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# Junshi Biosciences and Coherus Present Results of Phase 3 Study of Toripalimab in First Line Treatment of Recurrent or Metastatic Nasopharyngeal Carcinoma at 2022 AACR Annual Meeting

**- Toripalimab plus chemotherapy provided superior progression free survival, overall survival, overall response rate and duration of response compared to chemotherapy alone -**

SHANGHAI, China, and REDWOOD CITY, Calif., April 09, 2022 (GLOBE NEWSWIRE) -- Shanghai Junshi Biosciences Co., Ltd ("Junshi Biosciences", HKEX: 1877; SSE: 688180) and Coherus BioSciences, Inc. ("Coherus") announced the results of the prespecified final progression-free survival ("PFS") analysis and the interim overall survival ("OS") analysis of the JUPITER-02 study (NCT03581786), a pivotal Phase 3 trial in first-line treatment of recurrent or metastatic nasopharyngeal carcinoma ("NPC"). The JUPITER-02 results are summarized in a poster presentation at the annual meeting of the American Association for Cancer Research ("AACR").

In the final PFS analysis, results from JUPITER-02 demonstrated that toripalimab in combination with chemotherapy provided a statistically significant improvement in PFS assessed by the blinded independent review committee ("BIRC") compared to chemotherapy plus placebo, with an improvement in median PFS of 13.2 months (21.4 versus 8.2 months). Furthermore, the addition of toripalimab to chemotherapy provided significant improvements in the secondary endpoints of PFS assessed by the investigator, objective response rate ("ORR") and duration of response ("DoR"), while maintaining a safety profile consistent with that in previously reported toripalimab clinical trials. Although the median OS ("mOS") was not yet mature in either arm, the interim OS analysis showed a trend favoring the toripalimab arm and will be formally tested in a prespecified final analysis.

"First-line treatment options for advanced NPC remain limited for this difficult-to-treat tumor, resulting in poor outcomes for patients due to therapeutic resistance to chemotherapy, which is the current standard of care," said Professor Ruihua Xu, the poster's corresponding author from Sun Yat-sen University Cancer Center (SYSUCC). "The JUPITER-02 results validate the potential advancement that toripalimab in combination with chemotherapy would represent as a new standard-of-care first-line therapy for patients with advanced NPC."

Rosh Dias, MD, MRCP, Coherus' Chief Medical Officer, added, "Innovative immuno-oncology approaches including anti-PD-1 monoclonal antibody treatments represent a promising new option for advanced nasopharyngeal carcinoma, for which there are currently no approved immuno-oncology treatments in the United States. The significant improvement demonstrated in JUPITER-02 with the combination of toripalimab and chemotherapy across key clinically meaningful endpoints compared to chemotherapy alone supports its use as a potential new standard of care treatment option for advanced NPC."

"We are excited that the updated results from JUPITER-02 confirm that the addition of toripalimab to chemotherapy significantly extends the median PFS of patients with advanced NPC by more than a year," said Dr. Patricia Keegan, Chief Medical Officer of Junshi Biosciences. "We believe that toripalimab can revolutionize the treatment of advanced NPC and are working closely with the FDA and our partner, Coherus, to provide the first approved therapy for patients with this rare disease in the U.S."

The United States Food and Drug Administration ("FDA") granted breakthrough therapy designation for toripalimab in combination with gemcitabine and cisplatin as first-line treatment for patients with advanced recurrent or metastatic NPC and for toripalimab monotherapy for second-line or later treatment of recurrent or metastatic NPC after platinum-containing chemotherapy. A biologics license application ("BLA") for these indications is under priority review by the FDA. Junshi Biosciences and Coherus are working closely with the FDA to complete the review process and schedule any required inspections in China.

**About JUPITER-02 Study Results**

JUPITER-02, conducted in mainland China, Taiwan and Singapore, is the largest Phase 3 clinical study to date 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 or metastatic disease were randomized 1:1 to receive toripalimab 240 mg or placebo in combination with gemcitabine 1000 mg/m$^2$ (d1, 8) and cisplatin 80 mg/m$^2$ (d1), Q3W followed by toripalimab or placebo monotherapy until disease progression, intolerable toxicity or completion of two years of treatment. PFS and response were assessed by the BIRC and by the investigator per RECIST v1.1. There was one prespecified interim analysis of PFS at 130 (65%) PFS events and a final analysis at 200 PFS events.

At the final PFS analysis (cut-off date June 8, 2021), the median follow-up time was 22.1 months for the toripalimab arm and 21.4 months for the placebo arm.

A summary of the results is as follows:

- The addition of toripalimab to gemcitabine-cisplatin ("GP") chemotherapy as first-line treatment for advanced NPC patients provided superior PFS, OS, ORR and DoR than GP chemotherapy alone:
    - Significant improvement in PFS: mPFS 21.4 vs. 8.2 months, HR=0.52 (95% CI: 0.37, 0.73), *P* <0.0001.
    - Significant improvement in ORR: 78.8% vs. 67.1% (*P* = 0.0221).
    - Significant improvement in DoR: mDoR 18.0 vs. 6.0 months, HR=0.49, *P* = 0.0003.
    - Although mOS was not mature in either arm, a 41% reduction in risk of death was observed in the toripalimab arm over the placebo arm, HR=0.59 (95% CI: 0.37, 0.94), nominal *P* =0.0238.
- The safety profile was consistent with that previously reported in other toripalimab clinical trials with no new safety signals identified with toripalimab added to GP.

**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 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 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. Junshi Biosciences and Coherus 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 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 monoclonal antibody for tumors 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 COVID-19 pandemic, Junshi Biosciences responded swiftly and strongly, 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. Meanwhile, VV116, a new oral nucleoside analog anti-SARS-CoV-2 drug designed to hinder virus replication, is in global Phase III clinical trials. 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 2,800 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 building a leading immuno-oncology franchise funded with cash generated by its commercial biosimilar business. In 2021, Coherus in-licensed toripalimab, an anti-PD-1 antibody, in the United States and Canada. A biologics license application 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 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 biologics license application for 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™ and other products; Coherus' plans to file additional BLAs for toripalimab; beliefs about toripalimab's ability to enhance treatment of patients; and potential for toripalimab plus chemotherapy to represent a new standard of care in the future.

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, 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 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 Coherus files with the Securities and Exchange Commission.



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