November 5, 2020

Cellectar Biosciences' CLR 131 Demonstrates Preliminary Activity in Phase I Study for Pediatric Brain and Solid Tumors

CLR 131 crosses blood brain barrier delivering drug directly to brain tumors

FLORHAM PARK, N.J., Nov. 05, 2020 (GLOBE NEWSWIRE) -- Cellectar Biosciences, Inc. (NASDAQ: CLRB), a late-stage clinical biopharmaceutical company focused on the discovery, development and commercialization of drugs for the treatment of cancer, today announced CLR 131 has demonstrated preliminary activity in inoperable brain tumors in a Phase 1 study. The study is an international, open-label, dose escalation, safety study of CLR 131 in children and adolescents with relapsed or refractory cancers, specifically high grade gliomas (HGGs), high risk neuroblastomas and select soft tissue sarcomas.

Highlights from the study:

- Four dose levels (15, 30, 45 and 60mCi/m^2) have been evaluated to date with all deemed safe and tolerated by the independent Data Monitoring Committee; patients are currently being evaluated at the 75mCi/m^2 dose level
- Initial activity was expected to occur at doses of 60mCi/m^2 and higher; activity has been noted at lower dose levels
- CLR 131 has been measured in tumors, confirming that systemic administration of CLR 131 crosses the blood brain barrier and is delivered into tumors
- Disease control has been exhibited in heavily pretreated patients with ependymomas

"CLR 131's ability to cross the blood brain barrier along with the initial responses in pediatric brain tumors are most encouraging. CLR 131 may provide an attractive new treatment option for these patients beyond the current paradigms of external beam radiation and/or systemic targeted radiation as standards of care," said Dr. John Friend, CMO of Cellectar. "These ultra-orphan pediatric indications align with the development and regulatory strategy that we have successfully employed with our lead program in heme-oncology. We look forward to providing feedback from our recent FDA Guidance meeting, outlining the registrational pathway for our priority adult hematology indications and planned initiation of our pivotal trial later in the fourth quarter."

Similar to previous CLR 131 studies in adults, this study demonstrated that 20-40% of the

infused CLR 131 is delivered to the tumors. Additionally, the study demonstrated that systemic administration of CLR 131 results in a sufficient proportion of infused drug crossing the blood brain barrier and is delivered to different types of malignant brain tumors. CLR 131 has achieved disease control at multiple dose levels in rapidly progressing, heavily pretreated patients, including two patients at distinct dose levels with rapidly growing ependymomas. Pediatric HGGs are a collection of aggressive brain and central nervous system tumor subtypes (i.e. diffuse intrinsic pontine gliomas, glioblastomas, astrocytomas, ependymomas, etc.) with about 400 new pediatric cases diagnosed annually in the United States. Children with these tumors have a poor prognosis and limited 5 year survival.

It is noteworthy that CLR 131 is currently being dosed at 75mCi/m^2 and when compared to another targeted radiotherapeutic, MIBG-Iodine-131 (second line standard of care in neuroblastoma), CLR 131 achieves a nearly 16 fold increase in the amount of radiation delivered to the tumor. This enhanced delivery suggests that doses of CLR 131 between 60 and 75mCi/m^2 would be predicted to achieve similar responses in patients as an MIBG-Iodine-131 dose of up to 1,300mCi. Neuroblastoma is a cancer type that occurs in immature nerve cells of the adrenal gland, neck, chest or spinal cord with approximately 800 new cases diagnosed per year in the United States. Over 60% of the newly diagnosed cases of neuroblastoma are advanced with at least one site of metastasis resulting in a poor patient prognosis.

About CLR 131

CLR 131 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 unlike many traditional on-market treatment options. CLR 131 is the company's lead product candidate and is currently being evaluated in a Phase 2 study in B-cell lymphomas, and a Phase 1 dose-escalating clinical study in pediatric solid tumors and lymphomas. The company recently completed a Phase 1 dose-escalation clinical study in relapsed/refractory (r/r) multiple myeloma. The U.S. Food and Drug Administration (FDA) granted CLR 131 Fast Track Designation for both r/r multiple myeloma and r/r diffuse large B-cell lymphoma and Orphan Drug Designation (ODD) for the treatment of multiple myeloma, lymphoplasmacytic lymphoma (LPL)/Waldenstrom's macroglobulinemia (WM), neuroblastoma, rhabdomyosarcoma, Ewing's sarcoma and osteosarcoma. CLR 131 was also granted Rare Pediatric Disease Designations for the treatment of neuroblastoma, rhabdomyosarcoma, Ewing's sarcoma and osteosarcoma. Earlier this year, the European Commission granted an ODD for r/r multiple myeloma and most recently, the FDA granted Fast Track Designation for CLR 131 in LPL/WM in patients having received two prior treatment regimens or more.

About Cellectar Biosciences, Inc.

Cellectar Biosciences is focused on the discovery, development and commercialization 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 lead PDC therapeutic, CLR 131, is currently in two clinical studies. The CLOVER-1 Phase 2 study and the Phase 1 pediatric safety study. The CLOVER-1 study met the primary efficacy endpoints from the Part A dose-exploration portion, conducted in r/r B-cell malignancies, and is now enrolling in expansion cohorts evaluating in triple class refractory multiple myeloma and BTK inhibitor failed Waldenstrom's macroglobulinemia patients. The dosing regimen is designed to provide the optimal dose identified in Part A of >60mCi total body dose. The data from the Part A portion were announced on February 19, 2020.

The Phase 1 pediatric study is an open-label, sequential-group, dose-escalation study to evaluate the safety and tolerability of CLR 131 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.

The company's product pipeline includes one preclinical PDC chemotherapeutic program (CLR 1900) and multiple partnered PDC assets.

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 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 CLR 131, 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 CLR 131, 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, 2019 and our Form 10-Q for the quarters ended March 31, 2020 and June 30, 2020. These forward-looking statements are made only as of the date hereof, and we disclaim any obligation to update any such forward-looking statements. 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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