Coherus BioSciences to expand late-stage pipeline to immuno-oncology with in-license of Junshi Biosciences' PD-1, toripalimab, in United States and Canada

- Coherus to pay $150 million upfront for U.S. and Canada rights to toripalimab, an extensively studied, late-stage anti-PD-1 antibody
- First U.S. BLA filing expected this year for nasopharyngeal carcinoma with breakthrough therapy designation
- Options to PD-1 combination agents, TIGIT and IL-2, add long-term growth potential
- Conference call at 8:00 am Eastern Time today

REDWOOD CITY, Calif., Feb. 01, 2021 (GLOBE NEWSWIRE) -- Coherus BioSciences, Inc. ("Coherus", Nasdaq: CHRS) today announced a collaboration with Shanghai Junshi Biosciences, Co., Ltd ("Junshi Biosciences", HKEX: 1877; SSE: 688180) for the development and commercialization of toripalimab, Junshi Biosciences' anti-PD-1 antibody, in the United States and Canada. Upon satisfaction of closing conditions, Coherus and Junshi Biosciences will co-develop toripalimab, and Coherus will be responsible for all commercial activities in the licensed territory. Under the terms of the agreement, Coherus will also be granted options to Junshi Biosciences' TIGIT-targeted antibody and next generation engineered IL-2 cytokine for evaluation as potential combination therapies with toripalimab, as well as certain negotiation rights to two early-stage checkpoint inhibitor antibodies.

"Toripalimab has a compelling late-stage clinical profile and will be the cornerstone of our immuno-oncology franchise. This transaction expands our late-stage pipeline into the rapidly growing checkpoint inhibitor market, which is expected to exceed $25 billion in the United States by 2025, and provides us a PD-1 backbone for potential long-term growth with next-generation immuno-oncology combinations," said Denny Lanfear, CEO of Coherus. "Junshi Biosciences is an innovation-driven biopharmaceutical company with global clinical research capabilities, and we are excited to collaborate with them as we build on our success in oncology with biosimilars and broaden our mission of expanding patient access and delivering health care system savings to larger markets."

"We believe Coherus is the right partner for us in North America. Their commercial team has demonstrated remarkable ability to gain significant share of the oncology market against entrenched large competitors," said Dr. Ning LI, CEO of Junshi Biosciences. "Toripalimab could be the first marketed Chinese anti-PD-1 antibody in the overseas market. The collaboration with Coherus will be a critical step to build up our global commercial network. We look forward to working closely with Coherus to establish toripalimab's position in the United States and Canadian markets in order to provide patients with affordable high-quality innovative care."

More than 2,100 patients have received toripalimab treatment in clinical trials, and toripalimab is approved for second-line treatment of unresectable or metastatic melanoma in China where it is marketed by Junshi Biosciences and is included on the National Reimbursement Drug List ("NRDL") for the treatment of melanoma. Over the next three years, significant data are expected to read out from the extensive registrational development program, which includes 15 ongoing and completed pivotal clinical trials evaluating toripalimab in multiple treatment settings for a broad range of solid tumor types including cancers of the lung, nasopharynx, esophagus, stomach, bladder, breast, liver, kidney and skin.

The United States Food and Drug Administration ("FDA") has granted breakthrough therapy designation to toripalimab for 3 rd line nasopharyngeal carcinoma ("NPC"), and Coherus expects the first toripalimab biologics license application ("BLA") to be filed with the FDA for this indication later this year. 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. Coherus and Junshi Biosciences plan to file additional toripalimab BLAs with the FDA over the next three years for multiple rare and highly prevalent cancers, including non-small cell lung cancer ("NSCLC").

As part of the collaboration, Coherus will also be granted options and certain negotiation rights to four of Junshi Biosciences' novel oncology molecules for potential development in combination with toripalimab:

- JS006, an antibody targeting TIGIT, a clinically validated immune inhibitory checkpoint. Anti-TIGIT antibodies have demonstrated synergistic anti-tumor activity in combination with anti-PD-1 antibodies. Coherus expects this compound to enter clinical development later this year. The option to JS006 is exercisable prior to initiation of Phase 2 clinical development.
- JS018, a next-generation engineered IL-2 cytokine designed to inhibit stimulation of regulatory T cells while retaining stimulatory activity on effector T cells and natural killer ("NK") cells. The option to JS018 is exercisable prior to initiation of Phase 2 clinical development.
- Two additional undisclosed early-stage novel immuno-oncology drug candidates to which Coherus will also be granted certain negotiation rights.

