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Cellecstar and Evestia Clinical Announce Partnership to Support Auger-Emitting Radiopharmaceutical Clinical Trial in Triple-Negative Breast Cancer (TNBC)

Intends to Initiate Phase 1b Clinical Trial in TNBC at Mayo Clinic in Fourth Quarter 2025

FLORHAM PARK, N.J. and LONDON and CHARLOTTESVILLE, Va., Sept. 24, 2025 (GLOBE NEWSWIRE) -- Cellecstar Biosciences, Inc. ("Cellecstar") (NASDAQ: CLRB), a late-stage clinical biopharmaceutical company focused on the discovery and development of drugs for the treatment of cancer, and Evestia Clinical ("Evestia"), a leading independent global specialist Contract Research Organization (CRO), have entered into an agreement whereby Evestia will provide Cellecstar with full CRO services for their upcoming Phase 1b study evaluating CLR 125 for the treatment of triple-negative breast cancer (TNBC). CLR 125 is an iodine-125 Auger-emitting drug candidate targeting solid tumors, such as triple negative breast, lung and colorectal cancers.

The new contract will leverage Evestia Clinical's newly expanded global capabilities and oncology expertise, enhanced by its recent merger with Atlantic Research Group (ARG). Evestia's experience in oncology spans both adult and pediatric populations, with participation in more than 300 studies across a wide range of solid tumors and hematologic malignancies and collaboration with many reputable clinic sites, including the Mayo Clinic.

"ARG has been a trusted CRO partner for years and we are pleased to continue to work with the expanded team at Evestia Clinical, confident that their combined expertise and tailored approach will be instrumental in contributing to the success of this important clinical trial," said Jarrod Longcor, chief operating officer of Cellecstar. "We have unwavering confidence in CLR 125, and initiation of the Phase 1b trial in TNBC will represent a significant milestone toward bringing a new treatment option to patients."

"We have worked with the Cellecstar team for more than a decade and look forward to continuing to support them as they move CLR 125 into clinical development as a treatment for TNBC," added Paul Bishop, chief development officer of Evestia. "Following ARG's merger with Evestia Clinical, the combined Group now offers broader therapeutic expertise, an expanded US presence, and enhanced technologies that enable us to deliver truly bespoke, high-quality services to clients in complex, high-research therapeutic areas, such as oncology."

Additionally, Cellecstar has selected a Mayo Clinic Network site as a treatment center for the Phase 1b clinical trial of CLR 125 in TNBC and Pooja Advani, MBBS, MD, Mayo Clinic, as its lead investigator. Mayo Clinic will ensure that patients participating in the Phase 1b trial are treated by highly experienced clinicians with significant domain expertise.

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 Evestia Clinical

Evestia Clinical is a leading global specialist CRO. With a commitment to scientific excellence, innovation, and patient-centric research, Evestia Clinical partners with biotech companies to accelerate the development of life-saving therapies. Backed by Kester Capital, Evestia Clinical is dedicated to advancing healthcare through cutting-edge clinical research. Evestia Clinical's vision is to be the market-leading clinical service partner for biotechs and beyond – fuelling medical breakthroughs to improve global health within a culture that values, inspires, and empowers.

Evestia Clinical offers a full suite of customized clinical development services. This includes project management, site management, regulatory services, clinical monitoring, data management and biostatistics, medical affairs/medical writing, quality assurance services, pharmacovigilance, and Functional Service Provider solutions.

About Collectar Biosciences, Inc.

Collectar 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 Collectar 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.collectar.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 FDA and EMA regulatory pathways, ability to execute strategic alternatives, 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 quarterly period ending June 30, 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 <https://www.medicalnewstoday.com/articles/324272>

² <https://www.verywellhealth.com/triple-negative-breast-cancer-recurrence-after-mastectomy-6746068>

³ <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/triple-negative-breast-cancer>

Source: Collectar Biosciences, Inc.