September 9, 2025

Cellectar Biosciences to Participate at Oppenheimer 3rd Annual Targeted Radiopharmaceutical Therapies in Oncology Summit

Highlighting Continued Progress with EMA Regarding a Potential Conditional Marketing Authorization Submission for Iopofosine I 131 to Treat Waldenstrom Macroglobulinemia (WM) in the EU; Decision on Track for Late 3Q25/Early 4Q25

Intention to Pursue an Accelerated Approval with the U.S. Food and Drug Administration for Iopofosine I 131 as a Treatment for WM

Advancing Auger-Emitting Radiopharmaceutical Product Candidate into Phase 1b Clinical Trial for the Treatment of Triple-Negative Breast Cancer in 4Q25

FLORHAM PARK, N.J., Sept. 09, 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 Company management will participate at the upcoming Oppenheimer 3rd Annual Targeted Radiopharmaceuticals in Oncology Summit taking place on September 11, 2025, in New York City.

While participating at this radiopharmaceutical therapy summit, Cellectar management will be meeting with investors and discussing the Company's progress in recent months and future plans, including, among other topics:

- Progress with the European Medicines Agency's (EMA) regarding scientific advice on the company's continued preparation for a potential Conditional Market Authorization (CMA) submission.
    - Provided data to EMA data from the Phase 2b CLOVER WaM clinical trial where the company observed a statistically significant major response rate, meaningful duration of response and integrated summary of safety for all patients treated with iopofosine I 131 for hematologic malignancies.
    - A follow-up meeting with the EMA was completed and a final decision from the EMA on their recommendation whether to submit for a CMA is expected in late third quarter or early fourth quarter 2025.
- Plans to pursue a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) for the accelerated approval of iopofosine I 131 as a treatment for Waldenstrom's Macroglobulinemia (WM), subject to raising sufficient additional funding and once the confirmatory trial is underway.
    - The submission would be supported by data from the Phase 2b CLOVER WaM

clinical trial demonstrating a statistically significant major response rate compared to a null hypothesis of 20% and meaningful duration of response. The data set now includes the FDA-requested 12-month follow-up results on all patients from the trial and new subset analysis of data from patients immediately following Bruton Tyrosine Kinase inhibitor (BTKi) treatment failures regardless of line of therapy.
    - The Company plans to share these new data at an upcoming medical or scientific conference.
- Initiation of Phase 1b Dose Finding study of the company's Auger-emitting radiopharmaceutical, CLR 125, for the treatment of relapsed triple-negative breast cancer (TNBC), planned for the fourth quarter 2025. CLR 125 is an iodine-125 Auger-emitting drug candidate targeting solid tumors, such as triple negative breast, lung and colorectal cancers.
- Execution of long-term multi-isotope supply agreements to provide Cellectar with iodine-125 and actinium-225 to support its clinical studies and future commercial needs.

"We recently completed our scheduled meeting with the EMA and remain hopeful that the agency will recommend that we file for a fast track, conditional marketing authorization approval and expect their decision in the near term. As previously stated, we remain in active partnering discussions seeking capital to support global regulatory requirements and the potential worldwide marketing of iopofosine I 131," said Jim Caruso, president and chief executive officer of Cellectar. "Additionally, we continue to make strong progress with our novel phospholipid drug conjugate pipeline and are excited to advance our lead auger-emitting asset, CLR 125, into our planned Phase 1b trial for the treatment of TNBC in the fourth quarter of this year."

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 its lead assets: iopofosine I 131, a PDC designed to provide targeted delivery of iodine-131 (radioisotope); CLR 121225 (CLR 225), an actinium-225 based program being targeted to several solid tumors with significant unmet need, such as pancreatic cancer; and CLR 121125 (CLR 125), 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 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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Source: Cellectar Biosciences, Inc.