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# **Cellecstar Biosciences Reports Complete Response in a Relapsed/Refractory CNS Lymphoma Patient**

## **Response Achieved in Primary Central Nervous System Lymphoma for which there is no Approved Treatment**

FLORHAM PARK, N.J., Feb. 28, 2023 (GLOBE NEWSWIRE) -- Cellecstar 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 that a patient with primary central nervous system lymphoma (PCNSL) enrolled in its Phase 2 CLOVER-1 Trial demonstrated a complete response according to the 2005 Response Criteria for CNS Lymphoma with total resolution of the tumor on imaging studies.

Prior to study enrollment, the 61-year-old female patient was diagnosed with PCNSL, had received four lines of drug therapy including three lines of multi-drug therapy and a round of external beam radiation. She had BCL6 gene rearrangement which predicts worse outcomes and reduced survival.

The patient was enrolled in the Phase 2 CLOVER-1 trial and received two cycles (four doses of 15mCi/m<sup>2</sup>) of iopofosine I 131 over 71 days with a total administered dose of ~100mCi. Each infusion lasted less than 30 minutes. 50 days post cycle 1 day 1 infusion, a CT scan showed a very good partial response (VGPR) with a 93% reduction in tumor volume. The patient was administered the second cycle of iopofosine I 131 on days 57 and 71 and demonstrated complete resolution of the tumor as determined by CT scan by day 92 from initial dosing.

“Complete resolution of this patient’s primary CNS lymphoma, which had been relapsed or refractory to four lines of therapy, is extraordinary and provides further evidence of iopofosine’s ability to cross the blood/brain barrier and target cancer. Importantly, these patients currently have very poor prognoses and there is no approved therapy for CNS lymphoma,” said Dr. Andrei Shustov, senior vice president, medical of Cellecstar. “Beyond iopofosine’s demonstrated activity across all Waldenstrom’s macroglobulinemia (WM) genotypes currently tested, it is our belief that iopofosine will also demonstrate activity in WM patients with CNS involvement such as patients with Bing Neel syndrome.”

### **About CNS Lymphoma**

CNS lymphoma is a rare type of non-Hodgkin lymphoma (cancer of the lymph tissue) that develops in the central nervous system (CNS). It may form in the brain, spinal cord, spinal fluid or eye. When the lymphoma starts in the CNS and isn’t found anywhere else in your body, it is considered primary CNS lymphoma. If the lymphoma is found in other parts of your body, as well as the CNS, it is referred to as secondary CNS lymphoma. Patients with

CNS lymphoma typically have very poor prognoses (5-year survival of 30%) with most of the CNS lymphomas being diffuse large B-cell lymphomas. There is no currently approved treatment for CNS lymphoma.

### **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 to deliver 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), proprietary preclinical PDC chemotherapeutic programs and multiple partnered PDC assets. The company is currently investigating iopofosine in a global, open-label, 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.

The company has established exclusivity on a broad U.S. and international intellectual property rights portfolio around its proprietary cancer-targeting PLE technology platform, including iopofosine and its PDC programs.

In addition to the company's exclusivity to iopofosine and its phospholipid ethers conjugated to small molecules, peptides, and oligos, the company now has non-exclusive rights to the use of the phospholipid ether platform when conjugating with a chelator to bind select metal radioisotopes.

For more information, please visit [www.cellectar.com](http://www.cellectar.com) and [www.wmclinicaltrial.com](http://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, including conducting required clinical trials, 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, 2021, our Form 10-Q for the quarter ended March 31, 2022, our Form 10-Q for the quarter ended June 30, 2022, and our Form 10-Q for the quarter ended September 30, 2022. 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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