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Cellectar Biosciences Announces New Positive Data from Phase I Clinical Study of CLR 131 in Multiple Myeloma

Single Dose Safety and Activity Performance Data from Second Patient Cohort Triggers Dose Escalation and Initiation of Third Cohort

MADISON, Wis., Sept. 29, 2016 (GLOBE NEWSWIRE) -- Cellectar Biosciences, Inc. (Nasdaq:CLRB) (the "company"), an oncology-focused biotechnology company, today announces positive data from the second cohort of patients enrolled in its orphan-drug designated Phase I study of CLR 131 in patients with relapsed or refractory multiple myeloma. Following these outcomes, the study's Data Monitoring Committee approved patient enrollment to the third cohort, which will include a 33 percent dose increase from 18.75 to 25mCi/m^2 of CLR 131 from the previous cohort.

All evaluable study participants (n=8) have achieved stable disease and progression-free survival (PFS), which includes four evaluable patients from Cohort 1 and four evaluable patients from Cohort 2. To date, Cohort 2 subjects have attained an average increase in PFS of greater than 30 percent as compared to Cohort 1. Cellectar continues to follow patient outcomes within Cohort 2, including PFS. After these patients have fully completed the study, the company looks forward to providing additional study data, including the full extent of the increase in PFS from Cohort 2 over Cohort 1. While patients in Cohort 2 received a 50 percent increase in dose, they did not experience a proportional increase in adverse events and demonstrated a similarly favorable safety and tolerability profile as experienced by patients in Cohort 1.

"As seen in the results to date, CLR 131 has demonstrated an outstanding safety profile in heavily pretreated, relapsed or refractory multiple myeloma patients with limited treatment options," stated Natalie Callander, MD, Associate Professor of Medicine, Director, University of Wisconsin Carbone Cancer Center Myeloma Clinical Program, and the study's lead investigator. "I am excited that Cellectar will open the next treatment cohort to offer patients access to this novel treatment's encouraging efficacy signals."

In this multi-center, open label Phase I dose escalation study, CLR 131 is administered as a single dose, 30-minute infusion. The primary study objective is to characterize the safety and tolerability of CLR 131 in patients with relapsed or refractory multiple myeloma. Prior to enrollment, all study participants had received a minimum of three systemic regimens and up to 12 lines of therapy. Many also received a stem cell transplant. Secondary study objectives include establishment of a recommended Phase II dose, both with and without dexamethasone, as well as an assessment of therapeutic activity.

"This important clinical milestone further validates the potential of our patented PDC delivery platform as well as the clinical benefits of CLR 131 for the treatment of an extremely

challenging hematologic cancer," said Jim Caruso, president and CEO of Cellectar Biosciences. "We are focused on successfully executing this Phase I Study for relapsed or refractory multiple myeloma, as well as initiating our National Cancer Institute-supported Phase II study to further explore dose, regimen and clinical utility of CLR 131 in multiple myeloma and other selected hematologic malignancies with unmet medical need."

About CLR 131
CLR 131 is an investigational compound under development for a range of hematologic malignancies. It is currently being evaluated in a Phase I clinical trial in patients with relapsed or refractory multiple myeloma. The company plans to initiate a Phase II clinical study to assess efficacy in a range of B-cell malignancies in the first half of 2017. Based upon pre-clinical and interim Phase I study data, treatment with CLR 131 provides patients with a novel approach to treating hematological diseases and may provide patients with 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 Cellectar an orphan drug designation for CLR 131.

About Phospholipid Drug Conjugates (PDCs)
Cellectar's product candidates are built upon its patented cancer cell-targeting delivery and retention platform of optimized phospholipid ether-drug conjugates (PDCs). Its phospholipid ether (PLE) carrier platform was deliberately designed 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 over 70 different xenograft models of cancer.

About Relapsed or Refractory Multiple Myeloma
Multiple myeloma is the second most common blood or hematologic cancer with approximately 30,000 new cases in the United States every year. It affects a specific type of blood cells known as plasma cells. Plasma cells are white blood cells that produce antibodies to help fight infections. While treatable for a time, multiple myeloma is incurable and almost all patients will relapse or the cancer will become resistant/refractory to current therapies.

About Cellectar Biosciences, Inc.
Cellectar 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. Cellectar'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. Cellectar'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. The company is also developing PDCs for targeted delivery of chemotherapeutics such as paclitaxel (CLR 1602-PTX), a preclinical stage product candidate, and plans to expand its PDC chemotherapeutic pipeline through both in-house and collaborative R&D efforts. For additional information please visit www.cellectar.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/A for the year ended December 31, 2015. 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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