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Cellectar Biosciences Provides Phase I Trial Update of CLR 131 in Multiple Myeloma: Median Progression-Free Survival Extends to 133 Days, Median Overall Survival Reaches 17.7 Months

MADISON, Wis., Feb. 27, 2017 (GLOBE NEWSWIRE) -- Cellectar Biosciences, Inc. (Nasdaq:CLRB), an oncology-focused clinical stage biotechnology company, today provides an update of its Phase I clinical study of CLR 131 in patients with relapsed or refractory multiple myeloma following the previously announced successful completion of its third cohort and initiation of Cohort 4 at a 31.25 mCi/m^2 dose.

The objectives of the multi-center, open label, Phase I dose escalation study include the characterization of the safety and tolerability of CLR 131 administered as a single dose, 30-minute infusion in patients with relapsed or refractory multiple myeloma, and the establishment of a recommended efficacious dose for Phase II, both with and without dexamethasone, as well as an assessment of therapeutic activity.

The data from Cohort 3 show that the 25 mCi/m^2 dose was safe and well tolerated, and those patients experienced a similar adverse event profile to that experienced by patients in the previous two cohorts. The average grade of adverse event by patient was 2.57 in Cohort 3, compared to Cohorts 1 and 2 with average grades of 2.05 and 2.71, respectively. Cohort 3 patients experienced an average of seven adverse events compared to Cohorts 1 and 2 with 4.75 and 4.25 events respectively. However, there were no unexpected adverse events and those adverse events experienced by patients were both predictable and manageable.

All four Cohort 3 patients achieved stable disease and continue to be followed for progression-free survival (PFS) and median overall survival (mOS). It is important to note, that similar to Cohort 2 vs. Cohort 1, patients in Cohort 3 experienced a more substantial and sustained reduction in m-protein, a surrogate marker of efficacy. The company expects to provide a more extensive efficacy data update for Cohort 3 in the near term.

While it is also premature to report survival-related efficacy data from Cohort 3, all patients in Cohorts 1 and 2 continue to experience overall survival benefit. Patients from Cohort 1, who received a single 12.5 mCi/m^2 dose, have experienced, to date, mOS of 17.7 months. Cohort 2 patients, who received a single 18.75 mCi/m^2 dose, have a current median overall survival of 8.4 months. Based on this data, the company has the option of using an 18.75 mCi/m^2 single or multi-dose regimen as monotherapy or in combination with other agents as a therapeutic dose in future clinical studies evaluating efficacy. Importantly, median overall survival for all evaluable patients in each cohort continues to increase, and the company will continue to follow these patients to determine the full extent of the overall survival benefit of

CLR 131.

In addition, all evaluable patients in the first two cohorts experienced PFS. The median PFS is 92 days for Cohort 1 and 133 days for Cohort 2, with one Cohort 2 patient continuing to experience PFS.

While no head-to-head studies have been conducted between CLR 131 and other therapies in this heavily pretreated population, a 2016 article published in the peer-reviewed journal, *Bone Marrow Transplantation*, showed that those patients evaluated that were refractory to both proteasome inhibitors and immunomodulatory drugs have mOS of 9 months and PFS of 5 months.[1] All patients enrolled in Cohorts 1 and 2 were previously treated with both proteasome inhibitors and immunomodulatory drugs and experienced disease progression.

“The clinical performance of CLR 131, particularly its safety, tolerability and survival benefits, continues to exceed our expectations as we begin our fourth cohort with patients receiving a 25 percent dose increase from Cohort 3. This speaks favorably to the potential of the drug in a single or multi-dose regimen,” said Jim Caruso, president and CEO of Cellectar Biosciences. “Based on these results, we look forward to providing a full Cohort 3 data update and the imminent initiation of our Phase II clinical trial of CLR 131 in multiple myeloma and other blood cancers, as well as the exploration of additional clinical benefits provided by a second dose midway through the Phase II trial.”

The company recently brought forward guidance for the initiation of its NCI-supported Phase II trial in multiple myeloma and other selected hematologic cancers to the first quarter of 2017. As the study is currently designed, all patients will receive, at a minimum, a single dose of CLR 131 at 25 mCi/m^2 infused over approximately 30 minutes, with the option of a second 25 mCi/m^2 dose 75-180 days later, based upon physician assessment. The Phase II study will be conducted in up to 15 centers across the United States and Cellectar anticipates initial efficacy data as early as the second 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 as a single-dose treatment in a Phase I clinical trial in patients with relapsed or refractory multiple myeloma. In the first quarter of 2017, the company plans to initiate a Phase II clinical study to advance its multiple myeloma program, assess efficacy in a range of B-cell malignancies, and explore the clinical benefits of a second dose. 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 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 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 more than 80 different xenograft models of cancer.

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 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.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.

[1] http://www.nature.com/bmt/journal/v51/n4/full/bmt2015307a.html

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