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Cellectar Biosciences Granted Orphan Designation for I-131-CLR1404 for the Treatment of Multiple Myeloma

MADISON, Wis., Dec. 4, 2014 (GLOBE NEWSWIRE) -- Cellectar Biosciences, Inc. (Nasdaq:CLRB), a clinical stage biopharmaceutical company developing innovative agents for the detection and treatment of cancer, announced that the U.S. Food and Drug Administration (FDA) has granted Cellectar's request for orphan drug designation of I-131-CLR1404 for the treatment of multiple myeloma, an incurable cancer of plasma cells.

"We are thrilled that I-131-CLR1404 has been designated an orphan drug for the treatment of multiple myeloma," commented Dr. Natalie Callander, principal investigator of Cellectar's I-131-CLR1404 multiple myeloma trial, Associate Professor of Medicine, and Director, University of Wisconsin Carbone Cancer Center Myeloma Clinical Program. "Despite advances in the last several decades, multiple myeloma remains an incurable malignancy and agents with new and unique mechanisms of action, such as I-131-CLR1404, are essential to improving outcomes and survival. This designation reflects both the FDA's and Cellectar's important focus on addressing the unmet clinical needs of patients with diseases such as multiple myeloma."

The Orphan Drug Act provides for economic incentives to encourage the development of drugs for diseases affecting fewer than 200,000 people in the United States. Orphan drug designation will entitle Cellectar to seven years of market exclusivity for I-131-CLR1404 as a treatment for relapsed or refractory multiple myeloma following marketing approval by the FDA. Additional benefits include tax credits related to clinical trial expenses, a possible exemption from the FDA-user fee, assistance in clinical trial protocol design, and fewer patients required for new drug applications.

"This orphan designation is a critical milestone in our program and will support our efforts to move I-131-CLR1404 as quickly as possible through the clinical and regulatory development process," said Dr. Simon Pedder, president and chief executive officer of Cellectar Biosciences. "We are in the final stages of preparing our clinical sites to initiate a proof-of-concept trial of I-131-CLR1404 in multiple myeloma and look forward to working with Dr. Callander to evaluate I-131-CLR1404 as a targeted therapeutic in this indication."

About Multiple Myeloma

Multiple myeloma is a form of blood cancer that primarily affects older adults and arises from plasma cells in the bone marrow. According to the National Cancer Institute, multiple myeloma is the second most common blood cancer in the United States and constitutes approximately 1 percent of all cancers. The National Cancer Institute estimates that 24,500 Americans will be diagnosed with multiple myeloma in 2014 and 11,090 will die from the disease.

About I-131-CLR1404

I-131-CLR1404 is a small-molecule, broad-spectrum, cancer-targeted radiopharmaceutical comprised of a proprietary optimized phospholipid ether (PLE) analog, acting as a cancer-targeted delivery and retention vehicle, covalently labeled with iodine-131, a cytotoxic radioisotope that is already commonly used to treat thyroid and other cancer types. I-131-CLR1404 is engineered to combine an intracellular radiation mechanism of cancer cell killing with targeted delivery to a wide range of malignant tumor types. Preclinical models have also demonstrated selective uptake and retention in cancer stem cells, suggesting the potential for longer lasting cancer remission.

About Cellectar Biosciences, Inc.

Cellectar Biosciences is developing agents to detect, treat and monitor a broad spectrum of cancers. Using a novel phospholipid ether analog (PLE) platform technology as a targeted delivery and retention vehicle, Cellectar's compounds are designed to be selectively taken up and retained in cancer cells including cancer stem cells. With the ability to attach both imaging and therapeutic agents to its proprietary delivery platform, Cellectar has developed a portfolio of product candidates engineered to leverage the unique characteristics of cancer cells to "find, treat and follow" malignancies in a highly selective way. I-124-CLR1404 is a small-molecule, broad-spectrum, cancer-targeted PET imaging agent currently being evaluated in a Phase II glioblastoma imaging trial. Additionally, multiple investigator-sponsored Phase I/II clinical trials are ongoing across 11 solid tumor indications. I-131-CLR1404 is a small-molecule, broad-spectrum, cancer-targeted molecular radiotherapeutic that delivers cytotoxic radiation directly and selectively to cancer cells including cancer stem cells. A Phase Ib dose-escalation trial of I-131-CLR1404 in patients with advanced solid tumors was completed in the first quarter of 2014 and results presented at the American Society of Clinical Oncology (ASCO) 2014 Annual Meeting. CLR1502 is a preclinical, cancer-targeted, non-radioactive optical imaging agent for intraoperative tumor margin illumination and non-invasive tumor imaging. For additional information please visit www.cellectar.com

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, 2013. 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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