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Cellectar Announces FDA Grants Exemption to Import Alert for CLR 131 Hematology Studies

Clinical Trials to Advance Across Multiple Hematology Programs

FLORHAM PARK, N.J., Nov. 12, 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 today that the U.S. Food and Drug Administration (FDA) has granted an exemption to the Import Alert placed on the Centre for Probe Development and Commercialization (CPDC), the sole supplier of the CLR 131. The exemption for CLR 131 is effective immediately for all hematology studies and, in response, Cellectar is preparing to dose patients in the second fractionated dose cohort of the Phase 1 relapsed refractory (R/R) multiple myeloma study and the Phase 2 study for R/R hematologic malignancies. The company awaits authorization from the FDA for any future shipments in connection with its Phase 1 study of pediatric patients with neuroblastoma, sarcomas, lymphomas (including Hodgkin's lymphoma) and malignant brain tumors.

"We thank the FDA for their diligence and for providing this exemption for CLR 131 hematology studies. Our ability to advance our clinical trials and achieve stated business objectives remains our top priority," said James Caruso, president and CEO of Cellectar Biosciences. "I also want to recognize our team for their outstanding execution in support of a rapid resolution."

In its efforts to obtain an exemption for CLR 131 from the Import Alert in hematology and pediatrics, Cellectar has collaborated with the various divisions within the FDA that oversee the company's investigational new drug applications evaluating CLR 131 in multiple indications. Cellectar executed a series of actions requested by the FDA to obtain an exemption to the Import Alert for its hematology programs. Similarly, the company continues to work with the appropriate division of the FDA to secure an exemption for the pediatric program.

As background, on August 10, 2018, Cellectar announced that CPDC was informed of an FDA Import Alert that prohibited CPDC from supplying CLR 131. While the Import Alert disrupted CLR 131 supply, the basis of the Import Alert was not related to CLR 131 specifically, or to CPDC's production facility associated with CLR 131. The company actively supported CPDC's efforts to have the Import Alert lifted as quickly as possible. The FDA subsequently initiated direct talks with Cellectar concerning a possible exemption for CLR 131 from the Import Alert. Those discussions and subsequent actions resulted in the exemption Cellectar is announcing today.

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 relapsed/refractory multiple myeloma (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 plans to initiate a Phase 1 study with CLR 131 in pediatric solid tumors and lymphoma as well as 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 plans to initiate a Phase 1 study with CLR 131 in pediatric solid tumors and lymphoma as well as 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 including 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.

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