

Cellecstar Biosciences Presented Compelling Data in Oral Session and Panel Discussions at the American Association for Cancer Research Special Conference on Discovery and Innovation in Pediatric Cancer

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., Sept. 30, 2025 (GLOBE NEWSWIRE) -- Cellecstar 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 Jarrod Longcor, chief operating officer of Cellecstar, delivered an oral presentation followed by a 55-minute panel discussion with other experts in the field at the American Association for Cancer Research (AACR) Special Conference on Pediatric Cancer that took place September 25-28 in Boston, Massachusetts. The oral presentation highlighted interim data from the Phase 1b dose and regimen optimization study of 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 U.S. Food and Drug Administration (FDA) previously granted Rare Pediatric Drug and Orphan Drug Designations for iopofosine I 131 for the treatment of pHGG.

“Presenting these promising interim results at AACR’s Special Conference on Pediatric Cancer before an audience of pediatric oncologists and other researchers in the field was a meaningful milestone for Cellecstar,” said James Caruso, Cellecstar’s president and CEO. “The data from our CLOVER-2 study demonstrate encouraging signs of tumor volume reduction, disease control and extended survival in children and young adults with relapsed or refractory high-grade gliomas—an area of devastating unmet need. We remain committed to advancing iopofosine I 131 as a targeted radiotherapeutic option for patients with few alternatives.”

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 r/r pHGG is poor; approximately 2.25 months and 5.6 months, respectively.

The interim data were delivered by Mr. Longcor in an oral presentation titled, *“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.”*

All patients receiving a minimum of 55 mCi total administered dose (n=7) and evaluable (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/m²/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/m²/dose) had her target lesion reduced from 252mm² to approximately 141mm². 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 in the study treated with iopofosine I 131 did not experience any cardiovascular, renal, or liver toxicities, 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 ongoing 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. The Clover 2 study is active but not enrolling at this time.

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 lead 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 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 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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