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After Much Anticipation, Cellecstar Biosciences Initiates NCI-Supported Phase II Trial of CLR 131 in Multiple Myeloma and Other Blood Cancers

MADISON, Wis., March 30, 2017 (GLOBE NEWSWIRE) -- Madison, Wis. Cellecstar Biosciences, Inc. (Nasdaq:CLRB), an oncology-focused clinical stage biotechnology company, today announces the initiation of a Phase II clinical study of its lead phospholipid drug conjugate (PDC) CLR 131 in patients with multiple myeloma and other hematologic malignancies.

The study will be conducted in up to 15 centers in the United States for patients with a variety of orphan-designated relapse or refractory hematologic cancers. The study's primary endpoint is objective response rate (ORR), with additional endpoints of progression free survival (PFS), median overall survival (OS) and other markers of efficacy following a single 25.0 mCi/m² dose of CLR 131, with the option for a second 25.0 mCi/m² dose approximately 75-180 days later. Cellecstar will receive approximately \$2 million in a non-dilutive grant to help fund the trial from the National Cancer Institute and initial efficacy data are expected as early as the second half of 2017.

"I would like to thank the entire team at Cellecstar whose diligent efforts enabled the company to initiate the Phase II trial a full quarter ahead of our original guidance. The prospect of extending patient survival with a one or two-dose treatment continues to drive a high sense of urgency for all involved in this study as we continue to focus on providing clinical benefit to patients who suffer from these difficult to treat conditions," said Jim Caruso, president and CEO of Cellecstar Biosciences. "Given the results from our Phase I trial of CLR 131 in multiple myeloma, we are enthusiastic about the potential outcomes of this Phase II trial, and look forward to reporting results as they become available."

The hematologic cancers to be studied include multiple myeloma (MM), chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL), lymphoplasmacytic lymphoma (LPL), marginal zone lymphoma (MZL), mantle cell lymphoma (MCL), and potentially diffuse large B-cell lymphoma (DLBCL).

In addition to the CLR 131 infusion(s), MM patients will receive 40 mg oral dexamethasone weekly for up to 12 weeks. Efficacy responses will be determined by the latest International Multiple Myeloma Working Group criteria. Efficacy for all lymphoma patients will be determined according to Lugano criteria. More information about the trial, including eligibility requirements, can be found at www.clinicaltrials.gov, reference NCT02952508.

About CLR 131

CLR 131 is an investigational compound under development for a range of hematologic

malignancies. It is currently being evaluated as a single-dose treatment in a Phase I clinical trial in patients with relapse or refractory (R/R) multiple myeloma as well as in a Phase II clinical trial for R/R MM and select R/R lymphomas with either a one- or two-dose treatment. Based upon preclinical and interim Phase I study data, treatment with CLR 131 provides a novel approach to treating hematological diseases and may provide patients with therapeutic benefits, including overall survival, an improvement in progression-free survival, surrogate efficacy marker response rate, and overall quality of life. CLR 131 utilizes the company's patented PDC tumor targeting delivery platform to deliver a cytotoxic radioisotope, iodine-131, directly to tumor cells. The FDA has granted Collectar an orphan drug designation for CLR 131 in the treatment of multiple myeloma.

About Phospholipid Drug Conjugates (PDCs)

Collectar's product candidates are built upon its patented cancer cell-targeting delivery and retention platform of optimized phospholipid ether-drug conjugates (PDCs). The company deliberately designed its phospholipid ether (PLE) carrier platform to be coupled with a variety of payloads to facilitate both therapeutic and diagnostic applications. The basis for selective tumor targeting of our PDC compounds lies in the differences between the plasma membranes of cancer cells compared to those of normal cells. Cancer cell membranes are highly enriched in lipid rafts, which are glycolipoprotein microdomains of the plasma membrane of cells that contain high concentrations of cholesterol and sphingolipids, and serve to organize cell surface and intracellular signaling molecules. PDCs have been tested in more than 80 different xenograft models of cancer.

About Collectar Biosciences, Inc.

Collectar Biosciences is developing phospholipid drug conjugates (PDCs) designed to provide cancer-targeted delivery of diverse oncologic payloads to a broad range of cancers and cancer stem cells. Collectar's PDC platform is based on the company's proprietary phospholipid ether analogs. These novel small-molecules have demonstrated highly selective uptake and retention in a broad range of cancers. Collectar's PDC pipeline includes product candidates for cancer therapy and cancer diagnostic imaging. The company's lead therapeutic PDC, CLR 131, utilizes iodine-131, a cytotoxic radioisotope, as its payload. CLR 131 is currently being evaluated under an orphan drug designated Phase I clinical study in patients with relapsed or refractory multiple myeloma, as well as a Phase II clinical study to assess efficacy in a range of B-cell malignancies. The company is also developing PDCs for targeted delivery of chemotherapeutics such as paclitaxel (CLR 1603-PTX), a preclinical-stage product candidate, and plans to expand its PDC chemotherapeutic pipeline through both in-house and collaborative R&D efforts. For more information please visit www.collectar.com.

This news release contains forward-looking statements. You can identify these statements by our use of words such as "may," "expect," "believe," "anticipate," "intend," "could," "estimate," "continue," "plans," or their negatives or cognates. These statements are only estimates and predictions and are subject to known and unknown risks and uncertainties that may cause actual future experience and results to differ materially from the statements made. These statements are based on our current beliefs and expectations as to such future outcomes. Drug discovery and development involve a high degree of risk. Factors that might cause such a material difference include, among others, uncertainties related to the ability to raise additional capital, uncertainties related to the ability to attract and retain partners for our technologies, the identification of lead compounds, the successful preclinical

development thereof, the completion of clinical trials, the FDA review process and other government regulation, our pharmaceutical collaborators' ability to successfully develop and commercialize drug candidates, competition from other pharmaceutical companies, product pricing and third-party reimbursement. A complete description of risks and uncertainties related to our business is contained in our periodic reports filed with the Securities and Exchange Commission including our Form 10-K for the year ended December 31, 2016. These forward-looking statements are made only as of the date hereof, and we disclaim any obligation to update any such forward-looking statements.

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