Coherus and Junshi Biosciences Announce FDA Approval of LOQTORZI™ (toripalimab-tpzi) in All Lines of Treatment for Recurrent or Metastatic Nasopharyngeal Carcinoma (NPC)

– LOQTORZI is the first and only FDA-approved treatment for NPC –

– Indicated in combination with chemotherapy for 1st line treatment and as monotherapy for patients with disease progression on or after platinum containing chemotherapy, irrespective of PD-L1 status –

– Conference today at 4:30 p.m. Eastern Daylight Time –

REDWOOD CITY, Calif. and SHANGHAI, China, Oct. 27, 2023 (GLOBE NEWSWIRE) -- Coherus BioSciences, Inc. ("Coherus", NASDAQ: CHRS), and Shanghai Junshi Biosciences Co., Ltd. (Junshi Biosciences, HKEX: 1877; SSE: 688180) today announced that the U.S. Food and Drug Administration (FDA) approved LOQTORZI™ (toripalimab-tpzi) in combination with cisplatin and gemcitabine for the first-line treatment of adults with metastatic or recurrent locally advanced NPC, and as monotherapy for the treatment of adults with recurrent, unresectable, or metastatic NPC with disease progression on or after platinum-containing chemotherapy. The approval was based on results of the JUPITER-02 Phase 3 study and the POLARIS-02 Phase 2 study and is irrespective of a patient's PD-L1 status. LOQTORZI is a next-generation, programmed death receptor-1 (PD-1) monoclonal antibody that blocks PD-1 ligands PD-L1 and PD-L2 with high potency at a unique site on the PD-1 receptor, enabling the immune system to activate and kill the tumor.

In the JUPITER-02 Phase 3 study, LOQTORZI combined with chemotherapy significantly improved progression-free survival (PFS), reducing the risk of disease progression or death by 48% compared to chemotherapy alone. LOQTORZI also demonstrated a statistically significant and clinically meaningful improvement in overall survival (OS), with treatment resulting in a 37% reduction in the risk of death versus chemotherapy alone.

The safety profile of LOQTORZI was consistent with the PD-1 inhibitor class. The incidence of Grade ≥3 adverse events (AEs) (89.7% vs 90.2%) and fatal AEs (3.4% vs 2.8%) was similar between the two arms. AEs leading to discontinuation of LOQTORZI versus placebo (11.6% vs 4.9%), immune-related adverse events (irAEs) (54.1% vs. 21.7%), and Grade ≥3 irAEs (9.6% vs. 1.4%) were more frequent in the LOQTORZI arm.

In the POLARIS-02 clinical study LOQTORZI demonstrated durable antitumor activity in patients with recurrent or metastatic NPC who failed previous chemotherapy, with an objective response rate (ORR) of 20.5%, a disease control rate (DCR) of 40.0%, and a median OS of 17.4 months with an acceptable safety profile.

NPC is an aggressive cancer that starts in the nasopharynx, the upper part of the throat behind the nose and near the base of skull. Due to the location of the primary tumor, surgery is rarely an option, and patients with localized disease are treated primarily with radiation and chemotherapy. LOQTORZI is the first FDA-approved agent for NPC patients.

"LOQTORZI's first approval is a pivotal event for Coherus as an innovative oncology company. As a next generation PD-1 inhibitor it is the keystone of our I-O strategy to extend cancer patient survival as shown with the impressive results in NPC," said Denny Lanfear, Chairman and Chief Executive Officer of Coherus. "We are particularly excited to now turn our attention to developing LOQTORZI across multiple tumor types in combination with I-O agents that target the tumor microenvironment, such as our IL27-targeted antibody, casdozokitug, and our CCR8 inhibitor CHS-114, potentially greatly expanding the number of cancer patients achieving improved survival benefit."

"Today's FDA approval of LOQTORZI is very encouraging for those living with NPC who currently have very limited treatment options and are in need of new therapies to treat this aggressive and life-threatening form of cancer," said Jong Chul Park, M.D., Assistant Professor, Harvard Medical School and attending physician at the Center for Head and Neck Cancers at Massachusetts General Hospital Cancer Center. "LOQTORZI is a new treatment option that has demonstrated the ability to significantly improve PFS and OS and should quickly emerge as the new standard of care when used in combination with chemotherapy."

The recommended LOQTORZI dose with cisplatin and gemcitabine is 240 mg every three weeks until disease progression, unacceptable toxicity, or up to 24 months. The recommended LOQTORZI dose as a single agent for previously treated NPC is 3 mg/kg every two weeks until disease progression or unacceptable toxicity.

LOQTORZI is expected to be available in the United States in Q1 2024.

"The impressive results from JUPITER-02 and POLARIS-02 have provided conclusive evidence that establishes toripalimab, in combination with chemotherapy or as monotherapy, as the standard therapy for advanced NPC," said Professor Ruihua Xu of Sun Yat-sen University Cancer Center, the principal investigator of JUPITER-02 and POLARIS-02. "This great achievement was only made possible through the solid foundation laid by countless oncology experts over decades of in-depth research, as well as the selfless dedication of the patients and research teams involved in our toripalimab studies. We hope that this promising therapy will close the treatment gap for international NPC patients struggling to find effective therapies, bringing them renewed hope for better survival."

