median time to onset was 227.5 days (range: 26 to 539 days), and the median duration was 51.5 days (range: 5 to 543+ days).

Immune-related ocular toxicities

Immune-related ocular toxicities were reported in 1.4% of patients treated with sugemalimab in combination with chemotherapy. All events were Grade 1 and 2 in severity and were reported in 0.7% and 0.7%, respectively. No serious events were reported. Events leading to treatment interruption and discontinuation were reported in 0.5% and 0.2% of patients, respectively. The median time to onset was 235.5 days (range: 137 to 482 days), and the median duration was 9.5 days (range: 1 to 181 days).

Immune-related upper gastrointestinal disorders

Immune-related upper gastrointestinal disorder was reported in 0.9% of patients treated with sugemalimab in combination with chemotherapy. Grade 1, 2 and 3 events

were reported in 0.5%, 0.2% and 0.2% of patients, respectively. Serious events were reported in 0.2% of patients. No events leading to treatment interruption or discontinuation were reported. The median time to onset was 146 days (range: 82 to 204 days), and the median duration was 385 days (range: 42 to 710 days).

Immune-related arthritis

Immune-related arthritis was reported in 0.9% of patients treated with sugemalimab in combination with chemotherapy. All events were Grade 1 and 2 in severity and were reported in 0.2% and 0.7% of patients, respectively. No serious events were reported. Events leading to treatment interruption were reported in 0.5% of patients. No events led to treatment discontinuation were reported. The median time to the onset was 173.5 days (range: 96 to 257 days), and the median duration was 98 days (range: 50 to 958^{+} days).

Immune-related pancytopenia/bicytopenia

Immune-related pancytopenia/bicytopenia was reported in 0.2% of patients treated with sugemalimab in combination with chemotherapy. The event occurred in a single patient, was of Grade 4 in severity and serious, and did not lead to treatment interruption or discontinuation.

Immune-related meningoencephalitis/encephalitis

Immune-related meningoencephalitis/encephalitis was reported in 0.2% of patients treated with sugemalimab in combination with chemotherapy. The event occurred in a single patient, was of Grade 2 in severity and led to treatment discontinuation.

Immune-related Guillain-Barre syndrome/demyelination

Immune-related Guillain-Barre syndrome/demyelination was reported in 0.2% of patients treated with sugemalimab in combination with chemotherapy. The event occurred in a single patient, was of Grade 2 in severity and serious, and did not lead to treatment interruption or discontinuation.

Immune-related rhabdomyolysis/myopathy

Immune-related rhabdomyolysis/myopathy was reported in 0.2% of patients treated with sugemalimab in combination with chemotherapy. The event occurred in a single patient, was of with Grade 2 in severity and led to treatment interruption.

Infusion-related reactions

Infusion-related adverse reactions were reported in 4.4% of patients treated with sugemalimab in combination with chemotherapy. Reported events were infusion related reaction (0.9%), anaphylactic reaction (0.7%), hyperhidrosis (0.5%), pyrexia (0.5%), erythema, rash, rash maculo-papular, skin depigmentation, skin disorder, skin swelling, chills, oedema peripheral, tenderness, nausea, breath holding and throat irritation (0.2% each), respectively.

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 the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

No events of sugemalimab overdose have been reported in clinical trials. In case of overdose, patients must be closely monitored for signs or symptoms of adverse reactions, and appropriate symptomatic treatment should be initiated as dictated by patient's clinical status.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antineoplastic agents, monoclonal antibodies and antibody drug conjugates, PD-1/PD-L1 (Programmed cell death protein 1/death ligand 1) inhibitors, ATC code: L01FF11.

Mechanism of action

Sugemalimab is a fully human immunoglobulin G4 monoclonal antibody, which binds to human programmed cell death ligand 1 (PD-L1) and blocks its interaction with PD□1 and CD80 (B7-1). By binding to PD-1 and CD80 on T cells and antigen presenting cells, PD-L1 suppresses cytotoxic T-cell activity, T-cell proliferation, and cytokine production. Sugemalimab releases the inhibition of immune responses, including activation of the anti-tumour immune response, by blocking PD-L1/PD-1 and PD-L1/CD80 interaction, without inducing antibody-dependent cell mediated cytotoxicity (ADCC).

