Coherus and Junshi Biosciences Announce Publication of Positive Results from CHOICE-01, a Phase 3 Clinical Trial Evaluating Toripalimab in Combination with Chemotherapy as First-Line Treatment for Non-Small Cell Lung Cancer, in the Journal of Clinical Onc

– Toripalimab in combination with chemotherapy was associated with significant improvements in PFS and OS compared with chemotherapy alone in patients with advanced NSCLC without EGFR/ALK mutations, regardless of PD-L1 expression

– Supports combination development of toripalimab plus anti-TIGIT in NSCLC and other solid tumor indications

REDWOOD CITY, Calif. and SHANGHAI, China, Oct. 12, 2022 (GLOBE NEWSWIRE) -- Coherus BioSciences, Inc. (“Coherus”, Nasdaq: CHRS) and Shanghai Junshi Biosciences Co., Ltd (“Junshi Biosciences”, HKEX: 1877; SSE: 688180) today announced the publication of ***toripalimab plus chemotherapy for patients with treatment-naïve advanced non-small cell lung cancer: a multi-center randomized phase 3 trial (CHOICE-01)*** in the *Journal of Clinical Oncology*.

Toripalimab in combination with chemotherapy was associated with significant improvements in progression-free survival (PFS) (primary endpoint) and overall survival (OS) (secondary endpoint) compared with chemotherapy alone in patients with advanced non-small cell lung cancer ("NSCLC") without epidermal growth factor receptor (EGFR)/anaplastic lymphoma kinase (ALK) mutations, regardless of PD-L1 expression. No new safety signals were observed with toripalimab in this study.

“These data support our strategy for toripalimab in non-small cell lung cancer where we plan to evaluate toripalimab in combination with other immuno-oncology agents, including our TIGIT-targeted antibody, CHS-006/JS006, in patients with NSCLC as well as for other indications in the U.S.,” said Rosh Dias, MD, MRCP, Chief Medical Officer at Coherus.

A total of 465 patients with treatment-naïve, advanced NSCLC without EGFR/ALK mutations were randomized 2:1 to receive toripalimab 240 mg (n=309, “the toripalimab arm”) or placebo (n=156, “the placebo arm”) in combination with chemotherapy for 4-6 cycles, followed by the maintenance of toripalimab or placebo plus standard care. PFS was the primary endpoint.

Statistically significant improvements in both PFS and OS were detected in the toripalimab arm compared with the placebo arm, with similar rates of adverse events (AEs). At the final analysis, PFS was significantly longer in the toripalimab arm than in the placebo arm (median PFS 8.4 vs 5.6 months; 1-year PFS rates 36.7% vs 17.2%). At the interim OS analysis, the toripalimab arm had a significantly longer OS than the placebo arm (median OS not reached vs 17.1 months). OS rates at 2 years were 51.2% vs 33.9%, in the two arms. The incidence of Grade > 3 AEs was similar between the two arms (78.6% vs 82.1%).

About CHOICE-01
The CHOICE-01 study was a multi-center, randomized double-blind, placebo-controlled phase 3 study conducted in 59 centers across China. 465 treatment-naïve advanced NSCLC patients without EGFR/ALK mutations were randomized to receive either toripalimab plus chemotherapy (n=309) or placebo plus chemotherapy (n=156). The primary endpoint was PFS assessed by the investigator. Secondary endpoints included PFS assessed by a blinded independent review committee (BIRC), OS, and safety. Patients from the placebo arm were actively crossed over to toripalimab treatment upon disease progression. The trial was conducted in full conformance with the ICH E6 guidelines for Good Clinical Practice and the principles of the Declaration of Helsinki.