Mr. Lanfear provided further comment on Coherus' corporate strategy: "We plan to invest the cash generated by our biosimilar commercial business to build a focused immuno-oncology franchise, which will leverage our development and commercial capabilities into large and growing markets. We will prudently allocate our R&D resources to realize the exciting potential of toripalimab in both the monotherapy and combination settings. With respect to biosimilars, our focus will be commercialization, as we continue to pursue UDENYCA® market share growth and prepare for projected launches through 2023 of biosimilars of Humira®, Avastin® and Lucentis®, if approved."

Coherus is discontinuing the development of CHS-2020 (Eylea® biosimilar candidate) and will direct those capital and development resources to the toripalimab monotherapy and combinations program.

Terms of the Coherus – Junshi Biosciences collaboration
Under the terms of the agreement, Coherus will pay $150 million upfront for exclusive rights to toripalimab in the United States and Canada, options in these territories to Junshi Biosciences' anti-TIGIT antibody and next-generation engineered IL-2 cytokine, and certain negotiation rights to two undisclosed preclinical immuno-oncology drug candidates. Coherus will also pay Junshi Biosciences a 20% royalty on net sales of toripalimab and up to an aggregate $380 million in one-time payments for the achievement of various milestones, including up to $290 million for attainment of certain sales thresholds. The option exercise fee for each of the anti-TIGIT antibody and the IL-2 cytokine is $35 million per program. Additionally, for each option program, Coherus will pay Junshi Biosciences an 18% royalty on net sales and up to an aggregate $255 million for the achievement of various

milestones, including up to $170 million for attainment of certain sales thresholds. The Companies will collaborate in the development of toripalimab and the other licensed compounds, and Coherus will pay for a portion of these co-development activities up to a maximum of $25 million per licensed compound per year.

Closing of the collaboration agreement is subject to clearance under the Hart-Scott Rodino Antitrust Improvements Act.

Jonathan Lanfear of Lanfear Advisors LLC led negotiations on behalf of Coherus, and Ropes & Gray LLP provided licensee's legal counsel.

Conference call at 8:00 am Eastern Time
Webcast: The conference call will be broadcast live in listen-only mode on the Company's investor relations website at https://investors.coherus.com/. If you would like to ask a question, the dial in number for the conference call is (844) 452-6826 (Toll Free U.S. and Canada) or (765) 507-2587 (International).
Conference ID: 7784059
Please dial-in 15 minutes early to ensure a timely connection to the call.

A link to the conference call replay will be available on the Coherus website for two weeks following the call.

About toripalimab (approved in China as TUOYI®)
Toripalimab is the first Chinese domestic anti-PD-1 monoclonal antibody to obtain a marketing approval in China. More than thirty company-sponsored toripalimab clinical studies covering more than 15 indications have been conducted globally, including in China and the United States. In December 2018, toripalimab obtained a conditional approval from China's National Medical Products Administration ("NMPA") for the second-line treatment of patients with unresectable or metastatic melanoma. Supplemental NDAs of toripalimab for the third-line treatment of recurrent/metastatic nasopharyngeal carcinoma and second-line treatment of metastatic urothelial carcinoma were accepted by the NMPA in April and May 2020, respectively. Both supplemental NDAs received priority review designations from the NMPA in July 2020. In December 2020, toripalimab was included in the NRDL for the treatment of melanoma by the China National Healthcare Security Administration (NHSA).

In the United States, the FDA has granted toripalimab breakthrough therapy designation for the treatment of recurrent/metastatic nasopharyngeal carcinoma, Fast Track designation for mucosal melanoma, and orphan drug designation for the treatment of nasopharyngeal carcinoma, mucosal melanoma and soft tissue sarcoma.

About the toripalimab clinical development program
Toripalimab is being evaluated in an extensive registrational clinical development program for a broad range of solid tumor types including cancers of the lung, nasopharynx, esophagus, stomach, bladder, breast, liver, kidney and skin.

