Junshi Biosciences and Coherus Announce Presentation 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, at March ASCO Plenary Series

– Toripalimab plus chemotherapy met both primary endpoint of progression free survival and prespecified secondary endpoint of overall survival compared to chemotherapy alone –

- Data support the use of toripalimab with chemotherapy as first-line treatment for advanced NSCLC patients without EGFR/ALK mutations -

SHANGHAI, China, and REDWOOD CITY, Calif., March 15, 2022 (GLOBE NEWSWIRE) -- Shanghai Junshi Biosciences Co., Ltd. ("Junshi Biosciences", HKEX: 1877; SSE: 688180) and Coherus BioSciences, Inc. ("Coherus", Nasdaq: CHRS), today announced the presentation of positive results and biomarker analyses from the pivotal study "CHOICE-01" (clinicaltrials.gov identifier# NCT03856411), a randomized, double-blind, placebo-controlled Phase 3 clinical trial evaluating toripalimab plus chemotherapy as first-line treatment of advanced squamous or non-squamous non-small cell lung cancer ("NSCLC"). The final progression-free survival ("PFS") analysis confirms the finding of the previous interim PFS analysis, demonstrating a statistically significant and clinically meaningful improvement in PFS per RECIST v1.1 compared to chemotherapy alone. The study also demonstrated an improvement in overall survival ("OS") in a prespecified interim OS analysis. These results will be summarized later today during the ASCO Plenary Series, in an oral presentation by Professor Jie Wang, MD, PhD, from the National Cancer Center/National Clinical Research Center for Cancer/Cancer Hospital, Chinese Academy of Medical Sciences & Peking Union Medical College. The abstract is now available on the ASCO website.

"We are excited about the consistently strong clinical evidence that toripalimab has displayed across multiple tumor types," said Dr. Patricia Keegan, Chief Medical Officer at Junshi Biosciences. "The addition of toripalimab to chemotherapy in patients with advanced NSCLC provided superior PFS and OS compared to chemotherapy alone with a manageable safety profile. These results support the use of toripalimab with chemotherapy as first-line therapy for advanced NSCLC patients without EGFR/ALK mutations."

"In the CHOICE-01 study in patients with non-small cell lung cancer, toripalimab has once again demonstrated the potential to delay disease progression and help patients live longer," said Theresa LaVallee, PhD, Chief Development Officer at Coherus. "The study investigators also reported interesting biomarker data with toripalimab plus chemotherapy having activity independent of PD-L1 expression as well as a statistically significant overall survival advantage in NSCLC patients who have alterations in the focal adhesion-PI3K-AKT signaling pathway, a finding which may inform the design of future toripalimab clinical trials."

About CHOICE-01
A total of 465 treatment-naïve advanced NSCLC patients without EGFR/ALK mutations were randomized (2:1): 309 to toripalimab plus chemotherapy (the "toripalimab arm") and 156 to placebo plus chemotherapy (the "placebo arm"). 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.

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 overall survival for the toripalimab arm over the placebo arm (median OS not reached vs. 17.1 months, HR = 0.69 (95% CI: 0.52-0.92)).
- The PFS benefits were observed in patients treated with toripalimab plus chemotherapy across key subgroups, including histologic subtype and tumor PD-L1 expression.
- Genomic analysis revealed a PFS benefit associated with high tumor mutation burden and with genetic alterations in the focal adhesion-PI3K-AKT and IL-7 pathways in patients treated with toripalimab plus chemotherapy.
- 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 adverse events (AEs) was 78.6% in the toripalimab arm vs. 82.1% in the placebo arm. AEs leading to discontinuation of toripalimab or placebo were 14.3% vs. 3.2%, respectively.

Junshi Biosciences and Coherus are evaluating potential registration avenues for toripalimab in combination with chemotherapy for the first-line treatment of advanced non-small cell lung cancer in the United States. In China, the supplemental New Drug Application for this indication was accepted in December 2021 by the National Medical Products Administration ("NMPA").

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 promote 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 four approved indications for toripalimab in China:

1. unresectable or metastatic melanoma after failure of standard systemic therapy;
2. recurrent or metastatic nasopharyngeal carcinoma (“NPC”) after failure of at least two lines of prior systemic therapy;
3. locally advanced or metastatic urothelial carcinoma that failed platinum-containing chemotherapy or progressed within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy;
4. in combination with cisplatin and gemcitabine as the first-line treatment for patients with locally recurrent or metastatic NPC.

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 addition, two supplemental New Drug Applications (“NDAs”) for toripalimab are currently under review by the National Medical Products Administration (“NMPA”) in China:

- in combination with chemotherapy as the first-line treatment of patients with advanced or metastatic ESCC.
- in combination with chemotherapy as the first-line treatment of patients with advanced or metastatic NSCLC without EGFR or ALK mutations.

In the United States, the FDA has granted priority review for the toripalimab biologics license application (“BLA”) for the treatment of recurrent or metastatic NPC, an aggressive head and neck tumor which has no FDA-approved immuno-oncology treatment options. The FDA has assigned a Prescription Drug User Fee Act (“PDUFA”) target action date for April 2022 for the toripalimab BLA. The FDA granted Breakthrough Therapy designation for toripalimab in combination with chemotherapy for the first-line treatment of recurrent or metastatic NPC in 2021 as well as for toripalimab monotherapy in the second or third-line treatment of recurrent or metastatic NPC in 2020. Additionally, the FDA has granted Fast Track designation for toripalimab for the treatment of mucosal melanoma and orphan drug designation for the treatment of esophageal cancer, NPC, mucosal melanoma and soft tissue sarcoma. In 2021, Coherus in-licensed rights to develop and commercialize toripalimab in the United States and Canada. Coherus and Junshi Biosciences plan to file additional toripalimab BLAs with the FDA over the next three years for multiple other cancer types.

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 45 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 solid tumors was the first in the world to be approved for clinical trials by the FDA and NMPA and its anti-PCSK9 monoclonal antibody was the first in China to be approved for clinical trials by the NMPA. In early 2020, Junshi Biosciences joined forces with the Institute of Microbiology of the Chinese Academy of Science and Eli Lilly to co-develop JS016 (etesevimab), China’s first neutralizing fully human monoclonal antibody against SARS-CoV-2. JS016 administered with bamlanivimab has been granted Emergency Use Authorizations (“EUA”) in over 15 countries and regions worldwide. The JS016 program is a part of our continuous innovation for disease control and prevention of the global pandemic. Junshi Biosciences has over 2,500 employees in the United States (San Francisco and Maryland) and China (Shanghai, Suzhou, Beijing and Guangzhou). 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 metastatic or recurrent nasopharyngeal carcinoma is currently under priority review by the FDA, with a target action date of April 30, 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® in the United States, and expects to launch the FDA-approved Humira® biosimilar YUSIMRY™ (adalimumab-aqvh) in the United States in 2023. The FDA is currently reviewing the BLA for CIMERLI™,, formerly known as CHS-201, a biosimilar of Lucentis® (ranibizumab), with a target action date of August 2022. Coherus is also developing CHS-305, a biosimilar of Avastin® (bevacizumab).

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™ (adalimumab-aqvh); and expectations for the potential of toripalimab plus chemotherapy to offer improved PFS and OS compared to chemotherapy.

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 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 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 of FDA-approved therapeutics to fund an immuno-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-K for the year ended December 31, 2021, filed with the Securities and Exchange Commission on February 23, 2022, including the section therein

captioned “Risk Factors” and in other documents we file with the Securities and Exchange Commission.
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Source: Coherus BioSciences, Inc.