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Cellectar Biosciences Submits Phase 1b Clinical Trial Protocol to US Food and Drug Administration for CLR 125 to Treat Triple-Negative Breast Cancer (TNBC)

Good Tolerability and Robust Tumor Uptake were Observed in TNBC Animal Models

Auger Emitters Offer the Potential Benefit of Enhanced Cytotoxicity, Safety and Ease-of-Use

FLORHAM PARK, N.J., June 24, 2025 (GLOBE NEWSWIRE) -- Cellectar Biosciences, Inc. (Nasdaq: CLRB), a late-stage clinical biopharmaceutical company focused on the discovery and development of drugs for the treatment of cancer, today announced that the company has submitted a protocol with the U.S. Food and Drug Administration (FDA) for a Phase 1b Dose Finding study of its Auger emitting radiopharmaceutical, CLR 125, for the treatment of relapsed TNBC. CLR 125 is an iodine-125 Auger-emitting drug candidate targeting solid tumors, such as triple negative breast, lung and colorectal cancers.

“Building on the promising preclinical results with CLR 125, we have submitted a Phase 1b dose-finding study protocol to the FDA for the treatment of triple-negative breast cancer, including metastatic disease. This study leverages the unique potential ability of our PLE to deliver iodine-125 directly to the nucleus and mitochondria, which is designed to achieve potent activity while minimizing the risk of adverse effects due to its limited transmission range,” said Jarrod Longcor, Cellectar’s chief operating officer. “Initiating this Phase 1b study is a significant milestone and an important step toward evaluating the safety and optimal dosing of CLR 125 in patients, ultimately providing a potential new treatment option for those afflicted by this challenging disease.”

The proposed Phase 1b dose finding study in relapsed TNBC will utilize imaging to determine tumor uptake to evaluate three doses of CLR 125 (32.75 mCi for 4 cycles, 62.5 mCi for 3 cycles, and 95 mCi for 2 cycles) with four doses per cycle in 15 patients per arm. The primary endpoint of the study will be to determine the recommended Phase 2 dose and dosing regimen and will also evaluate safety and tolerability, as well as initial response assessment (RECIST and progression-free survival).

“The integration of our PDC-targeted delivery platform with a precision-driven, Auger-emitting isotope represents a powerful therapeutic combination with the potential to deliver significant clinical benefit across a range of solid tumors, including TNBC. Our confidence in CLR 125 is grounded in its molecular similarity to iopofosine I 131, our PDC designed to provide targeted delivery of iodine-131 (radioisotope), for which we have evidence supporting proof-of-concept and tolerability in a Phase 2 clinical trial,” said James Caruso, chief executive officer of Cellectar. “Leveraging dosimetry imaging to measure drug delivered directly to tumors is expected to provide early proof-of-concept of the appropriate dose.”

About Triple Negative Breast Cancer
Triple-negative breast cancer (TNBC) is an aggressive subtype of breast cancer characterized by the absence of estrogen receptors, progesterone receptors, and HER2 protein expression. This lack of common therapeutic targets makes TNBC particularly challenging to treat, with limited options beyond chemotherapy. TNBC tends to grow and spread more quickly than other breast cancer types and disproportionately affects younger women and those of African descent. In the U.S., approximately 12% of breast cancer diagnoses are TNBC.[1] Studies suggest that approximately 25% (40,540) of TNBC cases relapse after standard treatments like surgery, chemotherapy, and radiation.[2] Due to its high recurrence rate and poor prognosis, there is a critical need for innovative, targeted therapies to improve outcomes for patients facing this difficult diagnosis.[3]

About Cellectar Biosciences, Inc.
Cellectar Biosciences is a late-stage clinical biopharmaceutical company focused on the discovery and development of proprietary drugs for the treatment of cancer, independently and through research and development collaborations. The company's core objective is to leverage its proprietary Phospholipid Drug Conjugate™ (PDC) delivery platform to develop the next-generation of cancer cell-targeting treatments, delivering improved efficacy and better safety as a result of fewer off-target effects.

The company's product pipeline includes: iopofosine I 131, a PDC designed to provide targeted delivery of iodine-131 (radioisotope), for which the FDA has granted Breakthrough Therapy Designation; CLR 121225, an actinium-225 based program being targeted to several solid tumors with significant unmet need, such as pancreatic cancer; and CLR 121125, an iodine-125 Auger-emitting program targeted in other solid tumors, such as triple negative breast, lung and colorectal, as well as proprietary preclinical PDC chemotherapeutic programs and multiple partnered PDC assets.

In addition, iopofosine I 131 has been studied in Phase 2b trials for relapsed or refractory multiple myeloma (MM) and central nervous system (CNS) lymphoma, and the CLOVER-2 Phase 1b study, targeting pediatric patients with high-grade gliomas, for which Cellectar is eligible to receive a Pediatric Review Voucher from the FDA upon approval. The FDA has also granted iopofosine I 131 six Orphan Drug, four Rare Pediatric Drug and two Fast Track Designations for various cancer indications.

For more information, please visit www.cellectar.com or join the conversation by liking and following us on the company's social media channels: X, LinkedIn, and Facebook.

Forward Looking Statement Disclaimer
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 identify suitable collaborators, partners, licensees or purchasers for our product candidates and, if we are able to do so, to enter into binding agreements with regard to any of the foregoing, or to raise additional capital to support our operations, or our ability to fund our operations if we are unsuccessful with any of the foregoing. 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, 2024, and our Form 10-Q for the quarter ended March 31, 2025. 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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[1] Source: Triple-negative breast cancer recurrence: Outlook and treatment
[2] Source: Triple-Negative Breast Cancer Recurrence After Mastectomy
[3] Source: National Cancer Institute

Source: Cellectar Biosciences, Inc.