Junshi Biosciences and Coherus BioSciences Announce Initiation of Rolling Submission of BLA for Toripalimab to the U.S. FDA for the Treatment of Nasopharyngeal Carcinoma

- BLA submitted with FDA's breakthrough therapy designation –

SHANGHAI, China, and REDWOOD CITY, Calif., March 03, 2021 (GLOBE NEWSWIRE) -- Shanghai Junshi Biosciences Co., Ltd. ("Junshi Biosciences", HKEX: 1877; SSE: 688180) and Coherus Biosciences, Inc. ("Coherus", Nasdaq: CHRS) announced today the initiation of the rolling submission of the Biologics License Application ("BLA") for toripalimab to the U.S. Food and Drug Administration ("FDA") for the treatment of recurrent or metastatic nasopharyngeal carcinoma ("NPC"). A rolling submission allows Junshi Biosciences to submit sections of the BLA to the FDA as they are completed.

Toripalimab has been granted Breakthrough Therapy Designation by the FDA for the treatment of recurrent or metastatic nasopharyngeal carcinoma based on preliminary clinical evidence indicating that the drug may demonstrate substantial improvement over existing therapies. The designation is intended to expedite the development and review of drugs for serious or life-threatening conditions. Toripalimab is the first anti-PD-1 monoclonal antibody developed in China with a BLA submission to the FDA in process.

In February 2021, Junshi Biosciences and Coherus entered into a collaboration for the development and commercialization of toripalimab in the United States and Canada. Coherus will be responsible for all commercial activities in the licensed territory. Closing of the collaboration agreement is subject to clearance under the Hart-Scott Rodino Antitrust Improvements Act, which is expected later this month.

"There has been limited development of treatment approaches for patients with advanced NPC in the U.S.," said Dr. Patricia Keegan, Chief Medical Officer of Junshi Biosciences. "We are determined to advance effective treatments in the U.S. by leveraging the successful experience with toripalimab, a safe and effective treatment for previously treated NPC that is now approved for marketing in China. We appreciate the FDA's recognition of this potentially important new treatment through its Breakthrough Therapy Designation, which enables the acceleration of the review process. We will work closely with the FDA to facilitate the review of the U.S. marketing application in order to make toripalimab available for patients in the U.S. as soon as possible."

"Toripalimab could address a significant unmet medical need as a new treatment for advanced NPC, and we are encouraged by the initiation of the BLA submission," said Denny Lanfear, CEO of Coherus. "With an extensive clinical development program across a range of tumor types, a broad therapeutic profile is developing for toripalimab. We look forward to working with Junshi Biosciences to bring this new anti-PD-1 antibody to patients in the U.S. and Canada."

Following potential approval of toripalimab for the treatment of recurrent or metastatic nasopharyngeal carcinoma, and assuming successful closing of their collaboration agreement, Coherus and Junshi Biosciences plan to file additional toripalimab BLA supplements with the FDA over the next three years for multiple rare cancers as well as highly prevalent cancers, including non-small cell lung cancer ("NSCLC").

About Toripalimab

Toripalimab was the first domestic anti-PD-1 monoclonal antibody approved for marketing in China. More than thirty company-sponsored clinical studies covering more than fifteen indications have been conducted globally, including in China and the United States. On December 17, 2018, Toripalimab obtained a conditional approval from the National Medical Products Administration (NMPA) for the second-line treatment of unresectable or metastatic melanoma. Toripalimab was included in the 2019 and 2020 Guidelines of Chinese Society of Clinical Oncology (CSCO) for the Diagnosis and Treatment of Melanoma. The supplemental NDA of Toripalimab for the second-line treatment of metastatic urothelial carcinoma was accepted by the NMPA in May 2020 and received priority review designation from the NMPA in July 2020. In September 2020, Toripalimab was granted Breakthrough Therapy Designation by the US Food and Drug Administration (FDA) for the treatment of recurrent or metastatic nasopharyngeal carcinoma. 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. Currently, Toripalimab has been granted 1 Breakthrough, 1 Fast Track, and 3 Orphan Drug Designations by the FDA for the treatment of mucosal melanoma, nasopharyngeal carcinoma, and soft tissue sarcoma.

About Junshi Biosciences

Founded in December 2012, Junshi Biosciences 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.

In February 2021, Coherus and Junshi Biosciences announced a collaboration in which Coherus would in-license toripalimab, an anti-PD-1 antibody, in the United States and Canada. Coherus' strategy is to build a leading immuno-oncology franchise funded with cash generated by its commercial

biosimilar business. Coherus markets UDENYCA® (pegfilgrastim-cbqv) in the United States and through 2023 expects to launch biosimilars of Humira®, Avastin® and Lucentis®, if approved.

For additional information, please visit www.coherus.com.

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; Coherus' ability to expand a late-stage pipeline into the rapidly growing checkpoint inhibitor market; any market size expectation for checkpoint inhibitor therapeutic agents in the United States; the potential for toripalimab to gain approval in the United States for nasopharyngeal carcinoma or any indication; toripalimab's possibility to be the first marketed Chinese anti-PD-1 antibody in the overseas market; Coherus' and Junshi Biosciences' plans to file additional toripalimab BLAs with the FDA over the next three years for any clinical indication; 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 risk that the parties are unable to obtain clearance under the Hart-Scott Rodino Antitrust Improvements Act, from the Committee on Foreign Investment in the United States, or any other statute or regulatory agency having jurisdiction with respect to the proposed transactions, 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, and its future periodic reports to be filed with the Securities and Exchange Commission. Our results for the year ended December 31, 2020 are not necessarily indicative of our operating results for any future periods.

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