Coherus and Junshi Biosciences Announce FDA Acceptance of Resubmission of BLA for Toripalimab for the Treatment of Nasopharyngeal Carcinoma

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- FDA has set a target action date of December 23, 2022 for the toripalimab BLA -

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

REDWOOD CITY, Calif., and SHANGHAI, China, July 06, 2022 (GLOBE NEWSWIRE) -- Coherus BioSciences, Inc. (“Coherus”, Nasdaq: CHRS) and Shanghai Junshi Biosciences Co., Ltd. (“Junshi Biosciences”, HKEX: 1877; SSE: 688180) announced today that the United States Food and Drug Administration ("FDA") has accepted for review the Biologics License Application (“BLA”) resubmission for toripalimab in combination with gemcitabine and cisplatin as first-line treatment for patients with advanced recurrent or metastatic nasopharyngeal carcinoma (“NPC”) and for toripalimab monotherapy for the second-line or later treatment of recurrent or metastatic NPC after platinum-containing chemotherapy.

The FDA has set a Prescription Drug User Fee Act ("PDUFA") action date for December 23, 2022. The Agency earlier communicated that the review timeline for the BLA resubmission would be six months, as onsite inspections in China would be required. Travel restrictions related to the COVID-19 pandemic previously hindered the FDA's ability to complete required inspections. Coherus plans to launch toripalimab in the United States in the first quarter of 2023, if approved.

“Toripalimab would address a critical unmet medical need for patients with nasopharyngeal carcinoma, an aggressive cancer for which there are currently no FDA-approved immunotherapy treatments. We collaborated closely with our partner, Junshi Biosciences, to complete the quality process changes requested by the FDA and facilitate the rapid resubmission of the toripalimab BLA,” said Dr. Theresa LaVallee, Chief Development Officer of Coherus.

“Although the COVID-19 pandemic has created tremendous challenges for everyone, our dedication to bring better treatment options to patients around the world remains steadfast,” said Dr. Patricia Keegan, Chief Medical Officer of Junshi Biosciences. “Through our concerted efforts with our partner, Coherus, we have made continual progress towards obtaining toripalimab’s first marketing authorization outside of China. Over the next several months, we will work closely with the FDA to facilitate the review of this novel drug.”

“For Coherus, the toripalimab resubmission is one of several key development and commercialization milestones we are sharply focusing on over the next twelve months, and we are pleased with the Company’s execution and progress on all of them,” said Denny Lanfear, CEO of Coherus. “We now look forward to the August 2, 2022 target action date for our BLA for CIMERLI™, our Lucentis® biosimilar, followed by product launch which we are confident will be very successful. The toripalimab December 2022 PDUFA date follows directly, and the projected toripalimab launch in Q1 2023 will formally mark our entry into immuno-oncology, where Coherus will be one of just a handful of companies with a proprietary PD-1 as a foundation stone to build its oncology franchise upon. Lastly, twelve months from now, in July 2023, we expect to begin marketing our Humira® biosimilar, YUSIMRY®, which was approved by the FDA in December 2021. Preparations for that commercial launch are going very well. Biosimilar market execution is a demonstrated Coherus competency, and we believe that our commercialization strategy provides a robust framework against which we can successfully execute to meet our market expectations and share projections.”

Following approval of toripalimab for NPC, Coherus’ strategy in the US includes evaluating toripalimab’s ability to deliver substantial clinical benefit in significant indications, in combination with other cancer drugs and immunotherapies, through co-development agreements.

About Toripalimab in 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.

The toripalimab BLA is supported by the results from JUPITER-02, a randomized, double blind, placebo-controlled, international multi-center Phase 3 clinical trial, as well as POLARIS-02, a multi-center, open-label, pivotal Phase 2 clinical study. The JUPITER-02 results were first presented in June 2021 in a plenary session of the American Society of Clinical Oncology (“ASCO”) annual meeting (#LBA2) and subsequently published in detail as the cover article of the September 2021 issue of Nature Medicine. The POLARIS-02 results were published online in January 2021 in the Journal of Clinical Oncology.

The FDA has granted Breakthrough Therapy designation (“BTD”) for toripalimab in combination with chemotherapy (gemcitabine and cisplatin) for the 1st line treatment of recurrent, locally advanced or primary metastatic non-keratinizing NPC and for toripalimab monotherapy for patients with recurrent or metastatic non-keratinizing NPC with disease progression on or after platinum-containing chemotherapy. Additionally, the FDA has granted Orphan Drug designation for toripalimab for NPC.

In China, the National Medical Products Administration (“NMPA”) in 2021 approved toripalimab for two NPC indications.

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. In China, toripalimab was the first domestic anti-PD-1 monoclonal antibody approved for marketing (approved in China as TUOYI®). Currently, there are five approved indications for toripalimab in China.

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 the treatment of various cancers is 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 FDA-approved products. In 2021, Coherus in-licensed toripalimab, an anti-PD-1 antibody, in the United States and Canada. The resubmission of the BLA for toripalimab for the treatment of NPC was accepted by the FDA in July 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) in the United States in 2023. The FDA is currently reviewing the biologics license application for CIMERLI™, a biosimilar of Lucentis® (ranibizumab injection), with a target action date of August 2022.

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 dates of toripalimab, CIMERL™ and YUSIMRY™; Coherus' plans to file additional BLAs for toripalimab and pursue co-development agreements for other indications; beliefs about toripalimab's ability to address an unmet need for patients; expectations about the success and timing of the FDA review of toripalimab and CIMERLI™; and Coherus' ability to meet market expectations and share projections 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, and the need to have the FDA finish inspections in China during a COVID-19 pandemic; 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' Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2022, filed with the Securities and Exchange Commission on May 5, 2022, including the section therein captioned "Risk Factors" and in other documents Coherus files with the Securities and Exchange Commission.

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