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Cellectar's CLR 131 Receives FDA Rare Pediatric Disease Designation for the Treatment of Ewing's Sarcoma

MADISON, Wis., Aug. 13, 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, announces today that the U.S. Food and Drug Administration (FDA) has granted Rare Pediatric Disease Designation (RPDD) to CLR 131, the company's lead Phospholipid Drug Conjugate™ (PDC) product candidate, for the treatment of Ewing's sarcoma, a rare pediatric cancer.

"We are delighted to announce receipt of our third RPDD from the FDA, which underscores Cellectar's commitment to rare pediatric cancers. There is a critical need to develop new therapies to fight deadly childhood cancers such as Ewing's sarcoma, and CLR 131 has shown early promise in this arena," said John Friend, M.D., chief medical officer of Cellectar Biosciences. "This designation, combined with our receipt of FDA Orphan Drug Designation for Ewing's sarcoma last month, will help support our efforts to optimize the drug development path in this indication and, if successful, enable this new therapeutic candidate is made available to patients as rapidly as possible."

Since March 2018 the FDA has granted RPDDs to CLR 131 for the treatment of three separate rare disease indications including neuroblastoma, rhabdomyosarcoma and now Ewing's sarcoma. Should CLR 131 be approved by the FDA in any of these indications, the RPDD may enable Cellectar to receive a priority review voucher. Priority review vouchers can be used by the sponsor to receive priority review designation for a future NDA or BLA submission, which could reduce the FDA review time from twelve months to eight months. Currently, these vouchers can also be transferred or sold to another entity. Since the beginning of 2017, six priority review vouchers were sold for between $80 million and $150 million each.

The FDA grants RPDD for diseases that primarily affect children from birth to age 18, and affect fewer than 200,000 persons in the U.S. This program is intended to encourage development of new drugs and biologics for the prevention and treatment of rare pediatric diseases.

Cellectar plans to evaluate CLR 131 in a Phase 1 clinical study for the treatment of pediatric patients with Ewing's sarcoma, rhabdomyosarcoma, osteosarcoma, neuroblastoma, high-grade glioma and lymphomas. Cellectar has received clearance from the FDA for an accelerated Phase 1 trial 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 Ewing's Sarcoma

Ewing’s sarcoma is the second most common bone malignancy among children and adolescents. According to a study published in the Journal of Hematology/Oncology, the incidence is about 3 cases per 1 million per year in children younger than age 20. Despite the favorable prognosis, an American Cancer Society study showed that approximately 30-40% of patients develop metastases or local recurrence, and the long-term survival rate for refractory or recurrent disease is only 22-24%. The relapsed and refractory statistics underscore the need for new treatment options.

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 or refractory (R/R) MM and a range of B-cell malignancies and a Phase 1 clinical study in patients with (R/R) MM exploring fractionated dosing. 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 relapsed or refractory (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 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. 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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