Coherus and Junshi Biosciences Announce Toripalimab in Combination with Chemotherapy Met Primary Progression Free Survival (PFS) Endpoint as First Line Treatment for Recurrent or Metastatic Nasopharyngeal Carcinoma (NPC)

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– In pivotal Phase 3 JUPITER-02 study, toripalimab plus chemotherapy significantly improved PFS compared to chemotherapy alone in high and low PD-L1 expression subgroups –

– Although median overall survival (OS) analysis was not yet mature, a 40% reduction in risk of death was observed in the toripalimab arm compared to placebo –

– Data to be presented June 6, 2021 at ASCO plenary session –

– Over 30 toripalimab abstracts in more than 10 tumor types published at ASCO 2021 –

SHANGHAI, China, and REDWOOD CITY, Calif., June 03, 2021 (GLOBE NEWSWIRE) -- Shanghai Junshi Biosciences Co., Ltd ("Junshi Biosciences", HKEX: 1877; SSE: 688180) and Coherus BioSciences, Inc. ("Coherus", Nasdaq: CHRS) today announced positive results from the pivotal study "JUPITER-02", a randomized, double-blind, placebo-controlled Phase 3 clinical trial evaluating toripalimab plus chemotherapy for the first-line treatment of recurrent or metastatic nasopharyngeal carcinoma (NPC). The interim analysis met the primary endpoint, demonstrating a statistically significant and clinically meaningful improvement in progression free survival (PFS) compared to chemotherapy alone (assessed by a blinded independent review committee, or BIRC, per RECIST v1.1). JUPITER-02 also met secondary endpoints of PFS assessed by the investigator and objective response rate (ORR) assessed by BIRC. There was also a longer duration of response (DoR), a higher disease control rate (DCR) and higher one- and two-year survival rates for the toripalimab arm. The safety profile of toripalimab was consistent with that observed in previously reported toripalimab clinical trials.

The results are summarized in a late-breaking abstract that will be presented during a plenary session at the 2021 annual meeting of the American Society for Clinical Oncology (ASCO) on Sunday, June 6, 2021 from 1–4 pm Eastern Daylight Time. The abstract (LBA2) is now available on the ASCO website.

"Nasopharyngeal carcinoma is an aggressive tumor—especially for patients with advanced NPC. For first line treatment, platinum-based chemotherapy remains the current standard of care, yet mPFS is only about 7 months. We are encouraged by the JUPITER-02 results showing the addition of toripalimab to chemotherapy as first-line treatment provided superior PFS and ORR and longer DoR than chemotherapy alone, and with a safety and tolerability profile consistent with the PD-1 antibody class of drugs," said Dr. Ruihua Xu, President and Professor, Sun Yat-sen University Cancer Center (SYSUCC), Guangzhou. "I believe that these results support the use of toripalimab with chemotherapy as the new standard of care for first-line treatment of patients with recurrent/metastatic NPC."

More than 30 toripalimab abstracts were accepted for ASCO 2021, including two selected for oral presentations (LBA2 and #9512), describing the antitumor activities observed from various cancers of the nasopharynx, skin, lung, esophagus, stomach, liver, biliary duct, head and neck, and pancreas. Importantly, ten of the abstracts demonstrated toripalimab's potential in perioperative, adjuvant, or neoadjuvant treatment settings.

"Given the outstanding results, JUPITER-02 is the first study to show a major therapeutic advance for first-line treatment of advanced NPC since the chemotherapy combination of gemcitabine and cisplatin was established as standard of care, which is why I believe this study was selected for presentation at the plenary session at ASCO 2021. We will work to expedite commercialization of toripalimab for this patient population in China, the United States, and other countries to make this exciting new treatment option broadly available to all patients with NPC," said Dr. Patricia Keegan, Chief Medical Officer of Junshi Biosciences. "In addition to the JUPITER-02 trial, results of multiple other studies of toripalimab will be presented during the ASCO annual meeting, which support the current development strategy, such as perioperative immunotherapy in patients with multiple solid tumors, including mucosal melanoma, esophageal cancer, gastric cancer, liver cancer and non-small cell lung cancer, as well as the exploration of toripalimab for treatment of ICC, for which no checkpoint inhibitors have been approved for use."

