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Cellectar Biosciences Provides Update on CLOVER-2 Phase 1 Clinical Trial of Iopofosine I 131 in Pediatric Patients with Relapsed/Refractory High-Grade Glioma

In Patients Receiving a Minimum of 55 mCi an Average 5.4 Months of PFS was Observed: Twice the Reported 2.25 Median

FLORHAM PARK, N.J., June 11, 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 initial results as of June 10, 2025, from the CLOVER-2 Phase 1 clinical trial evaluating iopofosine I 131 in relapsed/refractory pediatric high-grade glioma (pHGG) patients. Rare Pediatric Drug and Orphan Drug Designations for pHGG have previously been granted for iopofosine I 131.

Pediatric high-grade gliomas are a collection of aggressive tumors affecting the brain and central nervous system. The patients enrolled in CLOVER-2 with pHGG (n=14) were diagnosed with diffuse midline gliomas (DMG), ependymomas, diffuse intrinsic pontine gliomas (DIPG), diffuse hemispheric gliomas (DHG) and anaplastic ependymomas. As reported in the literature, median progression free survival (PFS) and overall survival (OS) for patients with relapsed pHGG is poor; approximately 2.25 months and 5.6 months, respectively. While MRI measures of tumor volume change can be helpful and are used as a surrogate in clinical trials, they often fail to predict survival.

All patients receiving a minimum of 55 mCi total administered dose (n=7) experienced an average of 5.4 months of PFS and 8.6 months of OS, ongoing. All patients experienced disease control, which according to the committee for the Response Assessment in Pediatric Neuro-Oncology (RAPNO) does correlate with survival benefit. Three patients who received additional dosing cycles (a minimum of four total infusions) had an average PFS of 8.1 months and an OS of 11.5 months (ranging from 4.9 to 14.9 months), ongoing, with two achieving an objective response (ORR).

“We are highly encouraged with these initial findings from the CLOVER-2 trial in pediatric patients with high-grade glioma. Iopofosine I 131 observed extended PFS and survival, indicating potential signs of clinical efficacy for the treatment of these deadly cancers,” said Jarrod Longcor, chief operating officer of Cellectar Biosciences. “We believe this outcome further validates the clinical potential of iopofosine I 131 to treat aggressive cancers for patients with limited treatment options.”

Iopofosine I 131 was well tolerated and its toxicity profile was consistent with the Company's previously reported safety data. Importantly, patients on iopofosine I 131 did not experience any cardiovascular, renal, or liver toxicities, and no peripheral neuropathy or significant bleeding. The safety profile was consistent with selective targeting of tumor sites with

clinically negligible off-target effect outside the hematologic system. The most frequently reported treatment emergent adverse events were hematologic in nature (thrombocytopenia, neutropenia and anemia) and were predictable and manageable. All patients recovered from cytopenias.

About the CLOVER-2 Trial
The ongoing Phase 1b trial of iopofosine I 131 consists of children, adolescents and young adults with relapsed/refractory high-grade glioma (HGG) at multiple sites in the United States and Canada. The study is designed to evaluate the safety and tolerability of iopofosine I 131 in two dosing cohorts, one cohort receiving two doses at 20mCi/m2 each separated by 14 days for two cycles with a third optional cycle. Patients in the second cohort will receive 10 mCi/m2 each, separated by 14 days for three cycles with a fourth optional cycle. The study will also determine therapeutic activity defined as progression free survival (PFS) and overall survival, antitumor activity defined as the reduction in tumor volume and identify the recommended Phase 2/3 dose of iopofosine I 131 in children, adolescents and young adults with relapsed/refractory HGG.

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 assets: 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 Breakthrough Therapy, 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 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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