Coherus Announces Positive Final Overall Survival Results of JUPITER-02 Phase 3 Trial Evaluating Toripalimab in Nasopharyngeal Carcinoma

– Toripalimab plus chemotherapy resulted in a 37% reduction in the risk of death, HR=0.63, versus chemotherapy alone, in nasopharyngeal carcinoma patients –

– No treatments are approved for NPC in the US; if approved, toripalimab will address a critical unmet need –

REDWOOD CITY, Calif., June 05, 2023 (GLOBE NEWSWIRE) -- Coherus BioSciences, Inc. (“Coherus”, Nasdaq: CHRS) announced the final overall survival (OS) results of the JUPITER-02 study presented today at the American Society for Clinical Oncology (ASCO) Annual Meeting. JUPITER-02 is a randomized, double-blind, placebo-controlled Phase 3 clinical trial evaluating toripalimab in combination with gemcitabine and cisplatin as a first-line treatment for patients with recurrent or metastatic nasopharyngeal carcinoma (NPC).

The final analysis of the JUPITER-02 clinical trial (NCT03581786) demonstrated a statistically significant and clinically meaningful improvement in OS for NPC patients who were treated with toripalimab in combination with gemcitabine and cisplatin chemotherapy, versus chemotherapy treatment alone. Median OS has not been reached in the toripalimab arm versus 33.7 months for chemotherapy treatment alone, HR=0.63 (95% CI 0.45-0.89); P=0.0083.

“There are limited options for patients living with this very aggressive form of head and neck cancer. These results are remarkable, with meaningful improvement over chemotherapy alone, and this is practice-changing," said Jennifer Choe, M.D., Ph.D., Assistant Professor of Medicine and the Head and Neck Medical Oncology Disease Team Lead in the Division of Hematology and Oncology at Vanderbilt University Medical Center. "I was impressed with the primary endpoint outcome, extending progression-free survival from 8.2 months with chemotherapy alone to 21.4 months with the addition of toripalimab, and now with the strong overall survival data, this will be a new standard of care for patients, if approved.”

Rosh Dias, M.D., Coherus’ Chief Medical Officer, echoed Dr. Choe's remarks, “This landmark trial demonstrates a significant survival advantage for patients with recurrent or metastatic nasopharyngeal carcinoma who were treated with toripalimab. No other PD-1 inhibitor currently approved in the U.S. has had a successful Phase 3 trial in recurrent or metastatic NPC that met its primary endpoints. Toripalimab, therefore, addresses an important unmet need for patients with NPC for whom there are currently no approved immunotherapies in the United States, and we look forward to bringing this important medicine to patients upon approval.”

The Biologics License Application (BLA) for toripalimab in combination with chemotherapy as treatment for recurrent or metastatic nasopharyngeal carcinoma is currently under review by the U.S. FDA. In May 2023, FDA completed the required pre-licensing inspection of partner Shanghai Junshi Biosciences Ltd.’s toripalimab manufacturing site in China, and Coherus continues to collaborate with FDA to complete the clinical site inspections. Coherus projects potential approval in the third quarter of 2023 and plans to launch toripalimab in the United States directly, if approved.

Toripalimab JUPITER-02 Overall Survival Results

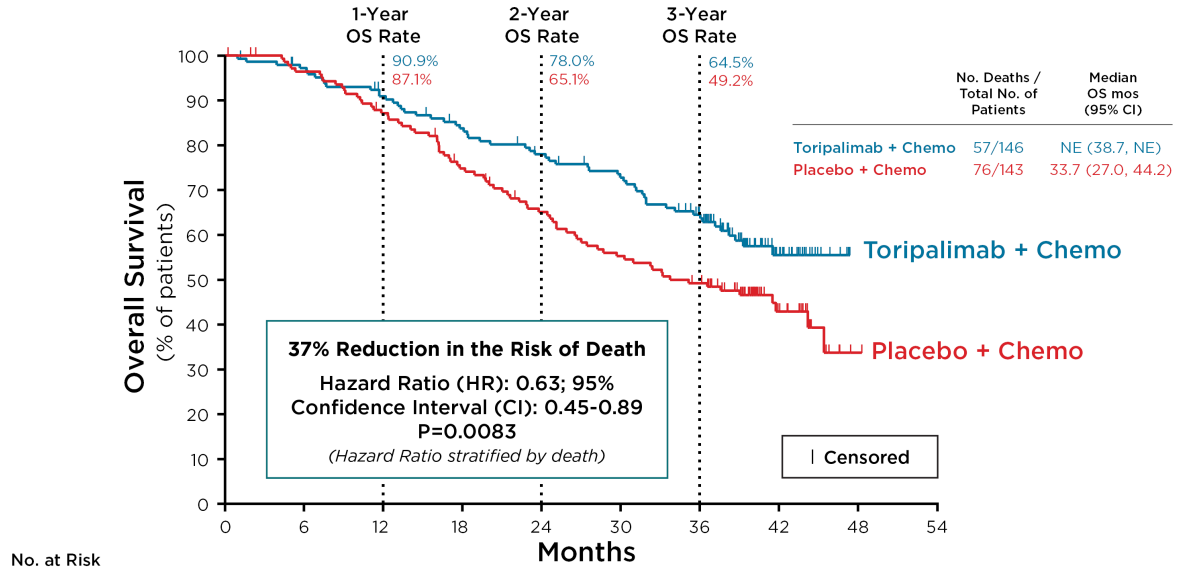
JUPITER-02 is a Phase 3, randomized study which examined the use of toripalimab versus placebo in combination with gemcitabine and cisplatin as a first-line treatment in recurrent/metastatic NPC.

