Coherus and Junshi Biosciences Receive Complete Response Letter from U.S. FDA for Toripalimab BLA

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- The CRL requests a quality process change Coherus and Junshi believe is readily addressable -

- BLA resubmission anticipated by mid-summer 2022 with expected six month FDA review timeline -

- Onsite inspections in China, impeded to date by COVID-19-related travel restrictions, are required for FDA's completion of BLA review -

- Toripalimab will be the first and only immuno-oncology agent for NPC in U.S., if approved -

SHANGHAI, China, and REDWOOD CITY, Calif., May 02, 2022 (GLOBE NEWSWIRE) -- Shanghai Junshi Biosciences Co., Ltd. ("Junshi Biosciences", "Junshi", HKEX: 1877; SSE: 688180) and Coherus BioSciences, Inc. ("Coherus", Nasdaq: CHRS) announced today that the U.S. Food and Drug Administration ("FDA", "the Agency") has issued a complete response letter ("CRL") for the Biologics License Application ("BLA") for toripalimab in combination with gemcitabine and cisplatin in the first-line treatment of patients with advanced recurrent or metastatic nasopharyngeal carcinoma ("NPC") and for toripalimab monotherapy in the second-line or later treatment of recurrent or metastatic NPC after platinum-containing chemotherapy.

The CRL requests a quality process change that Coherus and Junshi Biosciences believe is readily addressable. Coherus and Junshi Biosciences plan to meet with the FDA directly and expect to resubmit the BLA by mid-summer 2022. The Agency also communicated in the CRL that the review timeline for the BLA resubmission would be six months, as required onsite inspections have been hindered by travel restrictions related to the COVID-19 pandemic in China.

"We will continue to work closely with our partner, Junshi Biosciences, to facilitate the completion of the FDA's review of the toripalimab BLA. In late April, we responded quickly to an FDA request for a quality process change and implemented required actions," said Denny Lanfear, CEO of Coherus. "We plan to first meet with the FDA and directly thereafter to resubmit the BLA. The FDA has indicated that the existing toripalimab clinical data are supportive of the BLA submission, and we eagerly await scheduling and completion of the required inspections in China that have been impeded to date by COVID-related travel restrictions. We believe toripalimab addresses an important unmet need for patients with NPC for whom there are currently no approved immunotherapies in the United States, and the FDA has stated that this indication warrants regulatory flexibility with respect to the sufficiency of single country clinical data."

"Junshi Biosciences is dedicated to the discovery, development and commercialization of innovative new drugs on a global scale," said Dr. Ning Li, CEO of Junshi Biosciences. "Toripalimab, our PD-1 inhibitor, has demonstrated a compelling clinical profile in studies across multiple tumor types and is currently approved in China for four indications. We fully support our partner, Coherus, in its efforts to seek toripalimab approval in the United States for advanced nasopharyngeal carcinoma, as well as in the subsequent commercial launch, if approved. Our respective teams are working diligently together in a well coordinated effort to achieve these goals as partners."

About Nasopharyngeal Carcinoma (NPC)

NPC is a type of aggressive cancer that starts in the nasopharynx, the upper part of the throat behind the nose and near the base of skull. Due to the location of the primary tumor, surgery is rarely an option, and patients with localized disease are treated primarily with radiation and chemotherapy. In the United States, there are presently no immunotherapies approved for the treatment of NPC.

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 granted Breakthrough Therapy designation 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. Coherus and Junshi Biosciences plan to resubmit a BLA for toripalimab for advanced NPC by mid-summer 2022. 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, soft tissue sarcoma, and SCLC. 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 several 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. Coherus plans to resubmit a BLA for toripalimab for the treatment of advanced NPC by mid-summer 2022. Toripalimab is also being evaluated in pivotal clinical trials for the treatment of rare and highly prevalent cancers.

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) inthe 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 in combination with chemotherapy; expectations about the success and timing of the toripalimab BLA resubmission and the associated BLA review; and Coherus' expectations about being able to overcome COVID-19-related travel restrictions to finish required onsite inspections for toripalimab.

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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