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Cellecstar Biosciences Introduces Multiple Dose Regimen in Fifth Cohort of Phase 1 Trial of CLR 131 in Multiple Myeloma

MADISON, Wis., Oct. 24, 2017 (GLOBE NEWSWIRE) -- Cellecstar Biosciences, Inc. (Nasdaq:CLRB), an oncology-focused, clinical stage biotechnology company (the "company"), today announces the design of the multiple dose fifth cohort of its Phase I dose escalation safety trial of lead PDC™ compound, CLR 131, in relapse or refractory multiple myeloma. Cohort 5 will utilize two 15.625 mCi/m² doses given one week apart with the total combined dose equaling 31.25 mCi/m², the same total dose provided to patients that resulted in a partial response in Cohort 4. In previous cohorts, CLR 131 was given in a single infusion.

In September, the trial's Data Monitoring Committee (DMC) determined that the fourth cohort single dose of 31.25 mCi/m² was safe and tolerated. In addition, the DMC determined that the use of a split, or repeat dose might be advantageous. Given internal company data and recently announced results of preclinical studies in which 2 doses of CLR 131 demonstrated a statistically significant improvement in survival benefits and reduction of tumor volume in multiple mouse models (April 27, 2017), the company has enhanced the study's protocol such that subsequent cohorts will include repeat dosing.

"Given the encouraging results we've observed to date in previous cohorts, we hope to see similar, or perhaps even improved safety results in this arm of the trial," said Natalie Callander, M.D., professor of medicine, director, University of Wisconsin Carbone Cancer Center Myeloma Clinical Program, and the study's lead investigator. "Previous participants have asked us if it was possible to receive additional doses, as this therapy has been so well tolerated."

Patients participating in the fifth cohort will receive a total of two doses of CLR 131 as 30-minute infusions on their first and seventh days. They will then be evaluated over the course of 85 days to determine the safety and efficacy of the treatment as per the study protocol. During the previous cohort, one of three evaluable patients experienced a partial response to treatment with CLR 131, while the other two achieved stable disease. All Cohort 4 patients had heavily pretreated relapsed or refractory multiple myeloma (greater than five prior lines) and high degree of tumor burden upon entry into the trial, and the company expects to recruit similar trial subjects for Cohort 5. Despite the challenging patient population enrolled to date, 89 percent of all Phase 1 patients achieved a clinical benefit response.

"This fifth cohort represents an important opportunity to better understand the clinical utility of a split dose regimen and to further explore the safety and efficacy of CLR 131. Utilizing two doses provides an opportunity to increase the total amount of drug delivered to the patients which could result in an improvement in efficacy while maintaining similar or better safety profile," said Jim Caruso, president and CEO of Cellecstar Biosciences. "Clinical assessment, along with the improved benefits demonstrated by two doses in preclinical studies, suggest to us that the protocol changes should enhance our chances to see improved patient outcomes in this and future study arms."

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 1 clinical trial in patients with relapsed or refractory (R/R) multiple myeloma (MM) as well as in a Phase 2 clinical trial for R/R MM and select R/R lymphomas with either a one- or two-dose treatment. CLR 131 represents a novel approach to treating hematological diseases and based upon preclinical and interim Phase 1 study data may provide patients with therapeutic benefits including, overall survival, an improvement in progression-free survival, 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 Cellecstar an orphan drug designation for CLR 131 in the treatment of multiple myeloma.

About Phospholipid Drug Conjugates™ (PDCs™)

Cellecstar's product candidates are built upon its patented cancer cell-targeting delivery and retention platform of optimized phospholipid ether-drug conjugates™ (PDCs™). The company designed its phospholipid ether (PLE) carrier platform to be coupled with a variety of payloads to facilitate the discovery and development of improved targeted novel therapeutic compounds. 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 (Nasdaq:CLRB) 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, even sites of metastases. The company's lead therapeutic PDC, CLR 131, utilizes iodine-131, a cytotoxic radioisotope, as its payload. CLR 131 has been designated as an orphan drug by the US FDA and is currently being evaluated in a Phase 1 clinical study in patients with relapsed or refractory multiple myeloma and a Phase 2 clinical study to assess efficacy in a range of B-cell malignancies. The company is also developing proprietary PDCs for targeted delivery of chemotherapeutics and has several preclinical stage product candidates, 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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