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

Nov 1, 2021

- *FDA has granted the toripalimab BLA Priority Review with a target action date of April 2022*

REDWOOD CITY, Calif. and SHANGHAI, China, Nov. 01, 2021 (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”) for toripalimab in combination with gemcitabine and cisplatin for the first-line treatment for patients with advanced recurrent or metastatic nasopharyngeal carcinoma (“NPC”) and toripalimab monotherapy for the second-line or above treatment of recurrent or metastatic NPC after platinum-containing chemotherapy. The FDA has granted Priority Review Designation for the toripalimab BLA and set a Prescription Drug User Fee Act ("PDUFA") action date for April 2022. The FDA is not currently planning to hold an advisory committee meeting to discuss the application.

“Nasopharyngeal carcinoma is an aggressive tumor that currently has no FDA-approved immuno-oncology treatment options, and we believe that toripalimab in combination with chemotherapy, if approved, will establish a new standard of care for first line treatment of advanced NPC,” said Denny Lanfear, CEO of Coherus. “Toripalimab is the PD-1 cornerstone of our immuno-oncology strategy, and we are pleased that the FDA has accepted the BLA for review. Including the toripalimab application, Coherus now has three product candidate BLAs under review by the FDA, and our team is making rapid progress toward our goal to diversify and expand our commercial product portfolio.”

“We are excited by the continued progress of toripalimab toward a first marketing authorization outside of China,” said Dr. Patricia Keegan, Chief Medical Officer of Junshi Biosciences. “With the earlier approval in China, toripalimab became the world’s first immune checkpoint inhibitor for the treatment of nasopharyngeal carcinoma, bringing a novel therapy to a disease that has long lacked new drug development. We will cooperate closely with our partner, Coherus, to leverage the FDA’s Priority Review designation to accelerate the completion of the BLA review and believe toripalimab, if approved, will bring an important new treatment option for NPC patients in the United States.”

The toripalimab BLA is supported by the results from clinical studies “POLARIS-02” and “JUPITER-02”. The POLARIS-02 study is a multi-center, open-label, pivotal Phase II clinical study, the results of which were published online in January 2021 in the *Journal of Clinical Oncology*. The JUPITER-02 study is a randomized, double blind, placebo-controlled, international multi-center Phase 3 clinical trial, the results of which were recently presented at the American Society of Clinical Oncology annual meeting in a Plenary Session presentation (#LBA2) and were published as the cover article of the September 2021 issue of *Nature Medicine*.

In August 2021, the FDA 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 nasopharyngeal carcinoma (“NPC”) and in September 2020 granted BTD for toripalimab monotherapy for patients with recurrent or metastatic non-keratinizing NPC with disease progression on or after platinum-containing chemotherapy. The toripalimab BLA has been granted priority review with a six-month target action date, as compared to a 10-month standard review timeline. Priority review designation directs FDA resources to the evaluation of applications for drugs that, if approved, would represent significant improvements in the treatment of serious conditions.

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, 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®). On December 17, 2018, toripalimab was granted a conditional approval by 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 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, the 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 addition, two supplemental NDAs for toripalimab in combination with chemotherapy for the first-line treatment of patients with advanced, recurrent or metastatic NPC and for the first-line treatment of patients with advanced or metastatic esophageal squamous cell carcinoma were accepted by the NMPA for review in February and July 2021 respectively.

In the United States, the FDA has granted priority review for the toripalimab BLA for the treatment of recurrent or metastatic NPC. Earlier, the FDA granted Breakthrough Therapy designation for toripalimab in combination with chemotherapy for the 1st line treatment of recurrent or metastatic NPC and also for toripalimab monotherapy in the 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 designation for 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 other cancer types.

About Nasopharyngeal Carcinoma
Nasopharyngeal carcinoma ("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. NPC is rare in the United States with annual incidence of fewer than 1 per 100,000. The five-year survival rate for all patients diagnosed with NPC is approximately 60%; however, those who are diagnosed with advanced disease have a five-year survival rate of approximately 25%. 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. Patients with advanced or recurrent disease are treated with combination chemotherapy. There are currently no FDA-approved

immuno-oncology agents for NPC.

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.

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 44 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 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 of 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 been granted Emergency Use Authorizations (EUA) in 15 countries and regions worldwide. The JS016 program is a part of our continuous innovation for disease control and prevention of the global pandemic. Junshi Biosciences has over 2,500 employees in the United States (San Francisco and Maryland) and China (Shanghai, Suzhou, Beijing and Guangzhou). For more information, please visit: http://junshipharma.com.

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 ability for ex-US clinical trial data from a single country to support an approval by the FDA; whether the FDA will hold an advisory committee meeting to discuss the toripalimab BLA for nasopharyngeal carcinoma; the potential for toripalimab to gain approval in the United States for nasopharyngeal carcinoma, lung cancer, 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 speed of regulatory review and the timing of Coherus' regulatory filings; the risk of FDA review issues; 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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