LOQTORZI™ (toripalimab-tpzi)

Dosing and administration guide

INDICATIONS

LOQTORZI™ (toripalimab-tpzi) is indicated:

- In combination with cisplatin and gemcitabine, for the first-line treatment of adults with metastatic or with recurrent, locally advanced nasopharyngeal carcinoma (NPC).
- As a single agent, for the treatment of adults with recurrent unresectable or metastatic NPC with disease progression on or after a platinum-containing chemotherapy.

IMPORTANT SAFETY INFORMATION

Severe and Fatal Immune-Mediated Adverse Reactions

Immune-mediated adverse reactions listed herein may not include all possible severe and fatal immune-mediated adverse reactions. Immune-mediated adverse reactions, which can be severe or fatal, occur in any organ system or tissue, affect more than one body system simultaneously, and occur at any time after starting PD-1/PD-L1 blocking antibody. While immune-mediated adverse reactions usually manifest during treatment, they can also manifest after discontinuation of PD-1/PD-L1 blocking antibodies.

Please see Important Safety Information throughout and the Prescribing Information.

LOQTORZI™ (toripalimab-tpzi) injection

RECOMMENDED LOQTORZI™ (toripalimab-tpzi) DOSAGE[1]

Indication	Recommended dosage of LOQTORZI™	Duration of treatment
First-line NPC*	240 mg every 3 weeks	Until disease progression, unacceptable toxicity, or up to 24 months
Recurrent NPC	3 mg/kg every 2 weeks	Until disease progression or unacceptable toxicity

*LOQTORZI is indicated, in combination with cisplatin and gemcitabine, for the first-line treatment of adults with metastatic or with recurrent, locally advanced NPC. Refer to the Prescribing Information for cisplatin and gemcitabine for recommended dosing information.

NPC=nasopharyngeal carcinoma.

Administration

- Administer diluted solution intravenously via an infusion pump using an in-line aseptic filter (0.2 or 0.22 micron)
- First infusion: Infuse over at least 60 minutes
- Subsequent infusions: If no infusion-related reactions occurred during the first infusion, subsequent infusions may be administered over 30 minutes
- Do not co-administer other drugs through the same intravenous line
- When administered on the same day as chemotherapy, LOQTORZI™ should be administered prior to chemotherapy
- Refer to the Prescribing Information for cisplatin and gemcitabine for recommended dosing information

IMPORTANT SAFETY INFORMATION, cont'd

Severe and Fatal Immune-Mediated Adverse Reactions, cont'd

- Monitor for early identification and management. Evaluate liver enzymes, creatinine, and thyroid function at baseline and periodically during treatment. In cases of suspected immune-mediated adverse reactions, initiate appropriate workup to exclude alternative etiologies, including infection. Institute medical management promptly, including specialty consultation as appropriate.

Please see Important Safety Information throughout and the Prescribing Information.

DOSAGE MODIFICATIONS[1]

No dose reductions of LOQTORZI™ (toripalimab-tpzi) are recommended.

General guidelines:

- In general, withhold LOQTORZI™ for severe (Grade 3) immune-mediated adverse reactions
- Permanently discontinue LOQTORZI™ for:
  - Life-threatening (Grade 4) immune-mediated adverse reactions
  - Recurrent severe (Grade 3) immune-mediated reactions that require systemic immunosuppressive treatment
  - An inability to reduce prednisone to 10 mg per day or less (or equivalent) within 12 weeks of initiating steroids

See the following pages for dosage modifications for adverse reactions that require management different from these general guidelines.

IMPORTANT SAFETY INFORMATION, cont'd

Severe and Fatal Immune-Mediated Adverse Reactions, cont'd

- Withhold or permanently discontinue LOQTORZI™ based on severity and type of reaction (see Dosage and Administration in Prescribing Information). In general, if LOQTORZI™ requires interruption or discontinuation, administer systemic corticosteroid therapy (1 to 2 mg/kg/day prednisone or equivalent) until improvement to Grade 1 or less. Upon improvement to Grade 1 or less, initiate corticosteroid taper and continue to taper over at least 1 month. Consider administration of other systemic immunosuppressants in patients whose immune-mediated adverse reactions are not controlled with corticosteroid therapy.

Immune-Mediated Pneumonitis

LOQTORZI™ can cause immune-mediated pneumonitis.

