Coherus and Junshi Biosciences Announce Publication of Positive Final Overall Survival Results of JUPITER-02, a Phase 3 Trial Evaluating LOQTORZI™ (toripalimab-tpzi) as Treatment for Nasopharyngeal Carcinoma, in the Journal of the American Medical Association

Nov 28, 2023

– Final overall survival analysis of the JUPITER-02 trial shows first-line treatment with LOQTORZI plus chemotherapy significantly prolongs survival in patients with recurrent or metastatic NPC irrespective of PDL-1 status–

– Treatment resulted in a 37% reduction in the risk of death versus chemotherapy alone –

— LOQTORZI is the first and only FDA-approved treatment for recurrent or metastatic NPC in all lines of therapy and will be available to NPC patients in the U.S. in January 2024 –

REDWOOD CITY, Calif. And SHANGHAI, China, Nov. 28, 2023 (GLOBE NEWSWIRE) -- Coherus BioSciences, Inc. (Coherus, Nasdaq: CHRS) and Shanghai Junshi Biosciences Co., Ltd (Junshi Biosciences, HKEX: 1877; SSE: 688180) announced today the publication of the final overall survival (OS) results from the pivotal JUPITER-02 study (NCT03581786), a randomized, double-blind, placebo-controlled, international, multi-center Phase 3 clinical trial evaluating the immune checkpoint inhibitor LOQTORZI™ (toripalimab-tpzi), in combination with the chemotherapy agents gemcitabine and cisplatin, as a first-line treatment for patients with recurrent or metastatic nasopharyngeal carcinoma (NPC) in the Journal of the American Medical Association (JAMA). As previously reported at the 2023 American Society of Clinical Oncologists (ASCO) Annual Meeting, the final analysis revealed a 37% reduction in the risk of death in NPC patients treated with toripalimab plus chemotherapy versus chemotherapy alone.

In October, Coherus and Junshi announced the U.S. Food and Drug Administration (FDA) approval of LOQTORZI 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. Coherus plans to launch LOQTORZI in the United States in January 2024.

“There are limited options for patients living with this aggressive head and neck cancer. New treatment options are desperately needed for underserved cancer patients particularly ones with rare cancers,“ said Robert Ferris, M.D., Ph.D., director of UPMC Hillman Cancer Center in Pittsburgh, PA. “As these data demonstrate, toripalimab clearly has the potential to significantly extend both progression-free and overall survival for patients living with NPC, and I believe this approach will offer a new standard of care for patients.”

“The final OS data published in JAMA demonstrates the potential of LOQTORZI to significantly extend survival while slowing the progression of NPC, an aggressive form of cancer which up until now has had no approved therapies and therefore represents an important unmet need for patients in the US living with NPC,” said Rosh Dias, M.D., Chief Medical Officer at Coherus. “As a next-generation PD-1 monoclonal antibody showing both a statistically significant and clinically meaningful OS advantage, and as the first and only FDA approved treatment for NPC, LOQTORZI should quickly become the new standard of care when used in combination with chemotherapy to treat patients living with NPC.”

Titled ***Toripalimab plus Chemotherapy for Recurrent or Metastatic Nasopharyngeal Carcinoma***, the paper highlights the addition of LOQTORZI to gemcitabine-cisplatin (GP) chemotherapy as first-line treatment for patients with recurrent or metastatic NPC provided superior OS compared to GP alone [HR=0.63 (95% CI: 0.45-0.89), two-sided p=0.008]. The median OS was not reached in the LOQTORZI arm and was 33.7 months in the placebo arm. The 2-year and 3-year OS rates were 78.0% vs. 65.1%, and 64.5% vs. 49.2% respectively. A consistent effect on OS, favoring the LOQTORZI arm, was observed in the majority of the subgroups, including PD-L1 expression and EBV copy number high and low subgroups. The addition of LOQTORZI to chemotherapy also provided superior progression-free survival (PFS) compared to chemotherapy alone, with a median PFS of 21.4 vs. 8.2 months [HR=0.52 (95% CI: 0.37, 0.73)]. The safety profile was consistent with that previously reported in other toripalimab clinical trials and consistent with the PD-1 inhibitor class. The full results can be found in the online edition of JAMA.

"From the oral presentation at the ASCO Annual meeting’s Plenary Session, to the cover article of *Nature Medicine*, and now publication in *JAMA*, the survival benefits of JUPITER-02 have become increasingly evident, gradually establishing the status of toripalimab plus chemotherapy as the first-line standard treatment for advanced NPC. We are extremely proud to contribute to the international advancement of the clinical diagnosis and treatment of NPC," said Professor Ruihua Xu, JUPITER-02's principal investigator from Sun Yat-sen University Cancer Centre. "The latest 3-year follow-up data showed that the combination of toripalimab with GP chemotherapy significantly reduced the risk of death by 37% and the risk of disease progression by 48%, and the 3-year OS rate reached 64.5%, an encouraging result for the first-line treatment of advanced NPC. Moreover, the addition of toripalimab did not increase the incidence of grade≥3 adverse events, nor did it increase the incidence of fatal adverse events and displayed a manageable safety profile."

"Toripalimab in combination with chemotherapy is the world's first and only first-line treatment for recurrent/metastatic NPC to achieve both statistically and clinically significant OS benefits in a Phase 3 study," said Dr. Jianjun Zou, Global Research and Development President of Junshi Biosciences. "At present, this innovative treatment has been approved in China and the U.S. And through extensive cooperation, we strive for toripalimab to reach other parts of the world to provide more patients with better treatment options."

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

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 two on-going clinical studies: a Phase 1/2 study in advanced solid tumors and a Phase 2 study in hepatocellular carcinoma. 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 January 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 toripalimab, first China's homegrown and self-developed anti-PD-1 monoclonal antibody approved in China and the U.S. 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 find synergies between its I-O pipeline and its commercial operations; expectations for the launch date of LOQTORZI ™ and expectations that treatment with LOQTORZI ™ in combination with chemotherapy will become the new standard-of-care for patients with NPC.

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, the risks and uncertainties inherent in the clinical drug development process; risks related to realizing the anticipated benefits of the acquisition of Surface; risks related to Coherus' existing and potential collaboration partners; risks of Coherus' competitive position; the risks and uncertainties of the regulatory approval process, including the speed of regulatory review, international aspects of Coherus' business and the timing of Coherus' regulatory filings; the risk of FDA review issues; the risk that Coherus is unable to complete commercial transactions and other matters that could affect the availability or commercial potential of Coherus' products and product 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 for the fiscal quarter ended September 30, 2023 filed with the Securities and Exchange Commission on November 6, 2023, including the section therein captioned "Risk Factors" and in other documents Coherus files with the Securities and Exchange Commission.

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