Clinical efficacy and safety

The efficacy and safety of sugemalimab in combination with platinum-based chemotherapy for the treatment of adults aged ≥ 18 years with histologically or cytologically confirmed metastatic (stage IV) squamous or non-squamous NSCLC without sensitising EGFR mutations, ALK fusions, ROS1, or RET translocations was studied in a randomised, double-blind, placebo-controlled phase 3 study (GEMSTONE-302). Apart from testing for EGFR mutational status in participants with non-squamous NSCLC, testing for genomic tumour aberrations/oncogenic drivers was not mandatory for enrolment. Patients were excluded if they had history of autoimmune disease, administration of a live-virus vaccine within 28 days of randomisation, administration of systemic immunosuppressive medicinal product within 2 weeks of randomisation, active or untreated CNS metastases, HIV infection, hepatitis B or hepatitis C infection.

The primary endpoint of this study was progression-free survival (PFS) assessed by investigator according to RECIST v1.1. The secondary endpoints included overall survival (OS), PFS in participants with PD-L1 expression ≥ 1% (as assessed by investigators according to RECIST v1.1), objective response rate (ORR) assessed by investigators according to RECIST v1.1, and duration of response (DoR). The type I error was controlled using sequential testing method in the order of PFS, OS, PFS in participants with PD-L1 expression ≥ 1%, and ORR.

A total of 479 participants were randomly (2:1) assigned to receive:

- for squamous NSCLC, sugemalimab 1200 mg with carboplatin AUC = 5 mg/mL/min and paclitaxel 175 mg/m^2 intravenously administered every 3 weeks for up to 4 cycles, followed by sugemalimab 1200 mg every 3 weeks
- for non-squamous NSCLC, sugemalimab 1200 mg with carboplatin AUC = 5 mg/mL/min and pemetrexed 500 mg/m^2 intravenously administered every 3 weeks for up to 4 cycles followed by sugemalimab 1200 mg and pemetrexed 500 mg/m^2 every 3 weeks

or

- placebo plus the same platinum-based chemotherapy regimens for squamous or non-squamous NSCLC group receiving sugemalimab for up to 4 cycles; then followed by placebo for squamous NSCLC, or placebo plus pemetrexed for non-squamous NSCLC.

The maximum duration for the treatment with sugemalimab or placebo was 35 cycles (approximately 2 years) or until progressive disease, unacceptable toxicity, withdrawal of informed consent, death, or other reasons stipulated in the protocol.

Patients with radiographic disease progression confirmed by investigator were able to cross-over to receive sugemalimab monotherapy.

During the first year of the treatment period, imaging assessments were performed at Week 6 and 12 after the first dose, and every 9 weeks thereafter; after 1 year: imaging assessments were performed every 12 weeks until disease progression, loss to follow-up, death, or end of study, whichever occurred first.

All participants were Asian and had Stage IV NSCLC; the median age was 63.0 years [29, 75]; 80.0% were males; 73.3% were former or current smokers; 38.8% were ≥ 65 years; 40.1% had squamous NSCLC; 59.9% had non-squamous NSCLC; 60.8% had PD-L1 expression ≥ 1% of the tumour; 11.9% had liver metastases at baseline; 14.0% had brain metastases at baseline; 82.5% had an ECOG performance status of 1.

The median treatment duration was 10 cycles (range 1 to 49) with a median duration of 7.15 months for sugemalimab versus 6 cycles (range 1 to 44) with a median duration of 4.6 months for placebo. The efficacy results of the GEMSTONE-302 study are summarised in Table 3, Figure 1, and Figure 2.

Table 3. Efficacy results of the GEMSTONE-302 study

Efficacy endpoints	**Sugemalimab in combination with platinum-based chemotherapy** (n = 320)	**Placebo in combination with platinum-based chemotherapy** (n = 159)
Progression Free Survival (PFS)*		
Number (%) participants with event	223 (69.7%)	135 (84.9%)
Median in months (95% CI)	9.0 (7.4, 10.8)	4.9 (4.8, 5.1)
Hazard ratio (95% CI)‡	0.48 (0.39, 0.60)	
p-value‡	< 0.0001	
Overall Survival (OS)		
Number (%) participants with event	156 (48.8%)	97 (61.0%)
Median in months (95% CI)¶	25.4 (20.1, NR)	16.9 (12.8, 20.7)
Hazard ratio (95% CI)‡	0.65 (0.50, 0.84)	
p-value‡	0.0008	
Objective response rate*		
ORR n (%) (95% CI)	203 (63.4%) (57.9, 68.7)	64 (40.3%) (32.6, 48.3)
p-value§	< 0.0001	

CI = Confidence interval, ORR= Objective response rate

* Investigator assessed

‡ Hazard ratio (HR) is based on the stratified Cox model. P-value is based on the stratified log-rank test. The 3 stratification factors are ECOG performance status, PD-L1, and histology type from randomisation. See below for further explanation of histology type.