At the final OS analysis, the median overall survival follow-up time was 36.0 months. A significant improvement in OS was observed in the toripalimab arm, and median OS was not yet reached, compared to 33.7 months in the placebo arm. The 2-year and 3-year OS rates for toripalimab + chemotherapy versus placebo + chemotherapy were 78.0% vs. 65.1%, and 64.5% vs. 49.2% respectively.

A photo accompanying this announcement is available at https://www.globenewswire.com/NewsRoom/AttachmentNg/1c6824a5-8c2a-43f8-bd14-ee90d8f1ce5d

JUPITER-02 Final Overall Survival Analysis in Intent-To-Treat Population

Data cut-off date: Nov 18, 2022



No. at Risk										
Toripalimab + Chemo	146	139	128	116	106	97	79	25	0	0
Placebo + Chemo	143	135	121	102	86	73	64	21	1	0

CI – Confidence interval; **NE** – Not evaluable; **ITT** – Intent to treat; **OS** – Overall survival; **RCT** – Randomized controlled trial; **R/M-NPC** – Recurrent or metastatic NPC

A consistent effect on OS, favoring the toripalimab arm, was observed in nearly all subgroups, including PD-L1 high and PD-L1 low expression subgroups.
No new safety signals were identified in the toripalimab arm since the interim report. The incidence of Grade ≥3 adverse events (AEs) (89.7% vs 90.2%) and fatal AEs (3.4% vs 2.8%) were similar between the two arms. AEs leading to discontinuation of toripalimab versus placebo (11.6% vs 4.9%), immune-related (irAEs) (54.1% vs. 21.7%) and Grade ≥3 irAEs (9.6% vs. 1.4%) were more frequent in the toripalimab arm.

These data were presented in a poster discussion session today by Prof. Rui-hua XU, Sun Yat-sen University Cancer Center, JUPITER-02 principal investigator:

Abstract #6009/Poster #1: *"Final Overall Survival Analysis of JUPITER-02: a Phase 3 study of Toripalimab versus Placebo in Combination with Gemcitabine and Cisplatin as First-line Treatment for Recurrent or Metastatic Nasopharyngeal Carcinoma (NPC)"*

Commitment to the NPC Community
As there are limited resources for patients living with NPC and their caregivers, Coherus has launched a new educational resource, NPCFacts.com, for patients living with NPC which includes detailed information about the types of NPC, the causes, diagnosis, and current treatment options.

In addition to education about nasopharyngeal carcinoma, the website includes links to patient advocacy organizations providing additional resources for patients and their caregivers. Head and Neck Cancer Alliance, Support for People with Oral Head and Neck Cancer (SPOHNC), and Thyroid Head and Neck Cancer Foundation (THANC) are some of the organizations included on the website.

The website also includes a companion website for healthcare professionals treating patients with NPC with educational resources and peer-to-peer education.

Additional toripalimab clinical data presented at ASCO include:

CHOICE-01, NEOTORCH, and Torchlight Studies Demonstrate Clinical Benefit of Toripalimab in NSCLC and TNBC
Abstract # 9003: *"Final overall survival and biomarker analyses of CHOICE-01: A double-blind randomized phase 3 study of toripalimab versus placebo in combination chemotherapy for advanced NSCLC without EGFR/ALK mutations."*

- A significant improvement in OS was observed for the toripalimab arm over the placebo arm: HR=0.73 (95% CI: 0.57-0.93), two-sided p=0.0108, median OS 23.8 vs 17.0 months

Abstract #8501: *"Perioperative toripalimab + platinum-doublet chemotherapy vs. chemotherapy in resectable stage II/III non-small cell lung cancer (NSCLC): Interim event-free survival (EFS) analysis of the phase 3 NEOTORCH study."*

