Caribou Biosciences Provides Regulatory Update on CB-010 Pivotal Plan with Phase 3 Trial Initiation Expected by YE 2024

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-- Caribou met with the FDA and reached alignment on a pivotal trial in 2L LBCL with CB-010 versus a comparator arm of immunochemotherapy followed by HDCT and ASCT --

-- ANTLER Phase 1 trial continues dose expansion enrollment; initial dose expansion data and RP2D expected Q2 2024 --

-- Caribou plans to initiate Phase 3 pivotal trial by YE 2024 --

BERKELEY, Calif., Dec. 12, 2023 (GLOBE NEWSWIRE) -- Caribou Biosciences, Inc. (Nasdaq: CRBU), a leading clinical-stage CRISPR genome-editing biopharmaceutical company, today provided an update based on feedback from the U.S. Food and Drug Administration (FDA) following recent communications and a Type B clinical meeting regarding the CB-010 development program. The company has received the FDA's feedback on a Phase 3 randomized controlled trial for CB-010, an allogeneic anti-CD19 CAR-T cell therapy in development for patients with second-line relapsed or refractory large B cell lymphoma (r/r LBCL). The FDA stated that Caribou's proposed comparator arm of platinum-based immunochemotherapy followed by high dose chemotherapy (HDCT) and autologous stem cell transplantation (ASCT) is acceptable.

"FDA feedback on our CB-010 pivotal development plan represents an important step in advancing our lead therapy to enable broader access of CAR-T cell therapies for patients living with large B cell lymphoma," said Rachel Haurwitz, PhD, Caribou's president and chief executive officer. "As our ongoing ANTLER trial progresses, we look forward to engaging again with the FDA ahead of initiating our planned Phase 3 pivotal trial. Our goal is to establish a new second-line standard of care by delivering an off-the-shelf CAR-T cell therapy to patients as expeditiously as possible."

In the ongoing ANTLER Phase 1 trial, Caribou is enrolling second-line LBCL patients in the dose expansion portion based on promising data from the dose escalation portion of the trial. Currently, 22 sites are active in the U.S. and the first international site is active in Australia, with additional site activation underway in the U.S. and globally. To Caribou's knowledge, CB-010 is the first anti-CD19 allogeneic CAR-T cell therapy to be evaluated in the second-line LBCL setting and it has been granted Regenerative Medicine Advanced Therapy (RMAT), Fast Track, and Orphan Drug designations by the FDA. In Q2 2024, the company plans to report initial dose expansion data from the ANTLER trial and share the recommended Phase 2 dose (RP2D) for CB-010. Caribou plans to initiate a Phase 3 pivotal trial with this RP2D by year-end 2024.

About CB-010
CB-010 is the lead product candidate from Caribou's allogeneic CAR-T cell therapy platform and is being evaluated in patients with relapsed or refractory B cell non-Hodgkin lymphoma (r/r B-NHL). In the ongoing ANTLER Phase 1 trial, Caribou is enrolling second-line patients with large B cell lymphoma (LBCL) comprised of different subtypes of aggressive r/r B-NHL (DLBCL NOS, PMBCL, HGBL, tFL, and tMZL). CB-010 is an allogeneic anti-CD19 CAR-T cell therapy engineered using Cas9 CRISPR hybrid RNA-DNA (chRDNA) genome-editing technology. To Caribou's knowledge, CB-010 is the first allogeneic CAR-T cell therapy in the clinic with a PD-1 knockout, a genome-editing strategy designed to improve antitumor activity by limiting premature CAR-T cell exhaustion. Also, to Caribou's knowledge, CB-010 is the first anti-CD19 allogeneic CAR-T cell therapy to be evaluated in the second-line LBCL setting and it has been granted Regenerative Medicine Advanced Therapy (RMAT), Fast Track, and Orphan Drug designations by the FDA. Additional information on the ANTLER trial (NCT04637763) can be found at clinicaltrials.gov.

About Caribou's novel next-generation CRISPR platform
CRISPR genome editing uses easily designed, modular biological tools to make DNA changes in living cells. There are two basic components of Class 2 CRISPR systems: the nuclease protein that cuts DNA and the RNA molecule(s) that guide the nuclease to generate a site-specific, double-stranded break, leading to an edit at the targeted genomic site. CRISPR systems are capable of editing unintended genomic sites, known as off-target editing, which may lead to harmful effects on cellular function and phenotype. In response to this challenge, Caribou has developed CRISPR hybrid RNA-DNA guides (chRDNAs; pronounced "chardonnays") that direct substantially more precise genome editing compared to all-RNA guides. Caribou is deploying the power of its Cas12a chRDNA technology to carry out high efficiency multiple edits, including multiplex gene insertions, to develop CRISPR-edited therapies.

About Caribou Biosciences, Inc.
Caribou Biosciences is a clinical-stage CRISPR genome-editing biopharmaceutical company dedicated to developing transformative therapies for patients with devastating diseases. The company's genome-editing platform, including its Cas12a chRDNA technology, enables superior precision to develop cell therapies that are armored to potentially improve antitumor activity. Caribou is advancing a pipeline of off-the-shelf cell therapies from its CAR-T and CAR-NK platforms as readily available treatments for patients with hematologic malignancies and solid tumors. Follow us @CaribouBio and visit www.cariboubio.com.

Forward-looking statements
This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements include, without limitation, statements related to Caribou's strategy, plans, objectives, and expectations regarding its clinical and preclinical development programs, including its expectations relating to the timing of initiating patient enrollment in the Phase 3 pivotal trial by year-end 2024, reporting of initial dose expansion data from the ongoing ANTLER 1 Phase 1 trial and sharing the recommended Phase 2 dose for CB-010 in Q2 2024, and the timing of updates from its ANTLER Phase 1 clinical trial for CB-010. Management believes that these forward-looking statements are reasonable as and when made. However, such forward-looking statements are subject to risks and uncertainties, and actual results may differ materially from any future results expressed or implied by the forward-looking statements. Risks and uncertainties include, without limitation, risks inherent in the development of cell therapy products; uncertainties related to the initiation, cost, timing, progress, and results of Caribou's current and future research and development programs, preclinical studies, and clinical trials; and the risk that initial, preliminary, or interim clinical trial data will not ultimately be predictive of the safety and efficacy of Caribou's product candidates or that clinical outcomes may differ as patient enrollment continues and as more patient data becomes available; the risk that preclinical study results observed will not be borne out in human patients or different conclusions or considerations are reached once additional data have been received and fully evaluated; the ability to obtain key regulatory input and approvals as well as other risk factors described from time to time in Caribou's filings with the Securities and Exchange Commission, including its Annual Report on Form 10-K for the year ended December 31, 2022 and subsequent filings. In light of the significant uncertainties in these forward-looking statements, you should not rely upon forward-looking statements as predictions of future events. Except as required by law, Caribou

undertakes no obligation to update publicly any forward-looking statements for any reason.

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