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# **Collectar Announces Initiation of Phase II Imaging Trial With I-124-CLR1404 in Patients With Newly Diagnosed or Recurrent Glioblastoma**

## **Collectar Expects Results From This 36-Patient, Multi-Center Imaging Trial by Year-End 2014**

MADISON, Wis., March 4, 2014 (GLOBE NEWSWIRE) -- Collectar Biosciences, Inc. (OTCQX:CLRB) a biopharmaceutical company developing innovative agents for the detection and treatment of cancer, announced enrollment of the first patient in its Phase II imaging trial of I-124-CLR1404 in patients with glioblastoma.

Glioma, a type of tumor that starts in the brain and arises from glial cells, accounts for approximately 80% of all primary malignant brain tumors. Glioblastoma, a type of glioma, is the most common adult primary brain cancer. The current standard imaging modality used to characterize malignant gliomas is magnetic resonance imaging (MRI). However, the true extent of tumor infiltration is often inadequately characterized prior to surgery and adjuvant radiation and chemotherapies. Further complicating effective clinical follow-up imaging of glioma patients is the incidence of pseudoprogression and radiation necrosis following treatment. Pseudoprogression and radiation necrosis can appear similar to recurrent glioblastoma on MRI. So a false positive finding that is misinterpreted as tumor recurrence may result in premature cessation of an effective therapy, and possibly subject patients to additional surgeries or treatments.

This Phase II trial, being conducted at 10 NCI-designated cancer centers in the U.S., will compare the efficacy of I-124-CLR1404 positron emission tomography (PET) imaging in detecting glioblastoma with standard of care MRI based on pathology confirmation in approximately 36 patients.

"Developing new imaging agents that can reliably and selectively identify infiltrative tumor growth of malignant gliomas is an important priority for the neuro-oncology community," commented John Kuo, MD, PhD, Principal Investigator of the I-124-CLR1404 Phase II trial, Associate Professor of Neurological Surgery and Chair of the CNS Tumors group at the University of Wisconsin Carbone Cancer Center. "Preclinical and pilot human studies of I-124-CLR1404 conducted under investigator-sponsored INDs have suggested remarkable specificity in malignant tumor and cancer stem cell uptake, and potential distinction between true tumor progression and pseudoprogression in patients with newly diagnosed or recurrent glioblastoma. Validating these initial findings in a clinical trial would represent a significant advance towards potential approval of I-124-CLR1404 for clinical use in the diagnosis and treatment of glioblastoma. I look forward to working with Collectar and other investigators in

this trial to more fully determine administration parameters and characterize the clinical benefits of I-124-CLR1404."

## **Phase II Trial Design**

The primary objective of this trial is to determine the optimal dose and imaging time points of I-124-CLR1404 in subjects with newly diagnosed or recurrent glioblastoma. The Phase II trial is an open-label, multi-center study evaluating up to two doses (5 mCi and 7.5 mCi) of I-124-CLR1404 at multiple time points to determine the optimal parameters for PET/CT brain imaging.

A highly unique element of this clinical trial involves rigorous confirmation of imaging with pathology results. This permits exploratory analyses of the sensitivity and specificity of I-124-CLR1404 PET/CT compared to standard of care MRI. In addition, this will provide insights into the ability of I-124-CLR1404 PET to distinguish treatment-related effects such as pseudoprogression and radiation necrosis from true tumor recurrence.

For information about enrolling in the study, please visit [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

## **About Glioblastoma**

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 generally 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. Data from a Phase Ib dose-escalation trial of I-131-CLR1404 in patients with advanced solid tumors is anticipated in the first quarter of 2014. 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](http://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, 2012 and in our subsequent quarterly reports on Form 10-Q. 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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