Coherus and Junshi Biosciences Announce Positive Final Overall Survival Results of JUPITER-02, a Phase 3 Clinical Trial Evaluating Toripalimab as Treatment for Recurrent or Metastatic Nasopharyngeal Carcinoma

Final overall survival analysis of the JUPITER-02 trial shows first-line treatment with toripalimab plus chemotherapy significantly prolongs survival in patients with advanced NPC

SHANGHAI, China and REDWOOD CITY, Calif., Feb. 15, 2023 (GLOBE NEWSWIRE) -- Shanghai Junshi Biosciences Co., Ltd ("Junshi Biosciences", HKEX: 1877; SSE: 688180) and Coherus BioSciences, Inc. ("Coherus", Nasdaq: CHRS) today announced positive results of a final analysis of overall survival ("OS") from the pivotal study JUPITER-02 (NCT03581786), a randomized, double-blind, placebo-controlled Phase 3 clinical trial evaluating toripalimab in combination with gemcitabine and cisplatin as the first-line treatment for patients with recurrent or metastatic nasopharyngeal carcinoma ("NPC"). This final analysis demonstrated a statistically significant and clinically meaningful improvement in OS in NPC patients treated with toripalimab plus chemotherapy compared to chemotherapy alone. These data are being submitted for presentation at an upcoming medical meeting.

"In the pivotal JUPITER-02 trial, toripalimab has demonstrated a statistically significant and clinically meaningful overall survival benefit for patients with advanced NPC, an aggressive head and neck tumor with no current FDA-approved treatment options," said Rosh Dias, M.D., Coherus' Chief Medical Officer. "These mature overall survival data continue to demonstrate the benefit of toripalimab in the treatment of NPC patients, further building upon the data published in Nature Medicine and presented at the 2021 plenary session at the ASCO annual meeting, and clearly show that toripalimab has the potential to become the new standard-of-care for NPC patients, once approved. We look forward to sharing these data with the oncology community at an upcoming medical meeting."

"With the ongoing accumulation of data from the JUPITER-02 trial, we are thrilled to observe toripalimab gain more ground for becoming the preferred treatment for advanced NPC," said Dr. Patricia Keegan, Chief Medical Officer of Junshi/TopAlliance Biosciences. "Compared to chemotherapy alone, a combination containing the immune checkpoint inhibitor, toripalimab, clearly has the potential to bring unprecedented changes to the extension of life in patients with NPC. We are looking forward to bringing this promising therapy to patients around the world."

The FDA has granted Breakthrough Therapy designations and priority review for the toripalimab Biologics License Application ("BLA") for use in combination with gemcitabine and cisplatin as first-line treatment for patients with advanced recurrent or metastatic NPC and for toripalimab monotherapy for the second-line or later treatment of recurrent or metastatic NPC after platinum-containing chemotherapy. Recurrent or metastatic NPC is an aggressive head and neck tumor which has no FDA-approved treatment options.

About toripalimab

Toripalimab is an anti-PD-1 monoclonal antibody that blocks PD-L1 binding to the PD-1 receptor at a unique site that minimizes opportunities for the tumor cell to evade the immune system and decreases PD-1's expression on the T-cell as a second method of restoring the body's immune response.

The FDA granted Breakthrough Therapy designation for toripalimab in combination with chemotherapy for the first-line treatment of recurrent or metastatic NPC in 2021 and as monotherapy for patients with progression following platinum-based chemotherapy in the treatment of recurrent or metastatic NPC in 2020. Additionally, the FDA has granted Fast Track designation for toripalimab for the treatment of mucosal melanoma and Orphan Drug designations for the treatment of esophageal cancer, mucosal melanoma, soft tissue sarcoma, and small cell lung cancer ("SCLC").

More than thirty company-sponsored toripalimab clinical studies covering more than fifteen indications have been conducted globally by Junshi Biosciences, 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®). Currently, there are six approved indications for toripalimab in China:

1. unresectable or metastatic melanoma after failure of standard systemic therapy;
2. in combination with cisplatin and gemcitabine as the first-line treatment for patients with locally recurrent or metastatic NPC.
3. recurrent or metastatic NPC after failure of at least two lines of prior systemic therapy;
4. locally advanced or metastatic urothelial carcinoma that failed platinum-containing chemotherapy or progressed within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy;
5. in combination with paclitaxel and cisplatin in first-line treatment of patients with unresectable locally advanced/recurrent or distant metastatic esophageal squamous cell carcinoma ("ESCC");
6. in combination with pemetrexed and platinum as the first-line treatment in EGFR mutation-negative and ALK mutation-negative, unresectable, locally advanced or metastatic non-squamous NSCLC.

The first three indications have been included in the National Reimbursement Drug List ("NRDL") (2022 Edition). Toripalimab is the only anti-PD-1 monoclonal antibody included in the NRDL for melanoma.

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 an anti-PD-1 monoclonal antibody in China. Its first-in-human anti-BTLA antibody for the treatment of various cancers was 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 pandemic, Junshi Biosciences' response was strong and immediate, 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. As of December 3, 2021, over 700,000 patients have been treated with bamlanivimab or bamlanivimab and etesevimab, potentially preventing more than 35,000 hospitalizations and at least 14,000 deaths. Meanwhile, VV116, a new oral nucleoside analog anti-SARS-CoV-2 drug designed to hinder virus replication has been approved for marketing in China and Uzbekistan. 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 3,100 employees in the United States (San Francisco and Maryland) and China (Shanghai, Suzhou, Beijing, Guangzhou, etc.). For more information, please visit: http://junshipharma.com.

About Coherus BioSciences

Coherus is a commercial-stage biopharmaceutical company focused on the research, development and commercialization of innovative immunotherapies to treat cancer. Coherus' strategy is to build a leading immuno-oncology franchise funded with cash generated through net sales of its diversified portfolio of FDA-approved therapeutics.

In 2021, Coherus in-licensed toripalimab, an anti-PD-1 antibody, in the United States and Canada. The Biologics License Application for toripalimab in combination with chemotherapy as treatment for recurrent or metastatic nasopharyngeal carcinoma is currently under review by the FDA.

Coherus markets UDENYCA® (pegfilgrastim-cbqv), a biosimilar of Neulasta®(pegfilgrastim), and CIMERLI® (ranibizumab-eqrn), a biosimilar of Lucentis®(ranibizumab), in the U.S., and expects to launch the FDA-approved Humira®(adalimumab) biosimilar YUSIMRY™ (adalimumab-aqvh) in the U.S. in mid-2023. In January 2023, Coherus agreed to enter into definitive agreements providing for the acquisition of exclusive U.S. commercial rights to an Eylea® (aflibercept) biosimilar, FYB203, and plans to file a BLA for FYB203 in 2023.

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 date of YUSIMRY™; Coherus' expectations about entering into definitive agreements and closing on those agreements to acquire exclusive U.S. commercial rights to an Eylea® biosimilar; expectations about Coherus' ability to file a BLA for an Eylea® biosimilar; Coherus' expectations about toripalimab gaining approval and becoming the new standard-of-care for patients with NPC after approval. 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, 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, the need to schedule inspections in China and the timing of Coherus' regulatory filings; 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 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' Annual Report on Form 10-Q for the quarter-ended September 30, 2022, filed with the Securities and Exchange Commission on November 8, 2022, including the section therein captioned "Risk Factors" and in other documents that Coherus files with the Securities and Exchange Commission.

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