§ P value based on Cochran-Mantel-Haenszel test stratified by ECOG performance status, histology type and PD-L1 from randomisation.¶

Subgroup analysis showed improvements in PFS with sugemalimab, regardless of histological subtype and PD-L1, expression consistent with the overall intent-to-treat (ITT) population.

Efficacy analysis by PD-L1 expression

The PD-L1 expression was assessed at a central laboratory by immunohistochemistry using the Ventana PD-L1 (SP263) assay on a BenchMark autostainer assay (Roche Tissue Diagnostics, Oro Valley, AZ, USA) according to the manufacturer's instructions.

For participants with PD-L1 expression ≥ 1% (n = 292), the median PFS in the sugemalimab group (n = 196) versus placebo group (n = 96) was 10.9 months (95% CI: 8.9, 11.8) and 4.9 months (95% CI: 4.7, 5.9), respectively, the unstratified HR

was 0.48 (95% CI: 0.36, 0.63) For participants with PD-L1 expression < 1% (n = 187), the median PFS in sugemalimab group (n = 124) versus placebo group (n = 63) was 7.4 months (95% CI: 6.8, 9.0) and 4.9 months (95% CI: 4.0, 5.8), respectively, the unstratified HR was 0.57 (95% CI: 0.41, 0.78).

Efficacy analysis by histology type

For participants with non-squamous NSCLC, the median PFS in the sugemalimab group was 9.6 months (95% CI: 8.3, 11) versus 5.9 months (95% CI: 4.9, 7.1) in the placebo group. The unstratified HR was 0.59 (95% CI: 0.45, 0.79), indicating a 41% reduction in the risk of PD or death. For participants with squamous NSCLC, the median PFS in the sugemalimab group was 8.3 months (6.9, 10.9) versus 4.8 months (4.8, 4.9) in the placebo group. The unstratified HR was 0.37 (95% CI: 0.27, 0.52), indicating a 63% reduction in the risk of PD or death.

Figure 1. Kaplan-Meier curve for investigator assessed progression-free survival – ITT population – study GEMSTONE-302

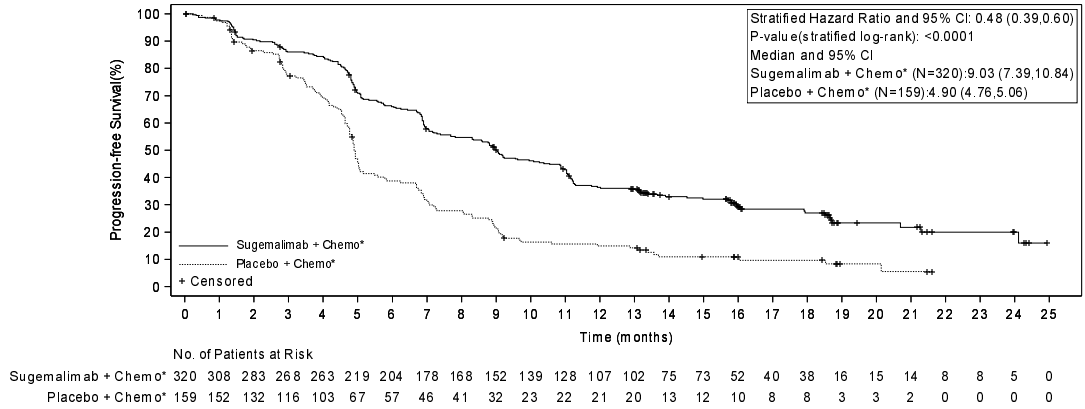
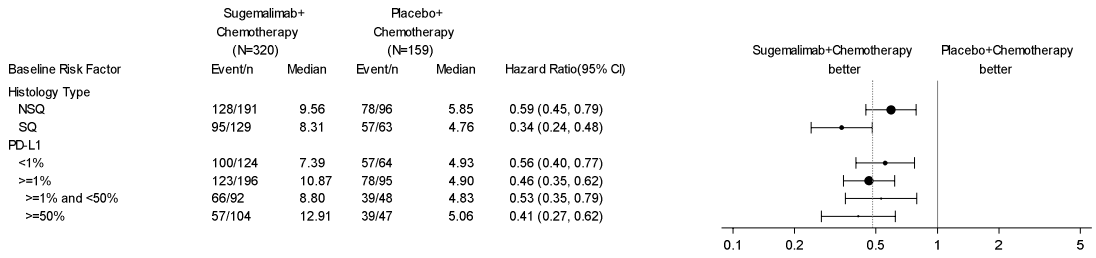
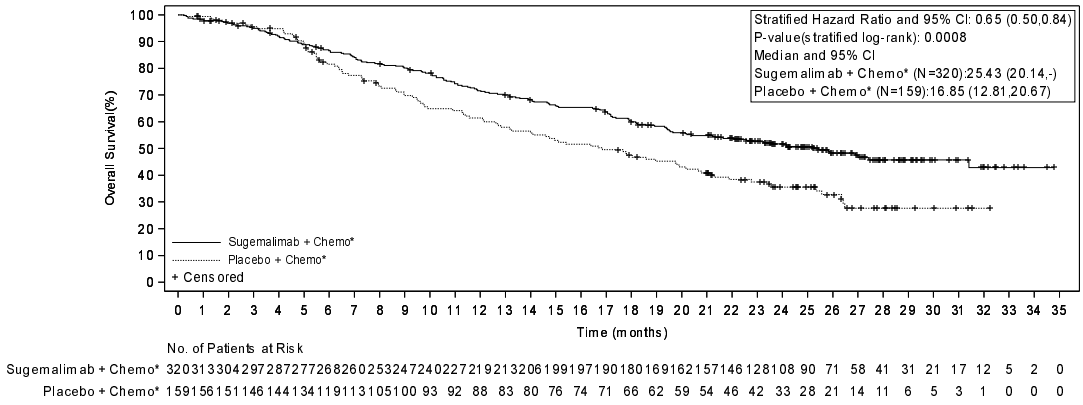


