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Cellectar Biosciences Provides Strategic Update on Clinical Development, Pipeline Programs and Corporate Restructuring

Evaluating strategic options for iopofosine I 131 a late-stage clinical program with compelling Phase 2 data and a substantial market opportunity

Focusing on advancing radiotherapeutic assets including alpha- and Auger-emitting radioconjugates into Phase 1 solid tumor studies

FLORHAM PARK, N.J., Dec. 10, 2024 (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 a strategic update on its clinical development programs for its proprietary phospholipid ether drug conjugate platform that delivers a broad array of therapeutic modalities to target cancers.

Due to recent communications with the U.S. Food and Drug Administration (FDA, or the Agency) regarding a confirmatory study to support accelerated approval and the regulatory submission for iopofosine I 131, the Company has decided to pursue strategic options for the further development and commercialization of this product candidate. The CLOVER-WaM study was conducted in accordance with earlier FDA communications from an end of Phase 2 meeting and from a meeting in early 2024, during which the Company was informed that positive results for major response rate (MRR) as the primary endpoint could be acceptable to support accelerated approval of iopofosine I 131 as a treatment for Waldenstrom's macroglobulinemia (WM). Based upon a recent Type-C meeting with the FDA, the Company now believes that a submission seeking accelerated approval would need to be based on the MRR data from CLOVER-WaM and enrollment in a randomized, controlled confirmatory study that is designed to generate data on progression-free survival (PFS).

"While iopofosine I 131's positive WM data along with the high unmet medical need for these patients support further investment, we have determined that such a program may best be brought to market by a larger organization with greater resources. Importantly, partnering or divesting this program supports our commitment to providing this potentially life-saving drug to the patients who need it as quickly as possible," stated James Caruso, president and CEO of Cellectar. "We believe iopofosine I 131 represents a compelling opportunity as it has shown strong efficacy and good tolerability based on our clinical studies. Moreover, the commercial work we conducted demonstrates iopofosine I 131's substantial market opportunity based upon the product profile, which includes off-the-shelf global distribution, orphan pricing and existing unmet medical need."

Cellectar remains confident in the potential of its phospholipid ether drug conjugate platform and the targeted radiotherapies in its development pipeline. Iopofosine I 131's clinical

success validates the platform's ability to target cancers and Cellectar will leverage its experience to focus on the development of its earlier clinical programs.

Specifically, Cellectar will focus on those assets it believes have the highest therapeutic potential and opportunity for value creation. As highlighted by recent acquisitions and collaborations within the radiopharmaceutical sector, precision isotopes like alpha- and Auger-emitters have emerged as the leading therapeutics of interest. Consequently, the Company will now focus its resources on targeting solid tumors by advancing CLR 121225, its actinium-225 based program, and CLR 121125, its iodine-125 Auger-emitting program into the clinic.

Cellectar expects to file Investigational New Drug applications in the first half of 2025 for both CLR-121225 and CLR-121125, which will allow the initiation of Phase 1 clinical studies in solid tumor cancers. Both programs have demonstrated robust *in vivo* activity, tolerability, excellent targeting and uptake in preclinical solid tumor models. The Company believes this approach will provide an expedited timeframe to achieve safety and proof-of-concept data in patients.

The Company's strategic reprioritization will impact all departments and result in an immediate reduction in headcount of approximately 60%, which should be complete by the end of the fourth quarter 2024. The Company anticipates that the implementation of the restructuring will extend its cash runway into the third quarter of 2025.

"We are being methodical in our efforts to reorganize the company with the goal of conserving cash while maintaining the flexibility to execute immediate priorities and build for long-term growth and value creation. This reorganization is difficult but necessary for the future growth potential of Cellectar," said Mr. Caruso. "I want to extend my deepest gratitude to our departing employees for their significant contributions to our work and their dedication to making a difference in the lives of patients."

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 lead asset, iopofosine I 131, a small-molecule 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 is under evaluation in Phase 2b studies for relapsed or refractory multiple myeloma (MM) and central nervous system (CNS) lymphoma, alongside 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 Orphan Drug and Fast Track Designations for various cancer indications.

New data from the CLOVER-WaM Phase 2 clinical trial were recently presented in an oral presentation at the 66th American Society of Hematology Annual Meeting and Exposition (ASH 2024).

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 review process 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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