



Coherus and Junshi Biosciences Announce Positive Interim Results of CHOICE-01, a Phase 3 Clinical Trial Evaluating Toripalimab in Combination with Chemotherapy as First-Line Treatment for Non-Small Cell Lung Cancer

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– Toripalimab plus chemotherapy met primary endpoint with significant improvement in PFS compared to chemotherapy alone –

- Data support the use of toripalimab with chemotherapy as first-line therapy for patients with NSCLC -

- Study to be presented September 13 at IASLC 2021 World Conference on Lung Cancer -

SHANGHAI, China and REDWOOD CITY, Calif., Aug. 18, 2021 (GLOBE NEWSWIRE) -- Shanghai Junshi Biosciences Co., Ltd. ("Junshi Biosciences", HKEX: 1877; SSE: 688180) and Coherus BioSciences, Inc. ("Coherus", Nasdaq: CHRS), today announced 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). 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 results will be summarized September 13 in an oral 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](#) is now available on the WCLC website.

"The CHOICE-01 study in patients with advanced non-small cell lung cancer has demonstrated the clinical benefit of toripalimab in yet another first-line setting, building on the evidence of efficacy in first-line studies in nasopharyngeal carcinoma and esophageal squamous cell carcinoma," said Dr. Patricia Keegan, Chief Medical Officer at Junshi Biosciences. "With an excellent clinical profile being established across multiple tumor types, we expect to pursue registration for toripalimab for a broad array of indications in China, the United States and other markets."

"The CHOICE-01 efficacy and safety data are compelling and demonstrate the potential for toripalimab to deliver the significant benefits of the PD-1 class of checkpoint inhibitor drugs to patients with non-small cell lung cancer," said Ildiko Csiki, MD, PhD, Chair of the Coherus Scientific Advisory Board and Chief Commercial Research and Development Officer at City of Hope, a comprehensive cancer center. "As data accumulate in the pivotal studies in the broad clinical development program, toripalimab is showing itself to be an excellent checkpoint inhibitor. We eagerly anticipate results from additional Phase 3 studies in esophageal, lung, liver, breast, kidney, bladder, stomach, and skin cancers."

About CHOICE-01

A total of 465 treatment-naïve advanced NSCLC patients (220 squamous and 245 non-squamous) were randomized (2:1): 309 to the toripalimab plus chemotherapy arm and 156 to the placebo plus chemotherapy arm. The primary endpoint of PFS was assessed by the investigator. Secondary endpoints included PFS assessed by a blinded independent review committee (BIRC), overall survival (OS), objective response rate (ORR) and duration of response (DoR). Crossover to toripalimab was allowed for patients from the placebo plus chemotherapy arm upon disease progression.

- As of November 17, 2020 (the data cut-off date of the interim analysis), 218 PFS events were observed, with a median follow-up of 7.1 and 7.0 months in the toripalimab arm and the placebo arm, respectively.
- At the interim analysis, a significant improvement in PFS was detected for toripalimab over placebo [hazard ratio (HR)=0.58, 95% confidence interval (CI): 0.44-0.77, P=0.0001] with median PFS of 8.3 vs. 5.6 months. The 1-year PFS rates for toripalimab and placebo arms were 32.6% and 13.1%, respectively.
- This improvement in PFS was observed in both squamous [HR = 0.55 (95% CI: 0.38-0.83)] and non-squamous [HR=0.59 (95% CI: 0.40-0.87)] NSCLC and regardless of PD-L1 expression.
- PFS assessed by BIRC showed similar results as PFS assessed by the investigator.
- Toripalimab in combination with chemotherapy, as compared with chemotherapy alone, resulted in better ORR (squamous NSCLC: 68.7% vs. 58.9%; non-squamous NSCLC: 58.6% versus 26.5%) and median DoR (squamous NSCLC: 6.9 months vs. 4.2 months; non-squamous NSCLC: 8.6 months vs. 5.1 months).
- Patients in the placebo plus chemotherapy arm were actively crossed over to toripalimab treatment at the time of disease progression.
- Overall survival data were not yet mature as of March 7, 2021. There was a trend favoring the toripalimab arm [median OS of 21.0 vs. 16.0 months, HR = 0.81 (95% CI: 0.57-1.17)].
- The addition of toripalimab to standard first-line chemotherapy in patients with advanced NSCLC showed a manageable safety profile with no new safety signal observed. The incidence of Grade ≥3 adverse events (AEs) was 76.3% in the toripalimab arm vs. 80.1% in the control arm. AEs leading to discontinuation of toripalimab or placebo were 12.3% vs. 1.9%, respectively.

Junshi Biosciences and Coherus plan to meet with the United States Food and Drug Administration to discuss a potential submission of a biologics license application for toripalimab for first line treatment of advanced NSCLC.

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. Pivotal clinical trials are ongoing or completed 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 from 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 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. In April, 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 the United States, a rolling submission of the first toripalimab Biologics License Application (BLA) is underway for the treatment of recurrent or metastatic nasopharyngeal carcinoma (NPC). The U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy designation for toripalimab in combination with chemotherapy for the 1st line treatment of recurrent or metastatic nasopharyngeal carcinoma ("NPC") and also for toripalimab monotherapy in 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 status for the development of 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 (HK: 1877; SH: 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 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. 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; 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, lung cancer, or any indication; Coherus' and Junshi Biosciences' plans to file toripalimab BLAs with the FDA over the next three years for nasopharyngeal carcinoma, 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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