



Coherus and Junshi Biosciences Announce Completion of Rolling BLA Submission to U.S. FDA for Toripalimab for the Treatment of Nasopharyngeal Carcinoma

SHANGHAI, China, and REDWOOD CITY, Calif., Sept. 01, 2021 (GLOBE NEWSWIRE) -- Shanghai Junshi Biosciences Co., Ltd. ("Junshi Biosciences", HKEX: 1877; SSE: 688180) and Coherus Biosciences, Inc. ("Coherus", Nasdaq: CHRS) announced today the completion of the rolling submission of the Biologics License Application ("BLA") to the U.S. Food and Drug Administration ("FDA") for toripalimab in combination with gemcitabine and cisplatin for first-line treatment for patients with advanced recurrent or metastatic nasopharyngeal carcinoma ("NPC") and toripalimab monotherapy for second-line or above treatment of recurrent or metastatic NPC after platinum-containing chemotherapy.

The FDA recently granted Breakthrough Therapy Designation ("BTD") for toripalimab in combination with chemotherapy (gemcitabine and cisplatin) for 1st line treatment of recurrent, locally advanced or primary metastatic non-keratinizing nasopharyngeal carcinoma ("NPC") and earlier in 2020 granted BTD for toripalimab monotherapy for patients with recurrent or metastatic non-keratinizing NPC with disease progression on or after platinum-containing chemotherapy. BTD is intended to expedite the development and regulatory review of drugs where preliminary clinical evidence demonstrates substantial improvement over existing therapies for a severe or life-threatening disease. Drugs with BTD will be granted more frequent FDA interaction and intensive guidance – including that from senior FDA officials – on the development program and ability to participate in various forms of expedited FDA review programs to provide patients with new therapy as soon as possible.

"Toripalimab was approved for marketing early this year in China as the world's first immune checkpoint inhibitor to treat advanced NPC, an aggressive tumor with limited treatment options," said Patricia Keegan, MD, Chief Medical Officer of Junshi Biosciences. "Toripalimab showed remarkable efficacy in the treatment of advanced NPC according to the results from POLARIS-02 and JUPITER-02 studies, as recognized by inclusion in plenary and other presentations at leading international medical professional conferences and publications in highly respected scientific journals. We look forward to working closely with the FDA in the review of this BLA and with our U.S. partner, Coherus, to bring this new treatment option forward as expeditiously as possible for patients in the U.S."

"Toripalimab, the foundation stone of our emerging immuno-oncology franchise, demonstrated compelling efficacy in the pivotal studies supporting the BLA for nasopharyngeal carcinoma," said Denny Lanfear, Coherus CEO. "As data read out from the extensive set of pivotal clinical trials potentially supporting a broad range of additional indications, we expect toripalimab to maintain a consistently strong efficacy profile. We will continue to work with our partner, Junshi Biosciences, to advance toripalimab through FDA approval."

The submission is supported by the results from "POLARIS-02" and "JUPITER-02". The POLARIS-02 study is a multi-center, open-label, pivotal Phase II clinical study, results of which were published online in January 2021 in *Journal of Clinical Oncology*. The JUPITER-02 study is a randomized, double blind, placebo-controlled pivotal Phase 3 clinical trial, results of which were recently presented at the ASCO plenary session (#LBA2) and published in the August 2021 [on-line edition of Nature Medicine](#).

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 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 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 designation for toripalimab in combination with chemotherapy for the 1st line treatment of recurrent or metastatic 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 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 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; 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 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 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.

Coherus Contact Information:

IR Contact:
McDavid Stilwell
Coherus BioSciences, Inc.
mstilwell@coherus.com
+1 (650) 395-0152

Media Contact:
Sheryl Seapy
Real Chemistry
sseapy@realchemistry.com
+1 (949) 903-4750

Junshi Biosciences Contact Information

IR Team:
Junshi Biosciences
info@junshipharma.com
+ 86 021-2250 0300

Solebury Trout
Bob Ai
bai@soleburytrout.com
+ 1 646-389-6658

PR Team:
Junshi Biosciences
Zhi Li
zhi_li@junshipharma.com
+ 86 021-6105 8800

