June 4, 2025

Cellectar Granted U.S. FDA Breakthrough Therapy Designation for Iopofosine I 131 in Waldenstrom Macroglobulinemia (WM)

Designation Supported by CLOVER WaM Phase 2 Study Data Which Reported an 83.6% Overall Response Rate (ORR)

Seeking Guidance from EMA to Determine if CLOVER WaM Phase 2 Data Meets Criteria to Apply for Fast-Track, Conditional Marketing Authorization, Answer Expected Late July

FLORHAM PARK, N.J., June 04, 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 the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy Designation for iopofosine I 131, a potential first-in-class, novel cancer targeting agent utilizing a phospholipid ether as a radioconjugate monotherapy, for the treatment of relapsed/refractory Waldenstrom macroglobulinemia (r/r WM).

WM is the dominant subtype of lymphoplasmacytic lymphoma and remains incurable with available therapies according to the International Waldenstrom's Macroglobulinemia Foundation. Approved WM treatment options are limited, underscoring the need for new therapies with novel mechanisms of action.

"The FDA's Breakthrough Therapy Designation underscores the potential of iopofosine I 131 as it may offer substantial improvement on at least one clinically significant endpoint over available therapies to address the substantial unmet medical need in this life-threatening cancer," said James Caruso, president and chief executive officer of Cellectar. "With robust clinical data, a favorable safety profile, expedited review designations in the United States and Europe and a compelling commercial market potential, we believe iopofosine I 131 represents an attractive candidate for potential collaborations or partners seeking impactful innovation and accelerated development pathways."

Data from the Phase 2 CLOVER WaM study (NCT02952508), including the 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, 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.

As previously announced, the FDA also granted iopofosine I 131 Fast Track Designation and Orphan Drug Designation. The European Medicines Agency (EMA) granted Orphan Drug Designation to iopofosine I 131 for treatment of r/r WM, as well as PRIME Designation for WM.

Separately, the company announced that it has provided the EMA with a data package that includes extensive supportive preclinical, regulatory and manufacturing data, as well as safety and efficacy data from the CLOVER WaM Phase 2b clinical trial. The EMA will review the package to determine whether there is enough clinical evidence to address the required criteria for Cellectar to apply for a fast-track, conditional marketing authorization approval. In late July 2025 the company expects a recommendation from the EMA on whether Cellectar should file a Medical Authorization Application (MAA).

About Breakthrough Therapy Designation
Breakthrough Therapy Designation is an FDA program intended to expedite the development and review of medicines for serious or life-threatening diseases with preliminary clinical evidence that the investigational therapy may offer substantial improvement on at least one clinically significant endpoint over available therapies. The designation provides increased interactions with the FDA and supports the possibility of receiving a six-month priority review of a New Drug Application.

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: 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; 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 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 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, 2024, and our Form 10-Q for the quarter ended March 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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Source: Cellectar Biosciences, Inc.