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# Cellectar Biosciences Granted Orphan Drug Designation for CLR 131 to Treat Neuroblastoma

MADISON, Wis., March 19, 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, today announces that the U.S. Food and Drug Administration (FDA) Office of Orphan Products Development has granted Orphan Drug Designation to CLR 131, the company's lead Phospholipid Drug Conjugate™ (PDC) product candidate, for the treatment of neuroblastoma, a rare pediatric cancer.

"Neuroblastoma is the third most common childhood cancer for which there are currently no approved treatments for children with relapsed or refractory disease," stated John Friend, M.D., chief medical officer of Cellectar. "The FDA's granting of orphan drug designation for CLR 131 highlights the significant need for new treatments for children with neuroblastoma, and we believe that the targeted delivery of CLR 131 represents a promising novel approach to its treatment."

Orphan drug designation provides seven year market exclusivity benefit, increased engagement and assistance from the FDA, tax credits for certain research, research grants and a waiver of the New Drug Application user fee. Neuroblastoma is recognized by the FDA as an orphan disease, usually defined as a condition that affects fewer than 200,000 people nationwide.

The FDA previously accepted the Company's Investigational New Drug application for a Phase 1 open-label, dose-escalating study to evaluate the safety and tolerability of a single intravenous administration of CLR 131 in up to 30 children and adolescents with cancers including neuroblastoma, sarcomas, lymphomas (including Hodgkin's lymphoma) and malignant brain tumors. Cellectar expects to initiate this study during the second quarter of 2018.

**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 [Howman-Giles 2007]. 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. Clinical consequences include abdominal distension, proptosis, bone pain, pancytopenia, fever and paralysis. 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% [Smith 2014].

**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 Phospholipid Drug Conjugate™ (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) multiple myeloma (MM) and a Phase 2 clinical study in R/R MM and a range of B-cell malignancies. 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. 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, 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, 2016. 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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