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FDA Grants Rare Pediatric Disease Designation to Cellectar Biosciences' CLR 131 for the Treatment of Rhabdomyosarcoma

MADISON, Wis., June 06, 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 rhabdomyosarcoma, a rare pediatric cancer.

"There is a critical need for new therapies in the fight against deadly diseases such as rhabdomyosarcoma and we continue to increase our focus on delivering innovative solutions to patients suffering from such rare cancers," said John Friend, M.D., chief medical officer of Cellectar. "The grant of a second RPDD represents an additional regulatory milestone for CLR 131 and we look forward to working with the FDA to advance development of CLR 131 as rapidly as possible, to fully evaluate its potential as a therapeutic option for rhabdomyosarcoma."

Last month, Cellectar announced that the FDA also granted RPDD for CLR 131 for the treatment of neuroblastoma. If CLR 131 is approved by the FDA for either neuroblastoma or rhabdomyosarcoma, 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 12 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.

The FDA grants RPDD 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.

About Rhabdomyosarcoma
Rhabdomyosarcoma (RMS), a malignant tumor of mesenchymal origin, is the most common soft tissue sarcoma in children, accounting for approximately 40% of childhood soft tissue sarcomas in the U.S. The annual incidence is about 4.5 cases per 1 million in children younger than 15 years and more than 50% are younger than 10 years at diagnosis. RMS has a 64% five-year survival in a pediatric population, with at least one-third of all patients experiencing disease progression or relapse [Ward 2014]. The median progression-free survival following the first recurrence or progression is approximately nine months.

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 2018 the company plans to initiate a Phase 1 study with CLR 131 in pediatric solid tumors and lymphoma, and 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. In the second half of 2018 the company plans to initiate a Phase 1 study with CLR 131 in pediatric solid tumors and lymphoma, and 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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