- In patients receiving LOQTORZI™ in combination with cisplatin and gemcitabine, immune-mediated pneumonitis occurred in 2.1% (3/146) of patients, including Grade 2 (1.4%) adverse reactions. Pneumonitis resolved in 67% (2/3) of these patients.
- In patients receiving LOQTORZI™ monotherapy, immune-mediated pneumonitis occurred in 2.6% (22/851) of patients, including fatal (0.2%), Grade 3 (0.7%), and Grade 2 (1.1%) adverse reactions. Systemic corticosteroids were required in 82% (18/22) of patients with pneumonitis. Pneumonitis led to permanent discontinuation of LOQTORZI™ in 1.2% (10/851) of patients. Pneumonitis resolved in 23% (5/22) of these patients.

Please see Important Safety Information throughout and the Prescribing Information.

RECOMMENDED DOSAGE MODIFICATIONS FOR ADVERSE REACTIONS[1]

Immune-related adverse reactions

Adverse reaction	Severity*	Dose modification
Pneumonitis	Grade 2	Withhold†
	Grades 3 or 4	Permanently discontinue
Colitis	Grades 2 or 3	Withhold†
	Grade 4	Permanently discontinue
Hepatitis with no tumor involvement of the liver	AST/ALT increases to >3 and up to 8× ULN ***OR*** Total bilirubin increases to >1.5 and up to 3× ULN	Withhold†
	AST or ALT increases to >8× ULN ***OR*** Total bilirubin increases to >3× ULN	Permanently discontinue
Hepatitis with tumor involvement of the liver‡	Baseline AST or ALT is >1 and up to 3× ULN and increases to >5 and up to 10× ULN ***OR*** Baseline AST or ALT is >3 and up to 5× ULN and increases to >8 and up to 10× ULN	Withhold†
	Baseline AST or ALT is above the ULN and increases to >10× ULN ***OR*** Total bilirubin increases to >3× ULN	Permanently discontinue

*Based on National Cancer Institute (NCI) Common Terminology for Adverse Events (CTCAE) version 5.0.
†Resume LOQTORZI™ (toripalimab-tpzi) in patients with complete or partial resolution to Grade 0-1 after corticosteroid taper. Permanently discontinue if no complete or partial resolution within 12 weeks of initiating steroids or inability to reduce prednisone to 10 mg per day or less (or equivalent) within 12 weeks of initiating steroids.
‡If AST and ALT are less than or equal to ULN at baseline in patients with liver involvement, withhold or permanently discontinue LOQTORZI™ based on recommendations for hepatitis with no liver involvement.
ALT=alanine aminotransferase; AST=aspartate aminotransferase; ULN=upper limit of normal.

IMPORTANT SAFETY INFORMATION, cont'd

Immune-Mediated Colitis

LOQTORZI™ can cause immune-mediated colitis, which may present with diarrhea. Cytomegalovirus (CMV) infection/reactivation has been reported in patients with corticosteroid-refractory immune-mediated colitis. In cases of corticosteroid-refractory colitis, consider repeating infectious workup to exclude alternative etiologies. In patients receiving LOQTORZI™ monotherapy, immune-mediated colitis occurred in 0.4% (3/851) of patients, including Grade 3 (0.2%) and Grade 2 (0.1%) adverse reactions. Colitis resolved in all 3 patients.

RECOMMENDED DOSAGE MODIFICATIONS FOR ADVERSE REACTIONS, CONT'D[1]

Immune-related adverse reactions, cont'd

Adverse reaction	Severity*	Dose modification
Endocrinopathies	Grades 3 or 4	Withhold until clinically stable or permanently discontinue depending on severity†
Nephritis with renal dysfunction	Grades 2 or 3 increased blood creatinine	Withhold†
	Grade 4 increased blood creatinine	Permanently discontinue
Exfoliative dermatologic conditions	Suspected SJS, TEN, or DRESS	Withhold†
	Confirmed SJS, TEN, or DRESS	Permanently discontinue
Myocarditis	Grades 2, 3, or 4	Permanently discontinue
Neurologic toxicities	Grade 2	Withhold†
	Grades 3 or 4	Permanently discontinue

Other adverse reactions

Adverse reaction	Severity*	Dose modification
Infusion-related reactions	Grades 1 or 2	Interrupt or slow the rate of infusion
	Grades 3 or 4	Stop infusion; permanently discontinue

*Based on NCI CTCAE version 5.0.
†Resume LOQTORZI™ (toripalimab-tpzi) in patients with complete or partial resolution to Grade 0-1 after corticosteroid taper. Permanently discontinue if no complete or partial resolution within 12 weeks of initiating steroids or inability to reduce prednisone to 10 mg per day or less (or equivalent) within 12 weeks of initiating steroids.
DRESS=drug rash with eosinophilia and systemic symptoms; SJS=Stevens Johnson syndrome; TEN=toxic epidermal necrolysis.

