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Cellectar Biosciences Announces CLR1502 Development Program to be Classified as Combination Product by U.S. Food and Drug Administration

Cellectar to Re-submit Investigational Application as Combination Product Prior to Initiating Proof-of-Concept Trial of Tumor Margin Illumination Agent in Breast Cancer Surgery

MADISON, Wis., June 11, 2015 (GLOBE NEWSWIRE) -- Cellectar Biosciences, Inc. (Nasdaq:CLRB), a clinical stage biopharmaceutical company developing innovative agents for the detection and treatment of cancer, announced today that, after review of the company's investigational new drug (IND) application, the U.S. Food and Drug Administration (FDA) has determined that Cellectar's tumor margin illumination agent, CLR1502, will be evaluated as a combination product and assigned to the Center for Devices and Radiological Health (CDRH). As a result of this classification, the FDA has advised Cellectar that it will need to submit a new investigational application for the combination product prior to initiating its planned proof-of-concept trial in breast cancer surgery.

"Our tumor illumination agent shares similar spectral qualities with indocyanine green (ICG), a fluorescent dye commonly used in medical diagnostics, and can therefore use several commercially available fluorescent imaging devices. Current labeling for such devices is limited to FDA approved applications such as cardiac, circulatory, hepatic and ophthalmic conditions," said Dr. Simon Pedder, president and chief executive officer of Cellectar Biosciences. "Because of the groundbreaking nature of our overall technology and the potential for an agent like CLR1502 to dramatically expand the utility of such imaging devices, we appreciate the agency's perspective and current interest in evaluating CLR1502 in combination with a light source technology. As previously disclosed, in the course of our discussions FDA regarding the CLR1502 registration program, the FDA has stressed that a combination product designation is not binding, can be revised later in our development program and that we are not necessarily precluded from filing a standalone NDA in the future."

About CLR1502

CLR1502 is a small-molecule, broad-spectrum, cancer-targeted, non-radioactive optical imaging agent developed by Cellectar to be the first of its kind for broad spectrum intraoperative tumor margin illumination and non-invasive tumor imaging. CLR1502 is comprised of a proprietary phospholipid ether (PLE) analog, acting as a cancer-targeted delivery and retention vehicle attached to a fluorophore to enable real-time visualization of

malignant tissue under near-infrared light.

CLR1502 is being developed for intraoperative imaging of cancer that will aid in the identification of malignant tissue during diagnostic, staging, debulking and curative cancer surgeries. In particular, the potential of CLR1502 in tumor margin illumination during oncologic resections raises the possibility that this operative aid may improve surgical outcomes.

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 Phase I and Phase II product candidates engineered to leverage the unique characteristics of cancer cells to "find, treat and follow" malignancies in a highly selective way. 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/A 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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