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Cellectar Biosciences to Highlight 2025 Strategic Initiatives at Upcoming Biotech Showcase during the JP Morgan Healthcare Conference

Oral Presentation Presented at ASH 2024 Showed Iopofosine I 131 Achieved an 83.6% ORR and Exceeded Primary and Secondary Efficacy Endpoints in Phase 2 CLOVER-WaM Study for Relapsed/Refractory Waldenstrom's Macroglobulinemia

Plans to Advance Iopofosine I 131 Internally, Through Strategic Partnerships and Other Approaches; Finalizing Confirmatory Study and Pathway for US FDA Accelerated Approval and EMA Prime Marketing Authorization

Advancing Radiotherapeutic Assets including Alpha- and Auger-emitting Radioconjugates into Phase 1/2a Solid Tumor Studies

FLORHAM PARK, N.J., Jan. 12, 2025 (GLOBE NEWSWIRE) -- Cellectar Biosciences, Inc. (NASDAQ: CLRB), a late-stage clinical biopharmaceutical company focused on the discovery, development and commercialization of drugs for the treatment of cancer, today announces plans to highlight the Company's 2025 strategic initiatives at Biotech Showcase, taking place January 13-15, 2025 in San Francisco during the 43rd Annual JP Morgan Healthcare Conference. James Caruso, president and CEO of Cellectar, will present a corporate update on Tuesday, January 14, 2025, at 11:30 am Pacific Time.

Iopofosine I 131 (iopofosine) is a potential first-in-class, novel cancer targeting agent utilizing a phospholipid ether as a radioconjugate monotherapy. The CLOVER-WaM study (NCT02952508) results demonstrated an overall response rate (ORR) of 83.6% and a major response rate (MRR) of 58.2% (95% CI, 0.42 to 0.67), which exceeded the agreed-upon primary endpoint of a 20% MRR. These data were presented as a podium presentation during the 66th Annual American Society of Hematology Conference in December 2024 by Sikander Ailawadhi, M.D., Professor of Medicine, Mayo Clinic.

"We remain committed to bringing iopofosine to WM patients, who have limited treatment options for this incurable disease," said James Caruso, president and CEO of Cellectar. "We believe our ongoing communications with the U.S. Food and Drug Administration (FDA) indicate there is a path forward for a conditional U.S. market approval as part of the accelerated approval process. This aligns with our understanding of feedback provided by the European Medicines Agency for conditional EU market authorization, and we are harmonizing recommendations from both agencies for a global approval strategy."

The Company expects the confirmatory study to be a comparator, randomized controlled study with 40-60 patients per arm and full patient enrollment projected within 18 months of

the first patient admitted to the study. The Company anticipates alignment with the FDA in the first half of 2025. With a current cash runway extending into the fourth quarter of 2025, the Company is assessing a variety of approaches to bring iopofosine to patients.

Mr. Caruso continued, “We believe iopofosine represents a compelling partnership opportunity for many reasons including the results observed from our clinical studies. The commercial work we conducted in WM provides strong evidence that iopofosine possesses a substantial market opportunity based upon patient outcomes, convenient fixed dosing, off-the-shelf global distribution, and orphan pricing. Cellectar’s goal to bringi lifesaving radioconjugates, such as iopofosine, CLR 121225, and CLR 121125, to patients remains steadfast and we look forward to advancing our objectives throughout 2025.”

Beyond iopofosine, the Company is focused on the development of its radioconjugate Phospholipid Drug Conjugate™ (PDC) programs, also known as phospholipid radioconjugates or PRCs. CLR 121225 is Cellectar’s lead alpha-emitting actinium-225 radioconjugate PRC. It has demonstrated activity and has been well tolerated in multiple solid tumor animal models, including pancreatic, colorectal, and breast cancer. It has also shown excellent biodistribution and uptake into tumors. In animal models of pancreatic adenocarcinoma, the single lowest dose tested provided tumor stasis, and the highest dose provided tumor volume reduction. The Company plans to file an Investigational New Drug (IND) application in the first quarter of 2025.

Cellectar’s lead Auger-emitting (iodine-125) PRC, CLR 121125, has demonstrated tolerability and activity in multiple animal models including triple negative breast cancer. Auger- emitters provide the greatest precision in targeted radiotherapy as the emissions only travel a few nanometers, therefore it is necessary for the isotope to be delivered intracellularly. The Company’s novel PDC platform uniquely provides the required targeted delivery. CLR121125 has received IND clearance and a Phase 1b/2a dose finding study in triple-negative breast cancer is planned.

The Company is evaluating the timing of study initiation for both CLR 121225 and CLR 121125.

Biotech Showcase

A live webcast and a replay of Mr. Caruso’s presentation at Biotech Showcase will be available on the Company’s investor relations website.

About Cellectar Biosciences, Inc.

Cellectar Biosciences is a late-stage clinical biopharmaceutical company focused on the discovery, development and commercialization 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 lead asset, iopofosine I 131, a PDC designed to provide targeted delivery of iodine-131 (radioisotope), CLR 121225, an actinium-225 based

program being targeted to several solid tumors with significant unmet need, such as pancreatic cancer, CLR 121125, an iodine-125 Auger-emitting program targeted in other solid tumors, such as triple negative breast, lung and colorectal, 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: Twitter, 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 raise additional capital, uncertainties related to the disruptions at our sole source supplier of iopofosine, the ability to attract and retain partners for our technologies, the identification of lead compounds, the successful preclinical development thereof, patient enrollment and the completion of clinical studies, the FDA and EMA review processes and other government regulation, our ability to obtain regulatory exclusivities, the availability of priority review vouchers, our 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, 2023, and our Form 10-Q for the quarter ended September 30, 2024. 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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