"ASCO 2021 is a pivotal moment for Coherus as it marks the U.S. medical meeting debut of the immuno-oncology franchise we are building to deliver life-changing medicines addressing both rare and highly prevalent cancers," said Denny Lanfear, CEO of Coherus. "The strong late-breaking data in advanced NPC add to the favorable efficacy and safety profile that is emerging for toripalimab in the broad development program with more than 15 pivotal clinical trials. Alongside Junshi Biosciences, we look forward to presenting clinical data from these studies and to working together to register toripalimab in the United States and Canada as a potential new therapeutic option across a broad range of tumor types, starting with NPC."

About JUPITER-02 Results

JUPITER-02, conducted in mainland China, Taiwan and Singapore, is the largest Phase 3 clinical study to evaluate a checkpoint inhibitor plus chemotherapy for the first-line treatment of recurrent or metastatic nasopharyngeal carcinoma. Two hundred eighty-nine patients with advanced NPC who had received no prior chemotherapy for recurrent/metastatic disease were randomized 1:1 to receive toripalimab 240 mg or placebo in combination with gemcitabine 1000 mg/m^2 (d1, 8) and cisplatin 80 mg/m^2 (d1), Q3W followed by toripalimab or placebo monotherapy until disease progression, intolerable toxicity or completion of two years of treatment. Progression-free survival and response were assessed by the BIRC and by the investigator per RECIST v1.1. There was one pre-specified interim analysis of PFS at 130 (65%) PFS events with a planned final analysis at 200 PFS events.

By May 30, 2020, the date of the interim analysis data cut, the median treatment duration was 39 weeks in the toripalimab arm and 36 weeks in the placebo arm. The ASCO presentation also includes an updated overall survival (OS) analysis with a data cut-off of February 18, 2021.

A summary of the results is as follows:

- A significant improvement in PFS (assessed by BIRC) was observed in the toripalimab plus chemotherapy arm compared to the chemotherapy alone arm (HR = 0.52 [95% CI: 0.36-0.74] two-sided p = 0.0003), median PFS of 11.7 vs. 8.0 months;

- The 1-year PFS rates were 49% and 28%, respectively, for the toripalimab arm compared to the placebo arm;
- An improvement in PFS was observed across relevant subgroups including patients with high PD-L1 expression (TC or IC ≥ 1%; mPFS 11.4 vs. 8.2 month, HR = 0.59 [95% CI: 0.388 – 0.893]) or low PD-L1 expression (TC and IC<1%; mPFS 11.0 vs. 6.0 months, HR=0.35 [95% CI: 0.153 – 0.808]);
- The ORR was 77.4% vs. 66.4% (P = 0.034); the median DoR was 10.0 vs. 5.7 months (HR = 0.50 [95% CI: 0.33-0.78]), P = 0.001);
- The first interim analysis of overall survival was not mature at the interim analysis of PFS. In the updated OS analysis conducted February 18, 2021, although median OS was not yet mature in either arm, a 40% reduction in risk of death was observed in the toripalimab arm compared to the placebo arm (HR = 0.60 [95% CI: 0.364-0.997], nominal P = 0.046);
- The incidence of grade ≥3 treatment emergent adverse events (TEAEs) (89.0% vs 89.5%), grade ≥3 treatment related adverse events (TRAE) (80.8% vs 83.2%), AEs leading to discontinuation of toripalimab/placebo (7.5% vs 4.9%), and fatal AEs (2.7% vs 2.8%) was similar between both arms. Immune-related (irAEs) (39.7% vs. 18.9%) and Grade ≥3 irAEs (7.5% vs. 0.7%) were more frequent in the toripalimab group.

A pre-specified second interim OS analysis will be performed at the same time as the final PFS analysis.

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 toripalimab Breakthrough Therapy Designation for this indication. 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. 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.

For additional information, please visit www.coherus.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 potential for toripalimab to gain approval in the United States for nasopharyngeal carcinoma or any indication; toripalimab's possibility to be the first marketed Chinese anti-PD-1 antibody in the overseas market; Coherus' and Junshi Biosciences' plans to file additional toripalimab BLAs with the FDA over the next three years for any clinical indication; 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, 2019, filed with the Securities and Exchange Commission on February 27, 2020, its Quarterly Report on Form 10-Q for the three and nine months ended September 30, 2020, filed with the Securities and Exchange Commission on November 5, 2020 and its future periodic reports to be filed with the Securities and Exchange Commission. Our results for the quarter ended September 30, 2020 are not necessarily indicative of our operating results for any future periods.

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