- Event free survival (EFS) was significantly improved in the toripalimab arm, HR=0.40, 95% CI (0.277-0.565), P<0.0001, and crossed the pre-specified efficacy boundary
- The median EFS was not reached in the toripalimab arm and was 15.1 months in the placebo arm

Abstract #LBA1013: *"TORCHLIGHT: a randomized, double-blind, phase III trial of toripalimab versus placebo, in combination with nab-paclitaxel (nab-P) for patients with metastatic or recurrent triple-negative breast cancer (TNBC)"*

- A statistically significant improvement in PFS was demonstrated for the toripalimab arm in the PD-L1 positive subgroup (mPFS 8.4 vs 5.6 months; HR = 0.653, 95% CI 0.470-0.906, P = 0.0102).
- PFS in the ITT population showed a similar trend (mPFS 8.4 vs 6.9 months, HR = 0.773, 95%CI 0.602-0.994)

- OS showed a trend towards improved OS in the PD-L1 positive (mOS 32.8 vs 19.5 months; HR = 0.615, 95%CI 0.414-0.914)

More than 20 toripalimab abstracts were accepted for ASCO 2023, including two selected for oral presentations (LBA1013 and #8501), describing the antitumor activities observed from various cancers of the nasopharynx, hypopharynx, skin, breast, lung, esophagus, stomach, liver, biliary duct, sarcoma, urothelial, head and neck, endometrial, thyroid, laryngeal, and pancreas.

Coherus Continues to Innovate to Address Unmet Patient Need in Cancer Patients with U.S. Launch of UDENYCA® Autoinjector
Coherus recently announced the introduction of a prefilled autoinjector presentation of UDENYCA® (pegfilgrastim-cbqv) in the United States. UDENYCA® is designed to be administered the day after chemotherapy to decrease the incidence of infection as manifested by febrile neutropenia. The autoinjector has a streamlined, easy-to-use design for both in-clinic and at-home care settings, and features push-on-skin activation to reliably deliver a complete dose.

About toripalimab
Toripalimab is an anti-PD-1 monoclonal antibody that blocks PD-L1 binding to the PD-1 receptor at a unique site with high affinity and activates antitumor immunity demonstrating improvement in the overall survival of cancer patients in several tumor types. The BLA for toripalimab in combination with chemotherapy as treatment for recurrent or metastatic nasopharyngeal carcinoma is currently under review by the FDA. The FDA granted Breakthrough Therapy designation for toripalimab in combination with chemotherapy for the first-line treatment of recurrent or metastatic NPC in 2021 as well as for toripalimab monotherapy in the second or third-line 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 ESCC, NPC, mucosal melanoma, soft tissue sarcoma, and small-cell lung cancer (SCLC).

More than 30 company-sponsored toripalimab clinical studies covering over fifteen indications have been conducted globally by Junshi Biosciences, including in China, the United States, Southeast Asia, and European countries. Ongoing or completed 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.

About UDENYCA®
UDENYCA® is the only pegfilgrastim brand offering two on-demand options—prefilled syringe (PFS) and autoinjector (AI) providing more choice and flexibility customized to meet the needs of patients and practices. UDENYCA® (pegfilgrastim-cbqv) administered via a proprietary on-body injector (OBI) device is under review by the FDA. If approved, UDENYCA® OBI would offer providers a highly desired alternative to the originator's on-body pegfilgrastim delivery system. Since 2019, over 263,000 patients have been treated with UDENYCA®.

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®, and CIMERLI® (ranibizumab-eqrn), a biosimilar of Lucentis®, in the U.S., and expects to launch the FDA-approved Humira® biosimilar YUSIMRY™ (adalimumab-aqvh) in the U.S. in July 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™ and other product candidates; Coherus' ability to gain approval for any of its product candidates and the timing of such approval; and expectations for the ability of toripalimab to become the new standard of care for NPC. 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 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' Quarterly Report on Form 10-Q the quarter ended March 31, 2023, filed with the Securities and Exchange Commission on May 8, 2023, including the section therein captioned "Risk Factors" and in other documents Coherus files with the Securities and Exchange Commission.

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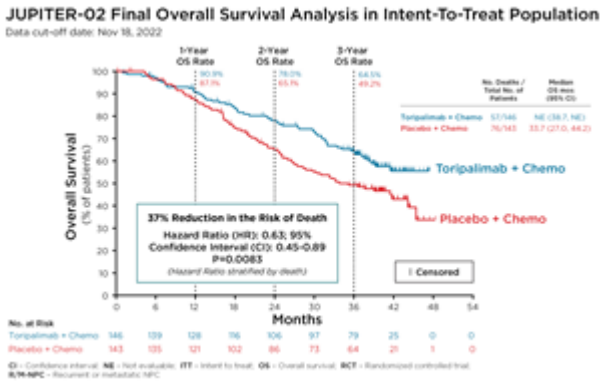
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