As of October 31, 2021:

- At the final analysis, a significant improvement in PFS was detected in the toripalimab arm over the placebo arm (hazard ratio (HR)=0.49; 95% confidence interval (CI): 0.39-0.61, P<0.0001) with median PFS of 8.4 vs. 5.6 months. The 1-year PFS rates for the toripalimab and placebo arms were 36.7% and 17.2%, respectively.
- PFS as assessed by BIRC was also significantly longer in the toripalimab arm.
- A prespecified interim analysis demonstrated a statistically significant improvement in OS for the toripalimab arm over the placebo arm (median OS not reached vs. 17.1 months, HR = 0.69 (95% CI: 0.53-0.92)).
- The PFS benefits were observed in patients treated with toripalimab plus chemotherapy across key subgroups, including histologic subtype and tumor PD-L1 expression.
- The addition of toripalimab to standard first-line chemotherapy in patients with advanced NSCLC showed a manageable safety profile with no new safety signals observed. The incidence of Grade ≥3 AEs was 78.6% in the toripalimab arm vs. 82.1% in the placebo arm. AEs leading to discontinuation rates of toripalimab or placebo were 14.3% vs. 3.2%, respectively.
- An exploratory genomic analysis showed that high tumor mutational burden was associated with significantly better PFS in the toripalimab plus chemotherapy arm and that mutations in the FA-PI3K-Akt pathway were associated with significantly better PFS and OS in the toripalimab plus chemotherapy arm

In China, the National Medical Products Administration ("NMPA") approved the supplemental new drug application for toripalimab in combination with pemetrexed and platinum as the first-line treatment in EGRF mutation-negative and ALK mutation-negative, unresectable, locally advanced or metastatic non-squamous NSCLC.

About Toripalimab
Toripalimab is an anti-PD-1 monoclonal antibody developed for its ability to block PD-1 interactions with its ligands, PD-L1 and PD-L2, and for

enhanced receptor internalization (endocytosis function). Blocking PD-1 interactions with PD-L1 and PD-L2 promotes the immune system's ability to attack and kill tumor cells.

More than thirty company-sponsored toripalimab clinical studies covering more than fifteen indications have been conducted globally by Junshi Biosciences, including in China, the United States, Southeast Asia, and European countries. Ongoing or completed pivotal clinical trials evaluating the safety and efficacy of toripalimab cover a broad range of tumor types including cancers of the lung, nasopharynx, esophagus, stomach, bladder, breast, liver, kidney and skin.

In China, toripalimab was the first domestic anti-PD-1 monoclonal antibody approved for marketing (approved in China as TUOYI®). Currently, there are six approved indications for toripalimab in China:

1. unresectable or metastatic melanoma after failure of standard systemic therapy;
2. in combination with cisplatin and gemcitabine as the first-line treatment for patients with locally recurrent or metastatic nasopharyngeal carcinoma ("NPC").
3. recurrent or metastatic NPC after failure of at least two lines of prior systemic therapy;
4. locally advanced or metastatic urothelial carcinoma that failed platinum-containing chemotherapy or progressed within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy;
5. in combination with paclitaxel and cisplatin in first-line treatment of patients with unresectable locally advanced/recurrent or distant metastatic esophageal squamous cell carcinoma ("ESCC");
6. in combination with pemetrexed and platinum as the first-line treatment in EGFR mutation-negative and ALK mutation-negative, unresectable, locally advanced or metastatic non-squamous NSCLC.

The first three indications have been included in the National Reimbursement Drug List ("NRDL") (2021 Edition). Toripalimab is the only anti-PD-1 monoclonal antibody included in the NRDL for melanoma and NPC.

In the United States, the FDA is reviewing the Biologics License Application ("BLA") resubmission for toripalimab in combination with gemcitabine and cisplatin as first-line treatment for patients with advanced recurrent or metastatic nasopharyngeal carcinoma ("NPC") and for toripalimab monotherapy for the second-line or later treatment of recurrent or metastatic NPC after platinum-containing chemotherapy. The FDA has set a Prescription Drug User Fee Act ("PDUFA") action date for December 23, 2022. The FDA has granted Breakthrough Therapy designations for toripalimab in combination with chemotherapy for the first-line treatment of recurrent or metastatic NPC as well as for toripalimab monotherapy in the second or third-line treatment of recurrent or metastatic NPC. Additionally, the FDA has granted Fast Track designation for toripalimab for the treatment of mucosal melanoma and Orphan Drug designations for the treatment of esophageal cancer, NPC, mucosal melanoma, soft tissue sarcoma, and small cell lung cancer ("SCLC").