"We're excited to reach another significant company milestone of 'going overseas'," said Dr. Ning LI, Chief Executive Officer of Junshi Biosciences. "Following etesevimab, toripalimab has become Junshi Biosciences' second product to receive FDA approval for commercialization—an achievement that will further enhance the company's international presence. Currently, the establishment of toripalimab's global commercialization network is in progress, and the network aims to span over 50 countries. In accordance with the company's 'In China, For Global' strategy, we will continue working with our collaborators to promote the commercialization of toripalimab in other regions, in order to provide innovative and high-quality drugs from China to more patients overseas."

About JUPITER-02
JUPITER-02 is the largest randomized, double-blind, placebo-controlled, international, multi-center Phase 3 clinical study to evaluate a checkpoint inhibitor plus chemotherapy for the first-line treatment of recurrent or metastatic NPC.

Two hundred eighty-nine patients with advanced NPC who had received no prior chemotherapy for recurrent/metastatic disease were randomized 1:1 to receive LOQTORZI (toripalimab-tzpi) 240 mg or placebo in combination with gemcitabine 1000 mg/m^2 (days 1 and 8) and cisplatin 80 mg/m^2 (day

1) of every three-week treatment cycle, followed by toripalimab-tzpi or placebo monotherapy every 3 weeks until disease progression, intolerable toxicity, or completion of two years of treatment. JUPITER-02 included all eligible patients regardless of PD-L1 status and histologies.

In this study, LOQTORZI met the primary endpoint, demonstrating a significant improvement in PFS (assessed by a Blinded Independent Review Committee (BIRC)) compared to the chemotherapy alone arm with toripalimab-tzpi, reducing the risk of disease progression or death by 48% (HR=0.52 [95% CI: 0.36, 0.74; P<0.0003). Improvement in PFS was observed irrespective of PD-L1 status.

LOQTORZI demonstrated a statistically significant and clinically meaningful improvement in OS with treatment resulting in a 37% reduction in the risk of death versus chemotherapy alone. Median OS has not been reached in the LOQTORZI arm versus 33.7 months for chemotherapy treatment alone (HR=0.63 [95% CI 0.45-0.89]; P=0.0083).

LOQTORZI also demonstrated an improvement in ORR, duration of response (DoR), and DCR. In the study, 77% of patients treated with LOQTORZI experienced a complete or partial response (19% and 58% respectively) and the median duration of response was 10 months in the LOQTORZI arm versus 5.7 months in the chemotherapy alone arm.

About LOQTORZI Solutions
Coherus is committed to supporting patients with programs for zero out-of-pocket costs or patient assistance for eligible patients so that they may benefit from a proven PD-1 immunotherapy, with less financial burden.
Our robust patient support services include:

- Reimbursement support
- Patient support
- Access support

Commitment to the NPC community
Given the limited resources available to patients and caregivers contending with NPC, Coherus has launched a new educational community resource, NPCFacts.com, which includes detailed information about the types of NPC as well as its causes, diagnosis, and treatment options.
In addition to education about nasopharyngeal carcinoma, the website includes links to patient-advocacy organizations providing additional resources, including the Head and Neck Cancer Alliance, Support for People with Oral Head and Neck Cancer, and Thyroid Head and Neck Cancer Foundation. The website includes a companion website for healthcare professionals treating patients with NPC, including educational resources and opportunities for peer-to-peer education.

About NPC
NPC is a type of aggressive cancer that starts in the nasopharynx, the upper part of the throat behind the nose and near the base of the skull. NPC is rare in the United States, with an annual incidence of fewer than one per 100,000. The five-year survival rate for all patients diagnosed with NPC is approximately 60%, however, those who are diagnosed with advanced disease have a five-year survival rate of approximately 49%.

Due to the location of the primary tumor, surgery is rarely an option, and patients with localized disease are treated primarily with radiation and chemotherapy. Patients treated with chemotherapy alone experience poor prognosis: only 20% experience one-year PFS; up to 50% developed distant metastasis during their disease course; and low median OS of 29 months.

LOQTORZI™ is the first FDA-approved therapy for NPC and will represent a new standard of care for treating the disease when used in combination with cisplatin and gemcitabine in the first line setting or as monotherapy in the second line or greater setting.

About LOQTORZI™ (toripalimab-tpzi)
LOQTORZI is a next generation anti-PD-1 monoclonal antibody that blocks PD-L1 binding to the PD-1 receptor at a unique site with high affinity and activates antitumor immunity demonstrating improvement in the overall survival of cancer patients in several tumor types.

INDICATIONS AND IMPORTANT SAFETY INFORMATION

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.

- 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.
- 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.

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.

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.

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.

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.

- 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.
- 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
- *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.

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. 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 and Medication Guide

Conference Call Information

When: Friday, October 27, 2023, starting at 4:30 p.m. Eastern Time / 1:30 p.m. Pacific Time

To access the conference call, please pre-register through the following link to receive dial-in information and a personal PIN to access the live call: https://register.vevent.com/register/BI5e94411d336341ba89d7e9eed804e892

Please dial-in 15 minutes early to ensure a timely connection to the call.