IMPORTANT SAFETY INFORMATION, cont'd

Hepatotoxicity and Immune-Mediated Hepatitis

LOQTORZI™ can cause immune-mediated hepatitis.

- In patients receiving LOQTORZI™ in combination with cisplatin and gemcitabine, immune-mediated hepatitis occurred in 0.7% (1/146) of patients, which was a Grade 3 (0.7%) adverse reaction. The patient with immune-mediated hepatitis required systemic corticosteroids.
- In patients receiving LOQTORZI™ monotherapy, immune-mediated hepatitis occurred in 3.3% (28/851) of patients, including Grade 4 (0.8%), Grade 3 (2.1%), and Grade 2 (0.4%) adverse reactions. Hepatitis led to permanent discontinuation of LOQTORZI™ in 1.1% of patients and withholding of LOQTORZI™ in 0.8% of patients. Hepatitis resolved in 54% (15/28) of these patients.

LOQTORZI™ (toripalimab-tpzi) PREPARATION AND STORAGE[1]

Preparation for intravenous infusion

- Visually inspect the solution for particulate matter and discoloration. The solution is clear to slightly opalescent, colorless to slightly yellow. Discard the vial if visible particles are observed
- Withdraw the required volume of LOQTORZI™ and inject slowly into a 100 mL or 250 mL infusion bag containing 0.9% Sodium Chloride Injection, USP. **Mix diluted solution by gentle inversion.** Do not shake. The final concentration of the diluted solution should be between 1 mg/mL to 3 mg/mL
- LOQTORZI™ is compatible with polypropylene infusion bags and infusion sets with 0.2 or 0.22 micron in-line filter
- Discard any unused portion left in the vial

IMPORTANT SAFETY INFORMATION, cont'd

Immune-Mediated Endocrinopathies

Adrenal Insufficiency

LOQTORZI™ can cause primary or secondary adrenal insufficiency. For Grade 2 or higher adrenal insufficiency, initiate symptomatic treatment, including hormone replacement as clinically indicated. Withhold or permanently discontinue LOQTORZI™ depending on severity. In patients receiving LOQTORZI™ monotherapy, adrenal insufficiency occurred in 0.5% (4/851) of patients, including Grade 2 (0.4%) and Grade 1 (0.1%) adverse reactions. Systemic corticosteroids were required in 75% (3/4) of the patients with adrenal insufficiency. Adrenal insufficiency led to withholding of LOQTORZI™ in 0.1% (1/851) of patients. In the one patient in whom LOQTORZI™ was withheld, LOQTORZI™ was reinitiated after symptom improvement.

Please see Important Safety Information throughout and the Prescribing Information.

LOQTORZI™ (toripalimab-tpzi) PREPARATION AND STORAGE, CONT'D[1]

Storage of diluted solution for infusion

LOQTORZI™ does not contain a preservative.

If the diluted solution is not administered immediately, store either:

- At **room temperature, 20 °C to 25 °C (68 °F to 77 °F), for no more than 8 hours** from the time of dilution to the completion of the infusion. Discard diluted solution stored at room temperature after 8 hours

  OR

- **Refrigerated at 2 °C to 8 °C (36 °F to 46 °F) for no more than 24 hours** from the time of dilution to the completion of the infusion. If refrigerated, allow the diluted solution to come to room temperature prior to administration. Discard the refrigerated diluted solution after 24 hours

Do not freeze.

IMPORTANT SAFETY INFORMATION, cont'd

Immune-Mediated Endocrinopathies, cont'd

Hypophysitis

LOQTORZI™ can cause immune-mediated hypophysitis. Hypophysitis can present with acute symptoms associated with mass effects such as headache, photophobia, or visual field defects. Hypophysitis can cause hypopituitarism. Initiate hormone replacement as indicated. Withhold or permanently discontinue LOQTORZI™ depending on severity. In patients receiving LOQTORZI™ monotherapy, hypophysitis occurred in 0.4% (3/851) of patients receiving LOQTORZI™, including Grade 3 (0.2%) and Grade 2 (0.1%) adverse reactions. All three patients received systemic corticosteroids. Hypophysitis led to permanent discontinuation of LOQTORZI™ in 0.1% (1/851) of patients and withholding of LOQTORZI™ in 0.1% (1/851) of patients. The one patient in whom LOQTORZI™ was withheld reinitiated LOQTORZI™.

