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Cellectar Biosciences Announces Receipt of Orphan Designation of I-124-CLR1404 as Diagnostic for the Management of Glioma from U.S. Food and Drug Administration

Company Expects to Complete Ongoing Multi-Center Phase II Imaging Trial of I-124-CLR1404 in Patients with Glioblastoma By Year-End

MADISON, Wis., May 5, 2014 (GLOBE NEWSWIRE) -- Cellectar Biosciences, Inc. (OTCQX:CLRB), a clinical stage biopharmaceutical company developing innovative agents for the detection and treatment of cancer, announced that it has received notification from the U.S. Food and Drug Administration (FDA) granting Cellectar's request for orphan drug designation for I-124-CLR1404 as a diagnostic for the management of glioma, the most common and aggressive form of brain cancer.

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-124-CLR1404 as a diagnostic for the management of glioma 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.

Existing data from 18 patients previously evaluated in multiple, investigator-sponsored brain tumor studies suggest that I-124-CLR1404 is selectively taken up and retained in malignant tumor cells, allowing for the identification of malignant glioma cells in newly diagnosed patients and distinguishing between true tumor progression and pseudoprogression or radiation necrosis in patients with recurrent malignant glioma.

"This orphan designation is a critical milestone in our program and will facilitate our goal of rapidly developing I-124-CLR1404 as a potentially new and effective imaging agent for patients with glioblastomas," said Dr. Simon Pedder, president and chief executive officer of Cellectar Biosciences. "We believe I-124-CLR1404 has the potential to dramatically improve the way glioma is managed by affording clinicians the ability to effectively and reliably characterize their findings as malignant tissue rather than pseudoprogression or radiation necrosis, reducing the risk of unnecessary surgical procedures or premature cessation of effective therapy. Earlier this year, we initiated our first company-sponsored Phase II imaging trial of I-124-CLR1404 in patients with glioblastoma and look forward to completing this trial and reporting results by the end of this year."

Dr. John S. Kuo, principal investigator of the Phase II I-124-CLR1404 glioblastoma imaging trial and associate professor at University of Wisconsin Carbone Cancer Center, states "During our national Brain Tumor Awareness month in May, the FDA's designation of I-124-CLR1404 as an orphan drug recognizes the critical need of glioblastoma patients for more effective diagnostic and therapeutic agents."

About Glioma

Glioma, a type of tumor that starts in the brain and arises from glial cells, is a broad category of tumors that are classified by cell type, grade and location and accounts for approximately 80% of all primary malignant brain tumors. The main glioma types are astrocytoma (which includes glioblastoma), oligodendroglioma, ependymoma, and mixed glioma. High-grade gliomas are rarely curable and the prognosis for patients is poor.

Over 20,000 Americans are diagnosed each year with malignant brain tumors. Glioblastoma, the most common primary adult brain cancer, is rapidly life-threatening with most patients succumbing to the disease within 15 months after diagnosis despite aggressive surgery, radiation and chemotherapies.

About I-124-CLR1404

I-124-CLR1404 pairs Cellectar's proprietary phospholipid ether analog (PLE), acting as a cancer-targeted delivery and retention vehicle, with iodine-124, a well-established positron emission tomography (PET) imaging isotope with a radiation half-life of four days. In studies to date, I-124-CLR1404 selectively illuminated malignant tumors in over 60 animal models of different cancer types, demonstrating broad-spectrum, cancer-selective uptake and retention. Cellectar expects to complete a Phase II trial evaluating I-124-CLR1404 in glioblastoma in 2014. Additionally, multiple investigator-sponsored Phase I/II clinical trials are ongoing across 11 solid tumor indications.

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 have been submitted to 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.

CONTACT: INVESTOR CONTACT
Kate McNeil, Vice President of IR, PR
& Corporate Communications
Cellectar Biosciences, Inc.
Phone: (347) 204-4226
Email: kmcneil@cellectar.com

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