Figure 2. Forest-plot of PFS – study GEMSTONE-302



Note: the subgroup analyses were not controlled for type 1 error.

Figure 3. Kaplan-Meier curve of overall survival – ITT population – study GEMSTONE-302



Paediatric population

The Medicines & Healthcare products Regulatory Agency has waived the obligation to submit the results of studies with sugemalimab in the paediatric population in the treatment of lung cancer (see section 4.2 for information on paediatric use).

Immunogenicity

In the phase 3 NSCLC study, anti-drug antibodies (ADA) were detected (9% of patients). No evidence of ADA impact on pharmacokinetics, efficacy or safety was observed, however data are still limited.

5.2 Pharmacokinetic properties

The PK of sugemalimab was characterised using population PK (PopPK) analysis with concentration data collected from 1002 participants who received sugemalimab doses in the range of 3 to 40 mg/kg and fixed dose of 1200 mg intravenous every 3 weeks.

Absorption

Sugemalimab is administered by intravenous infusion and therefore is immediately and completely bioavailable.

Following single- and multiple-doses escalation study of sugemalimab (n=29), sugemalimab exposures (AUC and C_{max}) increased in an approximately dose proportional manner within the dosing range of 3 mg/kg to 40 mg/kg, including a fixed dose of 1200 mg intravenous every 3 weeks. Following multiple intravenous infusions of 1200 mg every 3 weeks (n=16), there was approximately 2-fold accumulation of sugemalimab exposures (i.e., $R_{acc,Cmax}$ and $R_{acc, AUC}$ were 1.74 and 2.00, respectively).

Distribution

Consistent with a limited extravascular distribution of monoclonal antibodies, the volume of distribution of sugemalimab at steady-state (V_{ss}) from popPK analysis was small, with a geometric mean (CV%) V_{ss} of 4.88 L (27%).

Biotransformation

As an antibody, sugemalimab is catabolised through non-specific pathways; metabolism does not contribute to its clearance.

Elimination

In the PopPK analysis, geometric mean (CV%) of total CL after a single dose was estimated to be 0.211 L/day (28.5%). At steady state, geometric mean (CV%) total CL was estimated as 0.155 L/day (28.4%), i.e., 27% lower than after a single dose. Geometric mean (CV%) of the elimination half-life ($t_{1/2}$) estimated from the PopPK model was approximately 17 days (25.6%) at the end of cycle 1 and approximately 23 days (29.6%) at steady state.