Thyroid Disorders

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

Please see Important Safety Information throughout and the Prescribing Information.

Immune-Mediated Endocrinopathies, cont'd

Thyroid Disorders, cont'd

- In patients receiving LOQTORZI™ in combination with cisplatin and gemcitabine, thyroiditis occurred in 2.1% (3/146) of patients receiving LOQTORZI™, including Grade 2 (1.4%). Three patients required thyroid hormone replacement therapy. Thyroiditis resolved in one of the 3 patients. Hyperthyroidism occurred in 1.4% (2/146) of patients receiving LOQTORZI™ in combination with cisplatin and gemcitabine. Hyperthyroidism resolved in these 2 patients. Hypothyroidism occurred in 30% (44/146) of patients receiving LOQTORZI™ in combination with cisplatin and gemcitabine, including Grade 2 (24%) and Grade 1 (6%). Eighty percent of the 44 patients required thyroid hormone replacement therapy. LOQTORZI™ was withheld in 2.1% (3/146) of the patients. Of the 3 patients in whom LOQTORZI™ was withheld, 2 patients reinitiated LOQTORZI™.

- In patients receiving LOQTORZI™ monotherapy, thyroiditis occurred in 0.6% (5/851) patients receiving LOQTORZI™, including Grade 2 (0.1%). Two of these 5 patients received systemic corticosteroids and 2 required thyroid hormone replacement therapy. Thyroiditis resolved in 2 of the 5 patients. Hyperthyroidism occurred in 7% (55/851) of patients receiving LOQTORZI™, including Grade 2 (1.9%). Hyperthyroidism resolved in 85% (47/55) of the patients. Hypothyroidism occurred in 15% (128/851) of patients receiving LOQTORZI™, including Grade 2 (8%). Sixty three percent of the 128 patients required thyroid hormone replacement therapy. LOQTORZI™ was withheld in 0.5% of patients. Of the 4 patients in whom LOQTORZI™ was withheld, 3 patients reinitiated LOQTORZI™.

Type 1 Diabetes Mellitus, which can present with Diabetic Ketoacidosis

Monitor patients for hyperglycemia or other signs and symptoms of diabetes. Initiate treatment with insulin as clinically indicated. Withhold or permanently discontinue LOQTORZI™ depending on severity. In patients receiving LOQTORZI™ monotherapy, diabetes mellitus occurred in 0.9% (8/851) of patients receiving LOQTORZI™, including Grade 4 (0.1%), Grade 3 (0.7%), and Grade 2 (0.1%). Diabetes mellitus led to permanent discontinuation in 0.4% of patients. Six of the 8 (75%) patients with diabetes mellitus required long-term insulin therapy.

Immune-Mediated Nephritis with Renal Dysfunction

LOQTORZI™ can cause immune-mediated nephritis.

- In patients receiving LOQTORZI™ in combination with cisplatin and gemcitabine, immune-mediated nephritis occurred in 0.7% (1/146) of patients receiving LOQTORZI™. The one patient with immune-mediated nephritis (Grade 4) required systemic corticosteroids and nephritis led to discontinuation of LOQTORZI™. Nephritis resolved in this patient.

Please see Important Safety Information throughout and the Prescribing Information.

IMPORTANT SAFETY INFORMATION, cont'd

Immune-Mediated Nephritis with Renal Dysfunction, cont'd

- In patients receiving LOQTORZI™ monotherapy, immune-mediated nephritis occurred in 0.5% (4/851) of patients, including Grade 3 (0.5%) adverse reactions. Nephritis resolved in 75% (3/4) of these patients.

Immune-Mediated Dermatologic Adverse Reactions

LOQTORZI™ can cause immune-mediated rash or dermatitis. Exfoliative dermatitis, including Stevens-Johnson Syndrome (SJS), drug rash with eosinophilia and systemic symptoms (DRESS), and toxic epidermal necrolysis (TEN), has occurred with PD-1/PD-L1 blocking antibodies. Topical emollients and/or topical corticosteroids may be adequate to treat mild to moderate non-exfoliative rashes. Withhold or permanently discontinue LOQTORZI™ depending on severity.

