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Cellestar Biosciences Initiates Proof-of-Concept Trial of I-131-CLR1404 in Multiple Myeloma

MADISON, Wis., April 15, 2015 (GLOBE NEWSWIRE) -- Cellestar Biosciences, Inc. (Nasdaq:CLRB), a clinical stage biopharmaceutical company developing innovative agents for the detection and treatment of cancer, announced the initiation of patient dosing in a proof-of-concept trial of I-131-CLR1404 in patients with relapsed or refractory multiple myeloma, an indication for which I-131-CLR1404 previously received orphan drug designation from the U.S. Food and Drug Administration.

Multiple myeloma is an incurable malignancy for which novel therapies are needed. The radiosensitivity of multiple myeloma is well documented. I-131-CLR1404 is designed to allow for targeted delivery of ionizing radiation to malignant cells, allowing for an intracellular radiation mechanism of cancer cell killing regardless of anatomic distribution.

"We are excited to be developing a new treatment option for this difficult disease. Because of its unique mechanism of action, I-131-CLR1404 may represent an entirely different treatment approach for patients that are no longer responding to currently available therapies," commented Dr. Natalie Callander, principal investigator of Cellestar's I-131-CLR1404 multiple myeloma trial, Associate Professor of Medicine, and Director, University of Wisconsin Carbone Cancer Center Myeloma Clinical Program. "I-131-CLR1404 appears to be a promising investigational drug and pre-clinical data indicate that the combination of Cellestar's cancer-selective delivery and retention platform with a known radiotherapeutic could be highly effective in treating multiple myeloma. We look forward to working with Cellestar and other investigators to explore the potential of I-131-CLR1404 as a treatment for relapsed or refractory multiple myeloma."

This is a multi-center, open-label, sequential group, dose escalation, Phase I proof-of-concept study evaluating the safety and tolerability of I-131-CLR1404, with and without concurrent weekly dexamethasone, in multiple myeloma patients who have previously been treated with, or are intolerant of, an immunomodulator and a proteasome inhibitor. The secondary objectives of the study are to identify a recommended Phase II dose and assess therapeutic activity of I-131-CLR1404 in relapsed or refractory multiple myeloma. Therapeutic activity will be assessed by overall response rate, time to progression and duration of response.

Patients will be enrolled into cohorts that receive escalating single doses of I-131-CLR1404 combined with a set dose of dexamethasone. The first cohort of subjects will receive a 12.5 mCi/m² dose of I-131-CLR1404. A minimum of three subjects will be enrolled at each dose level. Dose escalation and level expansion will be guided by safety and will be performed after all subjects in a cohort have been followed for 12 weeks. Following identification of the highest tolerated dose, additional I-131-CLR1404-naïve subjects will be enrolled and treated with the identified dose of I-131-CLR1404 without concurrent oral dexamethasone.

"I-131-CLR1404 has been generally well tolerated in patients and we believe that its selectivity and potency provide a solid rationale for its use in multiple myeloma," said Dr. Simon Pedder, president and chief executive officer of Cellectar Biosciences. "Based on results from our Phase I trials and the radiosensitivity of multiple myeloma, we believe 12.5 mCi/m² is a meaningful starting dose of I-131-CLR1404 and evidence of clinical activity will be assessable relatively early in the dose escalation process."

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 were diagnosed with multiple myeloma in 2014 and approximately 11,000 myeloma patients die each year.

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. I-131-CLR1404 has been granted orphan drug designation from the U.S. Food and Drug Administration for the treatment of multiple myeloma.

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, 2014. 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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