Webcast Link: https://edge.media-server.com/mmc/p/hpvx6oka

A replay of the webcast will be archived on the “Investors” section of the Coherus website at http://investors.coherus.com.

About Coherus BioSciences
Coherus is a commercial-stage biopharmaceutical company focused on the research, development and commercialization of innovative immunotherapies to treat cancer. Coherus is developing an innovative immuno-oncology pipeline that will be synergistic with its proven commercial capabilities in oncology.

Coherus’ immuno-oncology pipeline includes multiple antibody immunotherapy candidates focused on enhancing the innate and adaptive immune responses to enable a robust immunologic response and enhance outcomes for patients with cancer. Casdozokitug is a novel anti-IL-27 antibody currently being evaluated in Phase 1/2 clinical trials in lung and liver cancer. CHS-114 is a highly selective, competitively positioned, ADCC-enhanced anti-CCR8 antibody currently in a Phase 1/2 study as a monotherapy in patients with advanced solid tumors.

Coherus’ earlier-stage immuno-oncology pipeline targets immune-suppressive mechanisms, including CHS-006, a TIGIT-targeted antibody, being evaluated in a Phase 1/2 clinical trial in combination with LOQTORZI in patients with advanced solid tumors, and CHS-1000, a preclinical program targeting the novel pathway ILT4.

Coherus markets UDENYCA® (pegfilgrastim-cbqv), a biosimilar of Neulasta®, CIMERLI® (ranibizumab-eqrn), a biosimilar of Lucentis®, YUSIMRY™ (adalimumab-aqvh), a biosimilar of Humira® and expects to launch LOQTORZI (toripalimab-tpzi), a novel next generation PD-1 inhibitor, in the U.S. in Q1 2024.

About Junshi Biosciences
Founded in December 2012, Junshi Biosciences (HKEX: 1877; SSE: 688180) is an innovation-driven biopharmaceutical company dedicated to the discovery, development, and commercialization of innovative therapeutics. The company has established a diversified R&D pipeline comprising more than 50 drug candidates, with five therapeutic focus areas covering cancer, autoimmune, metabolic, neurological, and infectious diseases. Four of the company's innovations have already reached the Chinese or international markets, one of which is China's first self-developed anti-PD-1 monoclonal antibody, toripalimab. Additionally, more than 30 drugs are currently in clinical development. During the COVID-19 pandemic, Junshi Biosciences actively shouldered the social responsibilities of a Chinese pharmaceutical company through its involvement in developing etesevimab, MINDEWEI®, and other novel therapies for the prevention and treatment of COVID-19.

With a mission of "providing patients with world-class, trustworthy, affordable, and innovative drugs", Junshi Biosciences is "In China, For Global." At present, the company has approximately 3,000 employees in the United States (California and Maryland) and China (Shanghai, Suzhou, Beijing, Guangzhou, etc). For more information, please visit: http://junshipharma.com.

Forward-Looking Statements
Except for the historical information contained herein, the matters set forth in this press release are forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995 including, but not limited to, statements regarding Coherus' ability to achieve synergies between its I-O pipeline and its commercial capabilities; Coherus' expectations for the selectivity and competitive positioning of any of its product candidates; Coherus' expectations that LOQTORZI ™ will represent the new standard of care for NPC; Coherus' projected timing for commercial availability of LOQTORZI ™; Coherus' expectations for the development of LOQTORZI™ in combination with I-O agents that target the tumor microenvironment; and Coherus' ability to gain approval for any of its product candidates and the timing of such approval. Such forward-looking statements involve substantial risks and uncertainties that could cause Coherus' actual results, performance or achievements to differ significantly from any future results, performance or achievements expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, risks and uncertainties inherent in the clinical drug development process; risks relating to the COVID-19 pandemic; risks related to our existing and potential collaboration partners; risks of the drug development position of Coherus' competitors; the risks and uncertainties of the integration process following Coherus' acquisition of Surface Oncology, Inc.; the risks and uncertainties of the regulatory approval process, including the speed of regulatory review, international aspects of Coherus' business; the timing of Coherus' regulatory filings; the risk of FDA review issues; the risk of Coherus' execution of its change in strategy from a focus on biosimilars to a strategy using cash from its portfolio to fund an oncology franchise; the risk that Coherus is unable to complete commercial transactions and other matters that could affect the availability or commercial potential of Coherus' drug candidates; and the risks and uncertainties of possible litigation. All forward-looking statements contained in this press release speak only as of the date of this press release. Coherus undertakes no obligation to update or revise any forward-looking statements. For a further description of the significant risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to Coherus' business in general, see Coherus' Quarterly Report on Form 10-Q the quarter ended June 30, 2023, filed with the Securities and Exchange Commission on August 2, 2023, including the section therein captioned "Risk Factors" and in other documents Coherus files with the Securities and Exchange Commission.

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A photo accompanying this announcement is available at https://www.globenewswire.com/NewsRoom/AttachmentNg/0309b960-26f3-48b4-97a8-2076d70bbb71

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