- Safety and Efficacy of Recombinant Humanized Anti-PD-1 mAb for Patients With Locally Advanced or Metastatic Melanoma (POLARIS-01) - NCT03013101
- Phase 1b/2 trial Evaluating Toripalimab in Patients with Advanced Gastric Adenocarcinoma, ESCC, NPC and Head and Neck Squamous Cell Carcinoma (POLARIS-02) - NCT02915432
- Safety and Efficacy of Toripalimab for Patients With Locally Advanced or Metastatic Bladder Urothelial Carcinoma (POLARIS-03) - NCT03113266
- A Study to Evaluate the Efficacy and Safety of Toripalimab Injection in the Treatment of Recurrent or Metastatic Gastric or Gastroesophageal Junction Adenocarcinoma Who Have Failed at Least Two Prior Lines of Therapy and Are Positive for Specific Markers - NCT04603040
- Phase III Study of Comparing TORIPALIMAB INJECTION Versus Placebo Combined With Chemotherapy for Recurrent or Metastatic Nasopharyngeal Cancer - NCT03581786
- Toripalimab or Placebo as Adjuvant Therapy in Hepatocellular Carcinoma After Curative Hepatic Resection (JUPITER-04) - NCT03859128
- A Phase III Study to Investigate Toripalimab Versus Dacarbazine as the First Line Therapy for Unresectable or Metastatic Melanoma (JS001) - NCT03430297
- A Study to Evaluate the Efficacy and Safety of Toripalimab or Placebo Combined With Chemotherapy in Treatment-naive Advanced NSCLC (CHOICE-01) - NCT03856411
- Toripalimab or Placebo With Paclitaxel and Cisplatin in Esophageal Squamous Cell Carcinoma (JUPITER-06) - NCT03829969
- Toripalimab Plus Pemetrexed+Platinus in Advanced Non-small-cell Lung cancer Patients Previously Treated with EGFR-TKI - NCT03924050
- Toripalimab in Combination With Nab-Paclitaxel For Patients With Metastatic or Recurrent Triple-Negative Breast Cancer (TNBC) With or Without Systemic Treatment (TORCHLIGHT) - NCT04085276
- Phase 3 Trial Comparing Toripalimab + Lenvatinib vs. Lenvatinib Alone as a 1st line Treatment for Patients with Advanced HCC - NCT04523493
- Toripalimab in Combination With Platinum Plus Etoposide in Patients With Extensive-Stage Small Cell Lung Cancer - NCT04012606
- A Study of Toripalimab or Placebo Plus Chemotherapy as Treatment in Early Stage NSCLC - NCT04158440
- Study to Evaluate the Efficacy and Safety of Toripalimab in Combination With Axitinib Versus Sunitinib Monotherapy in Advanced Renal Cell Cancer - NCT04394975
- A Study Evaluating Toripalimab Injection Combined With Standard Chemotherapy as a First-line Treatment for Locally Advanced or Metastatic Urothelial Carcinoma - NCT04568304

About JS006
JS006 is a recombinant humanized IgG4κ monoclonal antibody against human TIGIT specifically, developed independently by Junshi Biosciences. According to the results of preclinical studies, JS006 can specifically block the TIGIT-PVR pathway.

About JS018
JS018 is a next-generation engineered IL-2 cytokine designed to inhibit stimulation of regulatory T cells while retaining stimulatory activity on effector T cells and natural killer ("NK") cells.

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 27 innovative drug candidates and two 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 an 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, China's first neutralizing fully human monoclonal antibody against SARS-CoV-2, which has entered clinical trials and is now a part of the company's 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, Inc.
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.

In February 2021, Coherus and Junshi Biosciences announced a collaboration in which Coherus would in-license toripalimab, an anti-PD-1 antibody, in the United States and Canada. 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 biosimilars of Humira®, Avastin® and Lucentis®, if approved.

For additional information, please visit www.coherus.com.

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.
Eylea® is a registered trademark of Regeneron Pharmaceuticals, 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; Coherus' ability to use toripalimab as a PD-1 backbone for potential long-term growth with next-generation immuno-oncology drug combinations; Coherus' ability to build on its success in oncology with biosimilars; Coherus' ability to successfully compete against entrenched large competitors in the oncology and checkpoint inhibitor markets; Coherus' ability to broaden its mission of expanding patient access and delivering health care system savings to larger markets; 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; the expectation to obtain significant data to read out over the next three years for any indication; Coherus' intentions to exercise its option to JS006 prior to initiation of Phase 2 clinical development; Coherus' expectations for JS006 to enter clinical development later in 2021; Coherus' plans to invest the cash generated by its biosimilar commercial business to build a focused immuno-oncology franchise; Coherus' ability to prudently allocate its R&D resources to realize the potential of toripalimab in both the monotherapy and combination settings; Coherus' ability to prepare for projected launches through 2023 of biosimilars of Humira®, Avastin® and Lucentis®, if approved; Coherus' ability to discontinue the development of CHS-2020 (Eylea ® biosimilar candidate) and direct capital and development resources to the toripalimab monotherapy and combinations program.

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 risk that the parties are unable to obtain clearance under the Hart-Scott Rodino Antitrust Improvements Act, from the Committee on Foreign Investment in the United States, or any other statute or regulatory agency having jurisdiction with respect to the proposed transactions, 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.

Contact

McDavid Stilwell
EVP, Financial Strategy and IR
Coherus BioSciences, Inc.
mstilwell@coherus.com
+1 (650) 395-0152

Source: Coherus BioSciences, Inc.