



Positive Interim Results of CHOICE-01 Study Evaluating Coherus' and Junshi Biosciences' Toripalimab for First Line Treatment of Non-Small Cell Lung Cancer Presented at World Conference on Lung Cancer

Sep 13, 2021

REDWOOD CITY, Calif. and SHANGHAI, China, Sept. 13, 2021 (GLOBE NEWSWIRE) -- Coherus Biosciences, Inc. (Nasdaq: CHRS) and Shanghai Junshi Biosciences Co., Ltd. ("Junshi Biosciences", HKEX: 1877; SSE: 688180) announced the presentation today of positive interim results from the pivotal study "CHOICE-01" (NCT03856411), a randomized, double-blind, placebo-controlled Phase 3 clinical trial evaluating toripalimab plus chemotherapy as first-line treatment of advanced squamous or non-squamous non-small cell lung cancer (NSCLC) without driver mutations. The interim analysis met the primary endpoint, demonstrating a statistically significant and clinically meaningful improvement in progression free survival (PFS) per RECIST v1.1 compared to chemotherapy alone.

The interim results were summarized on September 13 in a presentation by Professor Jie Wang, MD, PhD, National Cancer Center/National Clinical Research Center for Cancer/Cancer Hospital, Chinese Academy of Medical Sciences & Peking Union Medical College, during the Mini Oral Session at the 2021 World Conference on Lung Cancer (WCLC) hosted by the International Association for the Study of Lung Cancer (IASLC). The [abstract](#) detailing the interim results was first made available on the WCLC website on August 18.

"The addition of toripalimab to standard 1st-line chemotherapy in patients with advanced non-small cell lung cancer showed superior progression free survival, overall response rate and duration of response over chemotherapy alone, with a safety profile consistent with the PD-1 inhibitor class of drugs," said Dr. Wang. "Overall survival data are still maturing, with a notable emerging trend favoring the toripalimab-chemotherapy combination. We look forward to additional data from this study and believe CHOICE-01 results will provide strong evidence to support the use of toripalimab with chemotherapy as a 1st-line therapeutic option for NSCLC."

A final analysis of progression free survival and an additional interim overall survival analysis are expected later this year. Junshi Biosciences and Coherus plan to meet with the United States Food and Drug Administration to discuss a potential submission to the pending biologics license application of an efficacy supplement for toripalimab for the first line treatment, in combination with platinum-based chemotherapy, of advanced, unresectable NSCLC without driver mutations.

"CHOICE-01 is the first of four pivotal clinical trials evaluating toripalimab for the treatment of lung cancer to have clinical data presented, and its positive results are a promising start for toripalimab in lung cancer. Lung cancer is the most common form of cancer worldwide and the leading cause of death due to cancer, so there is a clear need to develop complementary approaches to standard chemotherapy to improve patient outcomes, maintain quality of life, and seek to improve survival for patients diagnosed with this deadly disease. We will work closely with Coherus and the regulatory authorities to bring this new therapy to patients in the United States," said Dr. Patricia Keegan, Chief Medical Officer of Junshi Biosciences.

"The CHOICE-01 interim data presented at WCLC are encouraging early evidence for toripalimab's clinical benefit in the first-line setting in non-small cell lung cancer," said Denny Lanfear, CEO of Coherus. "We eagerly anticipate additional results from this study and the potential to advance toripalimab toward registration for this indication in the United States."

Toripalimab Phase 3 clinical trials in lung cancer

Junshi Biosciences and Coherus are currently evaluating toripalimab in four pivotal Phase 3 clinical trials in lung cancer.

- CHOICE-01, with 465 patients enrolled, is comparing toripalimab in combination with chemotherapy to chemotherapy alone as first-line treatment of advanced NSCLC. The study met the primary endpoint of progression free survival (PFS) at the interim analysis (data cut-off date: November 17, 2020). Patients receiving the placebo-chemotherapy combination were allowed to actively cross over to toripalimab treatment at the time of disease progression. Overall survival (OS) data are still maturing and exhibiting a trend favoring the toripalimab-chemotherapy arm as of a March 2021 observation. Final PFS and additional interim OS analyses are expected later in 2021.
- Toripalimab is also being evaluated in combination with standard platinum-based chemotherapy in patients with NSCLC harboring EGFR mutations whose tumors are no longer responding to EGFR TKI therapy. Enrollment of 350 subjects in this Phase 3 study is on track to be completed by the end of 2021. The primary endpoint of the study is PFS. Initial results are expected in 2022.
- In the neoadjuvant setting, toripalimab is being evaluated in combination with chemotherapy in a Phase 3 study with 406 patients with NSCLC scheduled to undergo surgical resection of their lung cancer. Enrollment is on track to be completed by the end of 2021. The primary endpoints of the study are major pathological response and event free survival. Initial results are expected in 2022.
- Toripalimab is being evaluated in combination with standard chemotherapy in a Phase 3 study with 442 patients with extensive stage small cell lung cancer. Enrollment is complete. PFS and OS are the co-primary endpoints. Results are expected by the first half of 2022.

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. Ongoing or completed pivotal clinical trials are 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 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 2021, 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 or 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 first toripalimab BLA has been submitted to the FDA for the treatment of recurrent or metastatic NPC. The FDA has granted Breakthrough Therapy designations for toripalimab in combination with chemotherapy for the 1st line treatment of recurrent or metastatic NPC and for toripalimab monotherapy in the 2nd line and subsequent treatment of recurrent or metastatic NPC. There are currently no PD-1 blocking antibodies approved 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 rare cancers and highly prevalent cancers.

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 more than 12 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>.

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; 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, lung cancer, or any indication; Coherus' and Junshi Biosciences' plans to file additional toripalimab BLAs with the FDA over the next three years for lung cancer or 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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