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Cellectar Biosciences Announces Results From the First Two Cohorts of Its CLR 131 Phase 1 Trial: Demonstrates Excellent Efficacy, Overall Survival Benefit, and Progression Free Survival Similar to or Better than Recently Approved Therapies

MADISON, Wis., Dec. 01, 2016 (GLOBE NEWSWIRE) -- Cellectar Biosciences, Inc. (Nasdaq:CLRB) (the "company"), an oncology-focused, clinical stage biotechnology company, today provides a data update on the first two cohorts of the company's Phase I clinical study of CLR 131 in patients with relapsed or refractory multiple myeloma.

The clinical benefit rate for this study is 80 percent despite patients receiving an average of four prior treatments, including stem cell transplant and triple drug combinations. The patients in Cohort 1 received a single 12.5 mCi/m^2 dose and patients in Cohort 2 received a single 18.75 mCi/m^2 dose. At this time, Cohort 1 and Cohort 2 patients have demonstrated post treatment median survival of 11.9 months and 4.9 months, respectively. The median survival for all evaluable patients in both cohorts continues to increase and will be followed to determine overall survival benefit. Currently, the median overall survival (mOS) for each cohort is not yet evaluable. All evaluable patients in the clinical study experienced progression free survival (PFS). In Cohort 1, patients averaged 88.5 days of PFS. While patients in Cohort 2 have already achieved an average PFS of 127 days, the average PFS in Cohort 2 continues to increase as one of the four patients is still experiencing PFS. It is important to note that overall survival of 11.9 months and PFS of 127 days in this heavily pretreated patient population is better than or equivalent to that reported by several recently approved multiple myeloma drugs.

"The efficacy observed with CLR 131 at the 12.5 and 18.75 mCi/m^2 single dose compares favorably to drugs recently approved for relapsed or refractory multiple myeloma. We believe that the 18.75 mCi/m^2 dose could represent an acceptable single dose or multi-dose regimen for future studies," said Jim Caruso, president and CEO of Cellectar Biosciences. "Combined with its clean safety profile, we are optimistic regarding the potential of CLR 131 and look forward to seeing results from our recently initiated Cohort 3 at a single 25mCi/m^2 dose."

An evaluation of adverse events between Cohort 1 and Cohort 2 reveal a similar profile. Patients in Cohort 1 experienced an average of 4.75 adverse events per patient while patients in Cohort 2 experienced an average of 4.25 events per patient. The median severity grade of the adverse events in both cohorts was 2.0 (mild to moderate), as graded

by the National Cancer Institute's Common Terminology Criteria for Adverse Events (NCI-CTCAE).

In the multi-center, open label Phase I dose escalation study, CLR 131 was administered as a single dose, 30-minute intravenous infusion on Day 1 with 40 mg dexamethasone orally weekly for 12 weeks. The primary study objective is to characterize the safety and tolerability of CLR 131 with and without dexamethasone in patients with relapsed and/or refractory multiple myeloma. Secondary study objectives include establishment of a recommended Phase II dose, both with and without dexamethasone, as well as an assessment of therapeutic activity, including progression-free survival (PFS) and additional efficacy endpoints.

Dose-escalation in this study uses a minimally modified, standard 3+3 schema with dose-limiting toxicities (DLTs) assessed through day 85 post-infusion. Each cohort consisted of four evaluable patients (three men, one woman in Cohort 1 and two men, two women in Cohort 2). Patients in both cohorts received an average of 4 prior treatments. All patients received and were relapsed or refractory to proteasome inhibitors and immunomodulatory drugs prior to enrollment, and all patients had received triple combination therapy as a single line of therapy at least once. One patient in Cohort 1 and three in Cohort 2 received autologous stem cell transplantation and three Cohort 1 patients and one Cohort 2 patient each received the latest approved drugs for multiple myeloma prior to enrollment. Patient's ages range between 55-76 (Cohort 1) and 55-85 (Cohort 2) and averages were essentially identical at 68 and 69 years of age, respectively.

The company is currently enrolling patients into the study's third cohort at a single 25 mCi/m^2 dose and plans to provide an additional data update in the first half of 2017.

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 quarter of 2017. Based upon pre-clinical 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 response rate (ORR), an improvement in progression-free survival (PFS) 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 in the treatment of multiple myeloma.

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). 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 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. In addition, the company plans to initiate a Phase II clinical study to assess efficacy in a range of B-cell malignancies in the first quarter of 2017. 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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