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Cellectar Announces Overall Survival Exceeding 19 Months in Phase 1b Trial with CLR 131 in Relapsed/Refractory Multiple Myeloma

MADISON, Wis., Oct. 02, 2018 (GLOBE NEWSWIRE) -- Cellectar Biosciences (Nasdaq: CLRB), a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of drugs for the treatment of cancer, today updates interim overall survival (OS) data from the company's ongoing Phase 1b clinical trial evaluating CLR 131 for the treatment of relapsed/refractory (R/R) multiple myeloma (MM).

The results to date show that OS is currently at 19.4 months. Cellectar continues to monitor these patients and intends to update OS results as data become available. All 15 patients from the Phase 1b, single-dose cohorts were heavily pretreated, receiving an average of 5 previous lines of multidrug therapy including anti CD38, immunomodulating drugs and proteasome inhibitors. All patients were relapsed or refractory to at least one proteasome inhibitor and IMiD. Most patients presented with advanced stage 2 or 3 disease and 67% had previously received at least 1 stem cell transplant.

"We are extremely pleased to announce that CLR 131 has achieved OS of 19.4 months in our Phase 1b trial in R/R MM. We view this outcome as impressive considering all patients were heavily pretreated and presented with high tumor burden," said James Caruso, president and chief executive officer of Cellectar Biosciences. "Most drugs currently approved for third-line or later R/R MM average approximately 12 months of survival, including several recent approvals. We believe extending OS to beyond 19 months with a more patient-friendly dosing regimen provides both a unique product profile and potential for beneficial patient outcomes."

The objective of this multicenter, open-label, Phase 1b dose-escalation study is the characterization of safety and tolerability of CLR 131 administered as a single-dose, 30-minute infusion in patients with R/R MM. Patients received doses of 12.5 mCi/m^2 up to 31.25 mCi/m^2. All doses were deemed safe and well tolerated by an independent data monitoring committee.

Data from a fifth cohort, released in August, evaluated a split or fractionated dose of 31.25 mCi/m^2 for tolerability and safety. The dosing schedule provided higher average drug exposure but lower peak serum levels than non-fractionated dosing potentially reducing adverse events and improving efficacy. The independent Data Monitoring Committee (DMC) determined the fractionated dose used in Cohort 5 to be safe and well tolerated and recommended advancement to a higher dose cohort.

About Phospholipid Drug Conjugates™
Cellectar's product candidates are built upon a patented delivery and retention platform that utilizes optimized phospholipid ether-drug conjugates (PDCs™) to target cancer cells. The PDC platform selectively delivers diverse oncologic payloads to cancerous cells and cancer stem cells, including hematologic cancers and solid tumors. This selective delivery allows the payloads' therapeutic window to be modified, which may maintain or enhance drug potency while reducing the number and severity of adverse events. This platform takes advantage of a metabolic pathway utilized by all tumor cell types in all cell cycle stages. Compared with other targeted delivery platforms, the PDC platform's mechanism of entry does not rely upon specific cell surface epitopes or antigens. In addition, PDCs can be conjugated to molecules in numerous ways, thereby increasing the types of molecules selectively delivered. Cellectar believes the PDC platform holds potential for the discovery and development of the next generation of cancer-targeting agents.

About CLR 131
CLR 131 is Cellectar's investigational radioiodinated PDC therapy that exploits the tumor-targeting properties of the company's proprietary phospholipid ether (PLE) and PLE analogs to selectively deliver radiation to malignant tumor cells, thus minimizing radiation exposure to normal tissues. CLR 131 is in a Phase 2 clinical study in R/R MM and a range of B-cell malignancies and a Phase 1b clinical study in patients with R/R MM exploring fractionated dosing. The objective of the multicenter, open-label, Phase 1b dose-escalation study is the characterization of safety and tolerability of CLR 131 in patients with R/R MM. Patients in Cohorts 1-4 received single doses of CLR 131 ranging from 12.5 mCi/m^2 to 31.25 mCi/m^2. All study doses have been deemed safe and well tolerated by an independent Data Monitoring Committee. The company is currently initiating a Phase 1 study with CLR 131 in pediatric solid tumors and lymphoma, and is planning a second Phase 1 study in combination with external beam radiation for head and neck cancer.

About Cellectar Biosciences, Inc.
Cellectar Biosciences is focused on the discovery, development and commercialization of drugs for the treatment of cancer. The company plans to develop proprietary drugs independently and through research and development (R&D) collaborations. The core drug development strategy is to leverage our PDC platform to develop therapeutics that specifically target treatment to cancer cells. Through R&D collaborations, the company's strategy is to generate near-term capital, supplement internal resources, gain access to novel molecules or payloads, accelerate product candidate development and broaden our proprietary and partnered product pipelines.

The company's lead PDC therapeutic, CLR 131, is in a Phase 1 clinical study in patients with R/R MM and a Phase 2 clinical study in R/R MM and a range of B-cell malignancies. The company is currently initiating a Phase 1 study with CLR 131 in pediatric solid tumors and lymphoma, and is planning a second Phase 1 study in combination with external beam radiation for head and neck cancer. The company's product pipeline also includes two preclinical PDC chemotherapeutic programs (CLR 1700 and 1900) and partnered assets include PDCs from multiple R&D collaborations.

For more information please visit www.cellectar.com.

Forward-Looking Statement Disclaimer

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 disruptions at our sole source supplier of CLR 131, 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, the volatile market for priority review vouchers, 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, 2017 and our Form 10-Q for the quarterly period ended June 30, 2018. These forward-looking statements are made only as of the date hereof, and we disclaim any obligation to update any such forward-looking statements.

CONTACT:
LHA Investor Relations
Miriam Weber Miller
212-838-3777
mmiller@lhai.com

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