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Cellectar Biosciences Announces Acceptance of Investigational New Drug Application to Evaluate I-131-CLR1404 in Clinical Trials in Relapsed or Refractory Multiple Myeloma

MADISON, Wis., Sept. 4, 2014 (GLOBE NEWSWIRE) -- Cellectar Biosciences, Inc. (Nasdaq:CLRB), announced today that the U.S. Food & Drug Administration (FDA) has accepted the Company's investigational new drug (IND) application to begin clinical study of I-131-CLR1404, a highly-selective, cancer-targeting radiopharmaceutical, in patients with relapsed or refractory multiple myeloma, an incurable cancer of plasma cells.

I-131-CLR1404 is radiotherapeutic comprised of a proprietary 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. Because Cellectar's PLE platform has been shown to reliably and universally accumulate in malignant cancer cells, and the therapeutic properties of the Iodine-131 isotope are well known, I-131-CLR1404 is engineered to combine an intracellular radiation mechanism of destroying cancer cells, including cancer stem cells, through targeted delivery specific to malignant tissue that spares critical normal tissues from consequential radiation dose.

Cellectar plans to initiate a Phase I/II, proof-of-concept trial during the fourth quarter 2014 in approximately 20 patients with relapsed or refractory multiple myeloma that have previously been treated with, or are intolerant of, an immunomodulator and a proteasome inhibitor. The primary objective of the study will be to determine the safety and tolerability of I-131-CLR1404, with and without concurrent weekly dexamethasone. In addition, the trial will seek to identify the recommended dose for future pivotal trials and determine therapeutic activity of I-131-CLR1404 in this patient population as measured by overall response rate, time to progression and duration of response.

"This trial affords us an opportunity to both assess the safety of I-131-CLR1404 in patients with multiple myeloma, but also to obtain near-term proof-of-concept data characterizing the activity of I-131-CLR1404 in this difficult-to-treat patient population," commented Dr. Simon Pedder, president and chief executive officer. "Having initiated a Phase II diagnostic imaging trial of our lead compound, I-124-CLR1404, in glioblastoma earlier in the year, we are pleased to now have this opportunity to initiate a second, company-sponsored clinical trial with the potential to showcase the therapeutic applications of our targeted delivery platform."

About Multiple Myeloma

According to the National Cancer Institute, multiple myeloma is the second most common hematologic cancer and results from an abnormality of plasma cells, usually in the bone marrow. It is estimated that 70,000 people are living with multiple myeloma and 24,000 new cases are diagnosed annually in the U.S., and that nearly 230,000 people are living with multiple myeloma and approximately 114,000 new cases are diagnosed annually, worldwide.

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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