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Cellectar's CLR 131 Receives FDA Orphan Drug Designation for the Treatment of Pediatric Osteosarcoma

MADISON, Wis., Sept. 25, 2018 (GLOBE NEWSWIRE) -- Cellectar Biosciences, Inc. (Nasdaq: CLRB), a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of drugs for the treatment of cancer, announces that the U.S. Food and Drug Administration (FDA) Office of Orphan Products Development has granted Orphan Drug Designation (ODD) to CLR 131, the company's lead Phospholipid Drug Conjugate™ (PDC) product candidate, for the treatment of pediatric osteosarcoma, a rare pediatric cancer. CLR 131 also received Rare Pediatric Disease Designation for osteosarcoma, as announced by the company on September 17, 2018.

"Osteosarcoma is the most common type of primary bone cancer occurring most frequently in children. Currently, there are no commercially available drugs for pediatric sarcoma, including osteosarcoma," said John Friend, M.D., chief medical officer of Cellectar. "This orphan designation for osteosarcoma is the fourth such designation granted by the FDA to CLR 131 for the treatment of rare pediatric cancers in the last six months, and we look forward to evaluating CLR 131 in these deadly and underserved diseases."

The FDA grants ODD to therapies targeting conditions that affect fewer than 200,000 people in the U.S. The designation provides seven-year market exclusivity, increased engagement and assistance from the FDA, tax credits for certain research, research grants and a waiver of the New Drug Application user fee. In 2018 the FDA also granted CLR 131 orphan drug and rare pediatric disease designations for the treatments of neuroblastoma, rhabdomyosarcoma and Ewing's sarcoma.

Cellectar plans to initiate a Phase 1 clinical study evaluating CLR 131 for the treatment of pediatric patients with osteosarcoma, Ewing's sarcoma, rhabdomyosarcoma, neuroblastoma, high-grade glioma and lymphomas. The trial is designed to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of CLR 131 in pediatric patients with these cancer types. Further details about the trial can be found at clinicaltrials.gov using the identifier number NCT03478462.

About Osteosarcoma
Osteosarcoma derives from bone forming mesenchymal, or connective tissue, cells and is the most commonly diagnosed primary bone malignancy among children and adolescents. The incidence is about 4.4 cases per 1 million per year in children younger than 24 years. While there is a 70% cure rate among patients with localized disease, 5-year overall survival rates are approximately 20% for among patients who develop metastatic disease. Additionally, among patients who experience disease progression or recurrence survival for is less than 30%.

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 as well as a fractionated dose of 15.625 mCi/m^2 given twice over seven days in Cohort 5. All study doses and regimens 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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