- In patients receiving LOQTORZI™ in combination with cisplatin and gemcitabine, immune-mediated dermatologic adverse reactions occurred in 8% (12/146) of patients, including Grade 3 (3.4%) and Grade 2 (1.4%) adverse reactions. Systemic corticosteroids were required in 25% (3/12) of the patients with immune-mediated dermatologic adverse reactions. Immune-mediated dermatologic adverse reactions led to permanent discontinuation of LOQTORZI™ in 2.1% (3) of patients. Immune-mediated dermatologic adverse reactions resolved in 92% (11/12) of these patients.

- In patients receiving LOQTORZI™ monotherapy, immune-mediated dermatologic adverse reactions occurred in 4% (34/851) of patients, including Grade 3 (0.4%) and Grade 2 (1.4%) adverse reactions. Immune-mediated dermatologic adverse reactions led to withholding of LOQTORZI™ in 0.4% (3) of the patients. Systemic corticosteroids were required in 12% (4/34) of the patients with immune-mediated dermatologic adverse reactions. Immune-mediated dermatologic adverse reactions resolved in 71% (24/34) of these patients.

Other Immune-Mediated Adverse Reactions

The following clinically significant immune-mediated adverse reactions occurred at an incidence of <1% (unless otherwise noted) in patients who received LOQTORZI™ or were reported with the use of other PD-1/PD-L1 blocking antibodies. Severe or fatal cases have been reported for some of these adverse reactions.

- *Cardiac/Vascular:* Myocarditis, pericarditis, vasculitis, pericardial effusion

- *Nervous System:* Meningitis, encephalitis, myelitis and demyelination, myasthenic syndrome/myasthenia gravis (including exacerbation), Guillain-Barré syndrome, nerve paresis, autoimmune neuropathy

Please see Important Safety Information throughout and the Prescribing Information.

Other Immune-Mediated Adverse Reactions, cont'd

- *Ocular:* Uveitis, iritis and other ocular inflammatory toxicities can occur. Some cases can be associated with retinal detachment. Various grades of visual impairment, including blindness, can occur. If uveitis occurs in combination with other immune-mediated adverse reactions, consider a Vogt-Koyanagi-Harada-like syndrome, as this may require treatment with systemic steroids to reduce the risk of permanent vision loss.

- *Gastrointestinal:* Pancreatitis, to include increases in serum amylase and lipase levels, gastritis, duodenitis

- *Musculoskeletal and Connective Tissue:* Myositis/polymyositis, rhabdomyolysis (and associated sequelae, including renal failure), arthritis, polymyalgia rheumatica, dermatomyositis

- *Endocrine:* Hypoparathyroidism

- *Hematologic/Immune:* Hemolytic anemia, aplastic anemia, hemophagocytic lymphohistiocytosis, systemic inflammatory response syndrome, histiocytic necrotizing lymphadenitis (Kikuchi lymphadenitis), sarcoidosis, immune thrombocytopenic purpura, solid organ transplant rejection

Infusion-Related Reactions

LOQTORZI™ can cause severe or life-threatening infusion-related reactions including hypersensitivity and anaphylaxis.

- In patients receiving LOQTORZI™ in combination with cisplatin and gemcitabine, infusion-related reactions have been reported in 4.1% of patients, including Grade 2 (0.7%) reactions.

- In patients receiving LOQTORZI™ monotherapy, infusion-related reactions occurred in 2% of 851 patients, including Grade 3 (0.1%) and Grade 2 (0.6%). LOQTORZI™ was withheld for one Grade 3 infusion related reaction. Monitor patients for signs and symptoms of infusion-related reactions including rigors, chills, wheezing, pruritus, flushing, rash, hypotension, hypoxemia, and fever. Interrupt or slow the rate of infusion for mild (Grade 1) or moderate (Grade 2) infusion-related reactions. For severe (Grade 3) or life-threatening (Grade 4) infusion-related reactions, stop infusion and permanently discontinue LOQTORZI™.

Please see Important Safety Information throughout and the Prescribing Information.