Special populations

Age, sex, body weight, tumour type, and anti-drug antibodies status

PopPK analysis showed non-statistically significant covariate effects of age (18-78 years) on sugemalimab exposure. The effect of other covariates (albumin, sex, anti-drug antibodies, and tumour type) on the systemic exposure of sugemalimab were not considered clinically meaningful. Based on the results from modelling and simulations, increasing the dosage to 1500 mg Q3W for patients with body weight more than 115 kg is anticipated to achieve comparable exposures to the patients in the pivotal study GEMSTONE 302 that were dosed with 1200 mg Q3W.

Race

The effect of race in participants with advanced solid tumours (including NSCLC) receiving sugemalimab was evaluated by PopPK analysis and no impact of race was identified on the PK of sugemalimab. More specifically, there was no observed PK difference in sugemalimab between Asian and non-Asian participants.

Hepatic impairment

The effect of mild hepatic impairment on sugemalimab PK was evaluated using PopPK analyses. Covariate analysis indicated no statistically significant effect of markers of liver function (AST, ALT, and total bilirubin) on sugemalimab exposure.

Renal impairment

The effect of renal impairment on the clearance of sugemalimab was evaluated using PopPK analyses in participants with mild or moderate renal impairment compared to participants with normal renal function. There was no impact of renal function on PK of sugemalimab.

5.3 Preclinical safety data

In studies in monkeys dosed intravenously over 6 months once weekly, no toxicity was identified.

No carcinogenicity studies have been done with sugemalimab.

No reproductive toxicity studies have been conducted with sugemalimab. However, based on the mode of action to inhibit signalling through PD-L1, a block on maternal tolerance to the foetus is expected and this may increase foetal loss (see section 4.6). Foetal exposure to sugemalimab may increase the risk of developing immune-mediated disorders or altering normal immune responses in the neonate.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Histidine

Histidine monohydrochloride

Mannitol (E421)

Sodium chloride

Polysorbate 80 (E433)

Water for injections

6.2 Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products in the same intravenous line except those mentioned in section 6.6.

6.3 Shelf life

Unopened vial

30 months

Diluted medicinal product prepared for infusion

Chemical and physical in-use stability has been demonstrated for up to 24 hours at 2°C to 8°C and for up to 4 hours at room temperature (up to 25°C) from the time of preparation. From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 4 hours at room temperature up to 25°C or 24 hours at 2°C to 8°C, unless dilution has taken place in controlled and validated aseptic conditions.

6.4 Special precautions for storage

Store in a refrigerator (2°C – 8°C).

Do not freeze.

Keep the vial in the outer carton in order to protect from light.

For storage conditions after dilution of the medicinal product, see section 6.3.

6.5 Nature and contents of container

20 mL of concentrate for solution for infusion in Type 1 glass vial with an elastomeric stopper and a blue flip-off aluminum seal containing 600 mg sugemalimab.

Pack size of 2 vials.

6.6 Special precautions for disposal

Eqjubi is supplied as a single-use vial and does not contain any preservatives. Aseptic technique must be used for preparation and administration.

See SmPCs of platinum-based chemotherapy medicines and pemetrexed or paclitaxel for preparation.

Preparation and administration of solution for infusion:

a) Do not shake the vial.

b) **1200 mg dose**

Withdraw 20 mL from each of the 2 vials (total 40 mL) of Eqjubi using sterile syringe and transfer into a 250 ml intravenous bag containing sodium chloride 9 mg/mL (0.9%) solution for injection for a total 1200 mg dose. Mix diluted solution by gentle inversion. Do not freeze or shake the solution.

1500 mg dose

Withdraw 20 mL from each of 2 vials and 10 ml from 1 vial (total 50 mL) of Eqjubi using sterile syringe and transfer into a 250 ml intravenous bag containing sodium chloride 9 mg/mL (0.9%) solution for injection for a total 1500 mg dose. Mix diluted solution by gentle inversion. Do not freeze or shake the solution.

c) Do not co-administer other medicinal products through the same infusion line. The infusion solution should be administered through an intravenous line containing a sterile, low-protein binding in-line or add-on polyether sulfone (PES) filter with a 0.22-micron pore size.

d) Allow the diluted solution to come to room temperature prior to administration.

e) Discard any unused portion left in the vial.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

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Germany

8 MARKETING AUTHORISATION NUMBER(S)

PLGB 54280/0003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30/10/2024

10 DATE OF REVISION OF THE TEXT

30/10/2024