Junshi Biosciences and Coherus Announce U.S. FDA Breakthrough Therapy Designation Granted for Toripalimab for 1st Line Treatment of Nasopharyngeal Carcinoma

–1st line nasopharyngeal indication and 2nd/3rd line indications to be concurrently submitted 3Q 2021 in the toripalimab BLA–

SHANGHAI, China, and REDWOOD CITY, Calif., Aug. 12, 2021 (GLOBE NEWSWIRE) -- Shanghai Junshi Biosciences Co., Ltd ("Junshi Biosciences", HKEX: 1877; SSE: 688180) and Coherus BioSciences, Inc. ("Coherus", Nasdaq: CHRS) today announced that the United States Food and Drug Administration ("FDA") has recently granted Breakthrough Therapy Designation ("BTD") for toripalimab in combination with chemotherapy (gemcitabine and cisplatin) for the 1st line treatment of recurrent or metastatic nasopharyngeal carcinoma ("NPC"). The FDA had earlier granted BTD for toripalimab monotherapy for patients with recurrent or metastatic NPC with disease progression on or after platinum-containing chemotherapy.

BTD is intended to expedite the development and regulatory review of drugs where preliminary clinical evidence demonstrates substantial improvement over existing therapies for a severe or life-threating disease. Drugs with BTD will be granted closer FDA guidance – including that from senior FDA officials - and various forms of support to avail patients with new therapy as soon as possible.

Junshi Biosciences expects to complete the biologics license application ("BLA") submission for toripalimab plus chemotherapy for 1st line NPC and for toripalimab monotherapy for 2nd or 3rd line NPC later this quarter.

"We are pleased to have received Breakthrough Therapy designation for our novel PD-1 blocking antibody, toripalimab, for nasopharyngeal carcinoma, which is an aggressive cancer with no immuno-oncology treatment options approved in the United States," said Dr. Patricia Keegan, Chief Medical Officer of Junshi Biosciences. "We look forward to working closely with the FDA during the BLA review process and with our partner, Coherus, to bring toripalimab to NPC patients in the U.S., if approved."

The Breakthrough Therapy designation is supported by data from the Phase 3 clinical trial "JUPITER-02" evaluating toripalimab in combination with chemotherapy for the first-line treatment of NPC. In this study, toripalimab in combination with chemotherapy demonstrated a statistically significant and clinically meaningful improvement in progression free survival ("PFS") compared to chemotherapy alone (assessed by a blinded independent review committee ("BIRC") per RECIST v1.1). JUPITER-02 also met secondary endpoints of PFS assessed by the investigator and objective response rate assessed by BIRC. There was also a longer duration of response, a higher disease control rate, and higher one- and two-year survival rates for the toripalimab arm. The safety profile of toripalimab is consistent with that observed in previously reported toripalimab clinical trials and the safety profile of this class of drugs. The result of JUPITER-02 was recently presented at the ASCO plenary session (#LBA2) and full results can be found in the August 2021 on-line edition of Nature Medicine.

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 is thought to recharge 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, including in China and the United States. Pivotal clinical trials are ongoing or completed evaluating the safety and efficacy of toripalimab for 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®). On December 17, 2018, toripalimab was granted a conditional approval from the National Medical Products Administration (NMPA) for the second-line treatment of unresectable or metastatic melanoma. In December 2020, toripalimab was successfully included in the updated National Reimbursement Drug List. In February 2021, the supplemental NDA for toripalimab in combination with chemotherapy for the first-line treatment of patients with advanced, recurrent or metastatic nasopharyngeal carcinoma was accepted by the NMPA. In the same month, the NMPA granted a conditional approval to toripalimab for the treatment of patients with recurrent or metastatic nasopharyngeal carcinoma (NPC) after failure of at least two lines of prior systemic therapy. In April, NMPA granted a conditional approval to toripalimab for the treatment of patients with locally advanced or metastatic urothelial carcinoma who failed platinum-containing chemotherapy or progressed within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy.

In the United States, a rolling submission of the first toripalimab Biologics License Application (BLA) is underway for the treatment of recurrent or metastatic nasopharyngeal carcinoma (NPC). The U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy designation for toripalimab in combination with chemotherapy for the 1st line treatment of recurrent or metastatic nasopharyngeal carcinoma ("NPC") and also for toripalimab monotherapy in second or third line treatment of recurrent or metastatic NPC. There are currently no PD-1 blocking antibodies indicated for use in NPC in the United States. Additionally, FDA has granted Fast Track status for the development of toripalimab for the treatment of mucosal melanoma and orphan drug designation for NPC, mucosal melanoma and soft tissue sarcoma. Earlier 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 rare cancers and highly prevalent cancers.

About Junshi Biosciences
Founded in December 2012, Junshi Biosciences (HK: 1877; SH: 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 28 innovative drug candidates and 2 biosimilars, 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 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 received Emergency Use Authorization (EUA) by US FDA in Feb 2021 for the treatment of recently diagnosed, mild to moderate COVID-19 in patients who are at high risk of progressing to severe COVID-19 and/or hospitalization. The JS016 program is a part of our continuous innovation for disease control and prevention of the global pandemic. Junshi

Biosciences has over 2,000 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 with the mission to increase access to cost-effective medicines that can have a major impact on patients' lives and to deliver significant savings to the health care system. Coherus' strategy is to build a leading immuno-oncology franchise funded with cash generated by its commercial biosimilar business. For additional information, please visit www.coherus.com.

Coherus markets UDENYCA® (pegfilgrastim-cbqv) in the United States and through 2023 expects to launch toripalimab, an anti-PD-1 antibody, as well as biosimilars of Lucentis®, Humira®, and Avastin®, if approved.

UDENYCA® is a trademark of Coherus BioSciences, Inc.
Avastin® and Lucentis® are registered trademarks of Genentech, Inc.
Humira® is a registered trademark of AbbVie Inc.

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, Coherus' ability to generate cash flow from its UDENYCA® business; Coherus' and Junshi Biosciences' ability to co-develop toripalimab, and Coherus' ability to commercialize toripalimab, or any other drug candidates developed as part of its collaboration with Junshi Biosciences in the licensed territory; the potential for toripalimab to gain approval in the United States for nasopharyngeal carcinoma or any indication; Coherus' and Junshi Biosciences' plans to file additional toripalimab BLAs with the FDA over the next three years for other clinical indications; Coherus' plans to invest the cash generated by its biosimilar commercial business to build a focused immuno-oncology franchise; Coherus' ability to prepare for projected launches through 2023 of biosimilars of Humira®, Avastin® and Lucentis®, if approved.

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; the risks and uncertainties of the regulatory approval process, including the timing of Coherus' regulatory filings; 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 patent litigation. All forward-looking statements contained in this press release speak only as of the date on which they were made. Coherus undertakes no obligation to update or revise any forward-looking statements. For a further description of the 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, 2020, filed with the Securities and Exchange Commission on February 25, 2021, its Quarterly Report on Form 10-Q for the three and six months ended June 30, 2021, filed with the Securities and Exchange Commission on August 5, 2021 and its future periodic reports to be filed with the Securities and Exchange Commission. Results for the quarter ended June 30, 2021 are not necessarily indicative of our operating results for any future periods.

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