Complications of Allogeneic Hematopoietic Stem Cell Transplant (HSCT)

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

Embryo-Fetal Toxicity

LOQTORZI™ can cause fetal harm when administered to a pregnant woman. Animal studies have demonstrated that inhibition of the PD-1/PD-L1 pathway can lead to increased risk of immune-mediated rejection of the developing fetus resulting in fetal death. Advise women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with LOQTORZI™ and for 4 months after the last dose.

Lactation

There are no data on the presence of toripalimab-tpzi in human milk; its effects on the breastfed child, or on milk production. Maternal IgG is known to be present in human milk. The effects of local gastrointestinal exposure and limited systemic exposure in the breastfed child to toripalimab-tpzi are unknown. Because of the potential for serious adverse reactions in breastfed children, advise lactating women not to breastfeed during treatment with LOQTORZI™ and for 4 months after the last dose.

Serious Adverse Reactions

- In JUPITER-02, when LOQTORZI™ was administered in combination with cisplatin and gemcitabine for the first-line treatment of recurrent, locally advanced or metastatic nasopharyngeal carcinoma, serious adverse reactions occurred in 43% of patients. Serious adverse drug reactions in ≥2% were thrombocytopenia (14%), neutrophil count decreased (10%), pneumonia (10%), anemia (9%), abnormal hepatic function (2.7%), and rash (2.1%). There were three fatal adverse reactions (2.1%): one due to epistaxis; one due to intracranial hemorrhage associated with immune-related thrombocytopenia and coagulopathy; and one due to pneumonia. Permanent discontinuation of LOQTORZI™, due to an adverse reaction occurred in 12% of patients.

Please see Important Safety Information throughout and the Prescribing Information.

IMPORTANT SAFETY INFORMATION, cont'd

Serious Adverse Reactions, cont'd

Adverse reactions resulting in permanent discontinuation of LOQTORZI™ in ≥1% were pneumonia (2.1%), pulmonary tuberculosis (1.4%), rash (1.4%), and vomiting (1.4%). The most common Grade 3 to 4 laboratory abnormalities (≥2%) were decreased neutrophils (58%), decreased lymphocytes (57%), decreased hemoglobin (50%) decreased platelets (33%), decreased potassium (10%), decreased sodium (9%), increased alanine aminotransferase (6%), increased or decreased magnesium (4.2% each), decreased calcium (3.5%), increased aspartate aminotransferase (2.7%), increased bilirubin (2.1%).

- In POLARIS-02, when LOQTORZI™ was administered as a single agent to patients with previously treated, unresectable or metastatic nasopharyngeal carcinoma, serious adverse reactions occurred in 24% of patients. Serious adverse drug reactions in ≥2% were pneumonia (4.7%), abnormal hepatic function (2.6%), and hyperbilirubinemia (2.1%). Fatal adverse reactions occurred in 3.7% of patients who received LOQTORZI™, including death not otherwise specified (1.6%), tumor hemorrhage (0.5%), hepatic failure and thrombocytopenia (0.5%), hyponatremia (0.5%), and sudden death (0.5%). Permanent discontinuation of LOQTORZI™ due to an adverse reaction occurred in 9% of patients. Adverse reaction resulting in permanent discontinuation of LOQTORZI™ in ≥1% included pneumonia (1.1%), abnormal hepatic function (1.1%), and hyperbilirubinemia (1.1%). The most common Grade 3 or 4 laboratory abnormalities (≥2%), were decreased sodium (11%), decreased lymphocytes (9%), decreased hemoglobin (6%), increased aspartate aminotransferase (3.8%), decreased phosphate (3.2%), and increased alkaline phosphatase (2.2%).

Common Adverse Reactions

- In JUPITER-02, the most common adverse reactions (≥20%) were nausea (71%), vomiting (68%), decreased appetite (55%), constipation (39%), hypothyroidism (38%), rash (36%), pyrexia (32%), diarrhea (31%), peripheral neuropathy (30%), cough (26%), musculoskeletal pain (25%), upper respiratory infection (23%), insomnia (23%), dizziness (21%), and malaise (21%).

- In POLARIS-02, in patients with previously treated, unresectable or metastatic nasopharyngeal carcinoma, the most common (≥20%) adverse reactions were hypothyroidism (27%), fatigue (22%), and cough (20%).

Please see Prescribing Information for LOQTORZI™.

Reference: 1. LOQTORZI™ (toripalimab-tpzi) Prescribing Information. Redwood City, CA: Coherus BioSciences, Inc.

Coherus BIOSCIENCES

LOQTORZI™ (toripalimab-tpzi)injection