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Cellectar's Iopofosine I-131 Exhibits Signals of Efficacy in Phase I Study for Pediatric Brain and Solid Tumors

FLORHAM PARK, N.J., Nov. 16, 2021 (GLOBE NEWSWIRE) -- Cellectar Biosciences, Inc. (NASDAQ: CLRB), a late-stage clinical biopharmaceutical company focused on the discovery, development and commercialization of targeted drugs for the treatment of cancer, today announced that patients in a Phase 1 study of iopofosine I-131 ("iopofosine") in children and adolescents with relapsed and refractory high grade gliomas (HGGs) and soft tissue sarcomas, exhibited positive changes in various tumor parameters. The Phase 1 study is an international, open-label, dose escalation, safety study of iopofosine in children and adolescents with relapsed or refractory cancers, specifically HGGs, high risk neuroblastoma and select soft tissue sarcomas.

The independent data monitoring committee (DMC) had previously determined that doses up to 60 mCi/m^2 were safe and tolerable and to initiate the 75 mCi/m^2 dosing cohort. The DMC advised, based upon the initial data, to enrich the 60 mCi/m^2 dose level for patients over the age of 10 with HGG and Ewing sarcoma. The initial response and tumor uptake were confirmed by further therapeutic responses, evidenced by changes in tumor parameters. This includes patients with relapsed HGGs experiencing over 5 months of progression free survival (PFS).

"Initial responses to iopofosine I-131 in relapsed pediatric brain tumors are most encouraging. Current treatment paradigms typically result in only 2-3 months[1] of PFS and while there is no comparator in this study, iopofosine data to date have demonstrated nearly double the PFS versus historical data," said Laurence Reilly interim chief medical officer of Cellectar. "Based upon these data we will continue to enroll patients with high grade gliomas and soft tissue sarcomas, and we look forward to engaging with the FDA in order to outline a potential registrational pathway."

Pediatric HGGs are a collection of aggressive brain and central nervous system tumor subtypes including diffuse intrinsic pontine gliomas, glioblastomas, astrocytomas and ependymomas. Children with these tumors have a poor prognosis and 5-year survival of less than 30%.

About iopofosine (also known as CLR 131)
Iopofosine is a small-molecule Phospholipid Drug Conjugate™ designed to provide targeted delivery of iodine-131 (radioisotope) directly to cancer cells, while limiting exposure to healthy cells. We believe this profile differentiates iopofosine from many traditional on-market treatments. Iopofosine is currently being evaluated in the CLOVER-WaM Phase 2 pivotal study in patients with relapsed/refractory (r/r) Waldenstrom's macroglobulinemia (WM), a Phase 2b study in r/r multiple myeloma (MM) patients and the CLOVER-2 Phase 1

study for a variety of pediatric cancers. The U.S. Food and Drug Administration granted iopofosine Fast Track Designation for WM patients having received two or more prior treatment regimens, as well as r/r MM and r/r diffuse large B-cell lymphoma (DLBCL). Orphan Drug Designations (ODDs) have been granted for WM, MM, neuroblastoma, rhabdomyosarcoma, Ewing's sarcoma and osteosarcoma. Iopofosine was also granted Rare Pediatric Disease Designation (RPDD) for the treatment of neuroblastoma, rhabdomyosarcoma, Ewing's sarcoma and osteosarcoma. The European Commission granted an ODDs for r/r MM and WM.

About Cellectar Biosciences, Inc.
Cellectar Biosciences is focused on the discovery and development of drugs for the treatment of cancer. The company is developing proprietary drugs 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 PDCs that specifically target cancer cells, delivering improved efficacy and better safety as a result of fewer off-target effects. The company's PDC platform possesses the potential for the discovery and development of the next-generation of cancer-targeting treatments, and it plans to develop PDCs independently and through research and development collaborations.

The company's product pipeline includes iopofosine, a small-molecule PDC designed to provide targeted delivery of iodine-131 (radioisotope), and proprietary preclinical PDC chemotherapeutic programs and multiple partnered PDC assets. The company is currently investigating iopofosine in a global, pivotal expansion cohort in relapsed or refractory WM patients who have received at least two prior lines of therapy, including those who have failed or had a suboptimal response to Bruton tyrosine kinase inhibitors. The WM cohort will enroll up to 50 patients to evaluate the efficacy and safety of iopofosine for marketing approval. The company is also evaluating iopofosine in highly refractory multiple myeloma patients in its Phase 2 CLOVER-1 study and relapsed/refractory pediatric cancer patients with sarcomas or brain tumors in the Phase 1 CLOVER-2 study.

The Phase 1 pediatric study is an open-label, sequential-group, dose-escalation study to evaluate the safety and tolerability of iopofosine in children and adolescents with relapsed or refractory cancers, including malignant brain tumors, neuroblastoma, sarcomas, and lymphomas (including Hodgkin's lymphoma). The Phase 1 study is being conducted internationally at seven leading pediatric cancer centers.

For more information, please visit www.cellectar.com and www.wmclinicaltrial.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 including our expectations of the impact of the COVID-19 pandemic. 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 maintain orphan drug designation in the United States for iopofosine, the volatile market for priority review vouchers, our pharmaceutical collaborators' 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 for the year ended December 31, 2020, and our Form 10-Q for the quarter ended September 30, 2021. 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