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Cellectar Biosciences Receives Rare Pediatric Disease Designation from U.S. Food and Drug Administration for Iopofosine I 131 in Relapsed or Refractory Pediatric High-Grade Glioma

CLOVER-2 Phase 1 Clinical Study Evaluating Iopofosine I 131 in Relapsed/Refractory Pediatric High-Grade Glioma Patients Showed Extended Progression Free Survival and Overall Survival

FLORHAM PARK, N.J., Oct. 27, 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 the U.S. Food and Drug Administration (FDA) has granted rare pediatric drug designation (RPDD) for iopofosine I 131 in inoperable relapsed or refractory pediatric high-grade glioma (r/r pHGG).

Iopofosine I 131 is a potential first-in-class, novel cancer targeting agent utilizing a phospholipid ether as a radioconjugate monotherapy. The FDA previously granted Orphan Drug Designation for iopofosine I 131 for the treatment of pHGG.

“Receiving Rare Pediatric Disease Designation for iopofosine I 131 underscores its potential to address one of the most devastating cancers affecting children and young adults. Combined with the encouraging interim results from our CLOVER-2 pHGG study, which showed meaningful improvements in progression-free and overall survival, this designation further validates the promise of our targeted radiotherapeutic approach,” stated James Caruso, president and CEO of Cellectar. “We believe iopofosine I 131 represents a compelling opportunity for strategic collaboration to accelerate development and bring a potentially first-in-class therapy to patients who urgently need new options.”

The FDA’s Rare Pediatric Disease Designation program is intended to encourage the development of new therapies for serious and life-threatening diseases that primarily affect individuals under 18 years of age. If a New Drug Application (NDA) for iopofosine I 131 is approved, upon reauthorization of the program Cellectar may be eligible to receive a Priority Review Voucher (PRV), which can significantly expedite the review process for future New Drug Applications or Biologic License Applications, may be redeemed to receive priority review for another marketing application or may be sold or transferred.

Pediatric high-grade gliomas are a collection of aggressive tumors affecting the brain and central nervous system. 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.

Interim data from CLOVER-2, the company's ongoing Phase 1b trial of iopofosine I 131 in children, adolescents and young adults with r/r pHGG at multiple sites in the United States and Canada, were highlighted in an oral presentation at the recent American Association for Cancer Research (AACR) Special Conference on Pediatric Cancer that took place in late September 2025.

The company's chief operating officer, Jarrod Longcor, delivered the update, *"Precision Radiotherapy for Incurable Brain Tumors: Phase 1b Dose & Regimen Optimization Study of Iopofosine I 131 in Inoperable Relapsed or Refractory Pediatric High-Grade Glioma, Interim Data Assessment,"* which showed that all patients receiving a minimum of 55 mCi total administered dose (n=6) 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).

Two case studies were highlighted in the oral presentation. Case Study 1 showed a 25-year-old male with diffuse hemispheric glioma with the H3 G34R/V mutation who had three prior therapies and who received a total administered dose of 126.6mCi of iopofosine I 131 over four doses (40mCi/m^2/dose) had his target lesion reduced by more than 50% approximately eight months post screening. This patient had PFS of 10.9 months and survival is ongoing at greater than 18 months as of July 25, 2025.

Case Study 2 showed a 15-year-old female with ependymoma who had eight prior therapies and who received a total administered dose of 58.9mCi of iopofosine I 131 over four doses (20mCi/m^2/dose) had her target lesion reduced from 252mm^2 to approximately 141mm^2. This patient had PFS of 11.2 months and her ongoing survival was greater than 17 months as of July 22, 2025.

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. No treatment-related deaths were reported.

The complete presentation can be accessed on the company's website here.

About Pediatric High-Grade Gliomas

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.

About the CLOVER-2 Trial
The Phase 1b trial of iopofosine I 131 consists of children, adolescents and young adults with r/r pHGG 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 r/r pHGG.

About Cellectar Biosciences, Inc.
Cellectar Biosciences is a late-stage clinical radiopharmaceutical company focused on the discovery and development of proprietary drugs for the treatment of cancer. 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 that deliver improved efficacy and better safety.

The company's product pipeline includes its lead assets: iopofosine I 131, a PDC designed to provide targeted delivery of iodine-131 (radioisotope) for the treatment of hematologic and solid tumor cancers such as Waldenstrom's macroglobulinemia (WM) and pediatric high grade gliomas; CLR 121125, an iodine-125 Auger-emitting program targeting solid tumors, such as triple negative breast, lung and colorectal cancers; CLR 121225, an actinium-225 based program targeting solid tumors with significant unmet need, such as pancreatic cancer; and proprietary preclinical PDC chemotherapeutic programs and multiple partnered PDC assets.

Iopofosine I 131 has been studied in Phase 2b trials for relapsed or refractory WM and multiple myeloma (MM), non-Hodgkin's lymphomas 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 granted iopofosine I 131 Breakthrough Designation, six Orphan Drug, four Rare Pediatric Drug and two Fast Track Designations for various cancer indications. The European Medicines Agency (EMA) has also granted PRIME and orphan drug designations for the treatment of WM.

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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