May 2, 2018

Cellectar Receives Rare Pediatric Disease Designation for CLR 131 to Treat Neuroblastoma

MADISON, Wis., May 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, announces today that the U.S. Food and Drug Administration (FDA) has granted rare pediatric disease designation (RPDD) to the company's lead phospholipid drug conjugate, CLR 131, for the treatment of neuroblastoma.

"Neuroblastoma is a devastating cancer most often found in infants and young children. The grant of RPDD for CLR 131 in conjunction with the orphan drug designation we received in March highlight the critical need for new treatments in the fight against this disease," said John Friend, M.D., chief medical officer of Cellectar. "We look forward to working with the FDA to bring this potential therapy to pediatric patients and expect to begin a clinical study in neuroblastoma during the second half of 2018."

The FDA grants Rare Pediatric Disease designation for diseases that primarily affect children from birth to 18 years old, 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. If CLR 131 is approved by the FDA for neuroblastoma, the rare pediatric disease designation may enable Cellectar to receive a priority review voucher. Priority review vouchers can be used by the sponsor to receive Priority Review for a future NDA or BLA submission which would reduce the FDA review time from twelve months to six months. Currently, these vouchers can also be transferred or sold to another entity. Over the last 16 months, five priority review vouchers were sold for between $110 million to $150 million each.

About Neuroblastoma
Neuroblastoma, a neoplasm of the sympathetic nervous system, is the most common extracranial solid tumor of childhood, accounting for approximately 7.8% of childhood cancers in the United States and is recognized by the FDA as an orphan disease. The incidence is about 10.54 cases per 1 million per year in children younger than 15 years and 90% are younger than 5 years at diagnosis. Approximately 50% of patients present with metastatic disease requiring systemic treatment. Although the prognosis is favorable in children under one year of age with an 86% to 95% 5-year survival, in children aged one to 14 years the 5-year survival ranges from 34% to 68%.

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. In the second half of 2018 the company plans to initiate a Phase 1 study with CLR 131 in pediatric solid tumors and lymphoma, as well as a 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 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. In the second half of 2018 the company plans to initiate a Phase 1 study with CLR 131 in pediatric solid tumors and lymphoma, as well as a 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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Source: Cellectar Biosciences, Inc.