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# Cellecstar Enrolls First Patient in CLR 125 Auger-Emitting Radioconjugate Phase 1b Clinical Trial Targeting Refractory Triple Negative Breast Cancer (TNBC)

**Study will evaluate tumor-specific uptake, safety, tolerability, and preliminary efficacy signals of CLR 125 in refractory TNBC, to determine recommended Phase 2 dose**

FLORHAM PARK, N.J., April 14, 2026 (GLOBE NEWSWIRE) -- Cellecstar 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 first patient has been enrolled in the Phase 1b trial of CLR 121125 (CLR 125) for the potential treatment of triple negative breast cancer (TNBC).

CLR 125 is Cellecstar's proprietary Auger-emitting radioconjugate incorporating iodine-125 to achieve intracellular delivery and direct DNA-level damage in tumor cells. The molecular structure of CLR 125 is identical to that of iopofosine I 131 (CLR 131) and the demonstrated clinical activity, safety, and tumor-targeting characteristics of iopofosine I 131 provide important validation of the platform and support translational relevance. However, these radioconjugates differ in their radiobiologic behavior at the tumor level, resulting in distinct mechanisms of action and therapeutic profiles. In preclinical studies, CLR 125 showed selective tumor uptake and statistically significant activity *in vivo* models of TNBC with no observed end-organ or hematologic toxicity at evaluated doses.

"Treating the first patient in this Phase 1b trial is a significant milestone for Cellecstar and for those impacted by triple negative breast cancer, a condition still defined by a profound lack of targeted therapies," said James Caruso, president and chief executive officer of Cellecstar. "CLR 125 embodies our commitment to optimize our proprietary PDC delivery platform to develop highly selective radioconjugates capable of delivering precise cytotoxic radiation while minimizing systemic toxicity. With additional study sites being activated in Q2, we are poised to rapidly advance this program and plan to provide dosimetry, safety, and efficacy updates throughout 2026."

The Phase 1b clinical trial is an open-label, dose-escalation study in patients with relapsed or refractory TNBC, designed to evaluate three dose levels and dosing regimens of CLR 125 (32.75 mCi administered over 4 cycles, 62.5 mCi over 3 cycles, and 95 mCi over 2 cycles), with approximately 15 patients enrolled per treatment arm. The study incorporates imaging-based assessments to characterize tumor uptake and biodistribution, supporting prediction of safety and therapeutic activity. Clinical endpoints include safety and tolerability, as well as preliminary efficacy measures, including tumor response per RECIST criteria and progression-free survival.

## **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. Studies suggest that approximately 25% of TNBC cases relapse after standard treatments like surgery, chemotherapy, and radiation. 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.

## **About Celectar Biosciences, Inc.**

Celectar 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, which is a PDC designed to provide targeted delivery of iodine-131 (radioisotope). Iopofosine I 131 has been tested in Phase 2b trials as a treatment for relapsed or refractory Waldenström Macroglobulinemia (WM), in relapsed or refractory multiple myeloma (MM) and central nervous system (CNS) lymphoma. The CLOVER-2 Phase 1b study is evaluating iopofosine I 131 in pediatric patients with high-grade gliomas, for which Celectar is eligible to receive a Pediatric Review Voucher from the FDA upon approval. The FDA has granted iopofosine I 131 Breakthrough, six Orphan Drug, four Rare Pediatric Drug and two Fast Track Designations for various cancer indications, and the EMA has granted iopofosine I 131 PRiority Medicines (PRIME) designation.

Additionally, the Celectar team is developing CLR 121225 (CLR 225), an actinium-225 based program targeting solid tumors in indications with significant unmet need, such as pancreatic cancer, as well as proprietary preclinical PDC chemotherapeutic programs and multiple partnered PDC assets.

For more information, please visit [www.celestar.com](http://www.celestar.com) or join the conversation by liking and following us on the company's social media channels: [X](#), [LinkedIn](#), and [Facebook](#).

## **Forward Looking Statements 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, 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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