December 6, 2016

Cellectar Biosciences Presents Poster at the 58th Annual Meeting of the American Society of Hematology

MADISON, Wis., Dec. 06, 2016 (GLOBE NEWSWIRE) -- Cellectar Biosciences, Inc. (Nasdaq:CLRB) (the "company"), an oncology-focused, clinical stage biotechnology company, today announced that it presented a poster at the 58th Annual Meeting of the American Society of Hematology in San Diego, which provides highlights of the company's ongoing Phase I dose escalation clinical study of CLR 131 to assess safety and tolerability of the compound in patients with relapsed or refractory multiple myeloma. The poster provided detailed data related to the first two study cohorts.

The poster followed patients from initial infusion of CLR 131, the company's lead PDC radiotherapeutic, through November 1, 2016. Results demonstrated all eight evaluable patients (of the total of ten enrolled) achieving a minimum of stable disease. The poster also reported a mean of approximately three months of progression-free survival (PFS) in Cohort 1 and four months in Cohort 2. To date, one patient in Cohort 2 continues to experience PFS. Significantly, four of eight patients experienced a greater than 50 percent reduction in serum free light chains (FLC), which are a key efficacy indicator for multiple myeloma. Per the International Myeloma Working Group (IMWG) criteria, in the absence of M protein, an FLC reduction of 50 percent or greater, is defined as a partial response. Overall, Cohort 2 patients experienced a more significant FLC reduction and a more sustained FLC response versus Cohort 1, with the difference in reduction being maintained across the entire study, and increasing at the subsequent evaluation time points. Cohort 2 patients achieved a 20 percent greater reduction in FLC on day 22 than was experienced by patients in Cohort 1, a 38 percent greater reduction at Day 43 and 43 percent greater FLC reduction at the final evaluation time point, Day 64.

Importantly, seven of eight evaluable patients achieved a reduction in either serum or urine M protein, which also are key efficacy indicators for multiple myeloma. Similar to the FLC marker, the Cohort 2 reduction of M protein was more sustained with the patients experiencing continued reduction in M protein beyond day 64. It is also important to note that based upon M protein reduction 38 percent of patients experienced a minimal response at these low, one-time doses.

The primary endpoint for this study is to determine the safety and tolerability of CLR 131 in a heavily pre-treated patient population. Evaluable study patients received an average of four prior lines of treatment. The adverse event profile in both cohorts was similar and showed no dose dependency. While the leading adverse events were leukopenia and thrombocytopenia (30 percent each) with a median grade of 2 (mild to moderate) for both, there have been no dose-limiting toxicity events to date. Importantly, no patients experienced non-hematologic adverse events as seen with many other compounds used to treat this patient population.

Specifically, there were no reports of peripheral neuropathy, fatigue, cardiovascular events, or venous thromboembolisms. The efficacy and safety profile of CLR 131 shown to date allows future development of the compound, either at the Cohort 2 dose of 18.75 mCi/m^2 or at one of the future higher doses being tested. The study is currently completing Cohort 3 at a single 25 mCi/m^2 dose.

“ASH is a prestigious conference and this presentation represents a peer reviewed opportunity to report encouraging efficacy and safety data from our Phase I study of CLR 131 in relapsed/refractory multiple myeloma,” said Jim Caruso, president and CEO of Cellectar Biosciences. “We look forward to reporting data from Cohort 3 at a single 25 mCi/m^2 dose and the initiation of our NCI-sponsored Phase II trial in multiple myeloma and other hematologic malignancies.”

The Phase I multi-center, open label, dose escalation study described in the poster outlines that CLR 131 was administered as a single dose, 30-minute intravenous infusion on Day 1 with a 40 mg oral dexamethasone dose weekly for 12 weeks. Each cohort consisted of five patients, of which four were evaluable (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. Half of all patients received a stem cell transplant. All patients received proteasome inhibitors and immunomodulatory drugs prior to enrollment as well as triple combination therapy at least once.

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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