In the European Union, toripalimab was also designated as an orphan medicinal product by the European Commission for the treatment of NPC.

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 over 50 drug candidates, with five therapeutic focus areas covering cancer, autoimmune, metabolic, neurological, and infectious diseases. Junshi Biosciences was the first Chinese pharmaceutical company that obtained marketing approval for anti-PD-1 monoclonal antibody in China. Its first-in-human anti-BTLA antibody for the treatment of various cancers was the first in the world to be approved for clinical trials by the FDA and NMPA and has since entered Phase Ib/II trials in both China and the US. Its anti-PCSK9 monoclonal antibody was the first in China to be approved for clinical trials by the NMPA.

In the face of the pandemic, Junshi Biosciences' response was strong and immediate, joining forces with Chinese and international scientific research institutions and enterprises to develop an arsenal of drug candidates to combat COVID-19, taking the initiative to shoulder the social responsibility of Chinese pharmaceutical companies by prioritizing and accelerating COVID-19 R&D. Among the many drug candidates is JS016 (etesevimab), China's first neutralizing fully human monoclonal antibody against SARS-CoV-2 and the result of the combined efforts of Junshi Biosciences, the Institute of Microbiology of the Chinese Academy of Science and Lilly. JS016 administered with bamlanivimab has been granted Emergency Use Authorizations (EUA) in over 15 countries and regions worldwide. As of December 3 2021, over 700,000 patients have been treated with bamlanivimab or bamlanivimab and etesevimab, potentially preventing more than 35,000 hospitalizations and at least 14,000 deaths. Meanwhile, VV116, a new oral nucleoside analog anti-SARS-CoV-2 drug designed to hinder virus replication, is in global Phase III clinical trials. A Phase III clinical study (NCT05341609) comparing the efficacy and safety of VV116 versus nirmatrelvir/ritonavir ("PAXLOVID") for patients with mild to moderate COVID-19 who are at high risk for progression to severe COVID-19, has reached its pre-specified primary endpoint and secondary efficacy endpoint. The study results show that compared to PAXLOVID, VV116 provided patients with a shorter median time to sustained clinical recovery, while achieving statistical superiority. The JS016 and VV116 programs are a part of the company's continuous innovation for disease control and prevention of the global pandemic.

Junshi Biosciences has more than 3,100 employees in the United States (San Francisco and Maryland) and China (Shanghai, Suzhou, Beijing, Guangzhou, etc). For more information, please visit: http://junshipharma.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' strategy is to build a leading immuno-oncology franchise funded with cash generated through net sales of its diversified portfolio of FDA-approved therapeutics.

In 2021, Coherus in-licensed toripalimab, an anti-PD-1 antibody, in the United States and Canada. A BLA for toripalimab for the treatment of nasopharyngeal carcinoma is under review by the FDA with a target action date of December 23, 2022. Toripalimab is also being evaluated in pivotal clinical trials for the treatment of cancers of the lung, breast, liver, skin, kidney, stomach, esophagus, and bladder.

Coherus markets UDENYCA® (pegfilgrastim-cbqv), a biosimilar of Neulasta®, and CIMERLI™ (ranibizumab-eqrn), a biosimilar of Lucentis®, in the U.S., and expects to launch the FDA-approved Humira® biosimilar YUSIMRY™ (adalimumab-aqvh) in the U.S. in 2023.

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 build its immuno-oncology franchise to achieve a leading market position; Coherus' ability to generate cash; Coherus' investment plans; Coherus' expectations for the launch date of YUSIMRY™ and Coherus' plans to evaluate toripalimab in combination with other immune-oncology agents. 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 regulatory approval process, including the speed of regulatory review, international aspects of Coherus' business, the need to schedule inspections in China and 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' Annual Report on Form 10-Q for the quarter ended June 30, 2022, filed with the Securities and Exchange Commission on August 4, 2022, including the section therein captioned "Risk Factors" and in other documents that Coherus files with the Securities and Exchange Commission.

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