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Cellectar Biosciences Announces Positive DMC Review of Pivotal Trial of Iopofosine in Waldenstrom's Macroglobulinemia

Unanimous Agreement on Successful Achievement of Futility/Efficacy Assessment

FLORHAM PARK, N.J., April 26, 2022 (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 an independent Data Monitoring Committee (DMC) has completed its planned futility/efficacy assessment of the company's pivotal Phase 2b study of iopofosine in Waldenstrom's macroglobulinemia (WM) and unanimously recommended continuation of the trial as planned.

"We remain highly encouraged with the consistent performance of iopofosine I-131 in this difficult-to-treat refractory patient population," said James Caruso, president and chief executive officer of Cellectar. "We have alignment with the FDA on a 20% major response rate hurdle as the primary endpoint of our pivotal study. In a poster presented at ASCO 2021, we showed an 83.3% major response rate with one complete response in six WM patients, which served as the basis for our pursuing this indication."

The pivotal trial is a global, non-comparator, single-arm, open-label expansion cohort of the currently ongoing Phase 2 CLOVER-1 study of CLR 131. The study will enroll 50 WM patients. Patients in the trial will receive up to four doses of iopofosine over two cycles (cycle one on days 1, 15, and cycle two on days 57 and 71). The primary endpoint of the trial is major response rate as defined as a partial response (a minimum of a 50% reduction in the biological marker IgM) or better in patients that receive a minimum total body dose of 60 mCi with secondary endpoints of treatment free survival, duration of response and progression free survival.

The DMC is an independent committee of clinical research experts who review data in ongoing clinical trials. The DMC assessment was based on a pre-specified futility analysis within the first 10 patients as defined in the study protocol.

About Waldenstrom's macroglobulinemia
Waldenstrom's macroglobulinemia (WM) is a rare and incurable disease defined by specific genotypic subtypes that defines patient responses and long-term outcomes. The U.S. annual incidence is 3,000 (anticipated annual growth rate of approximately 30% through 2025) with a current U.S. prevalence of approximately 45,000 patients. The U.S. represents approximately 43% of the global market. WM is a lymphoma, or cancer of the lymphatic system. The disease occurs in a type of white blood cell called a B-lymphocyte or B-cell, which normally matures into a plasma cell whose job is to manufacture immunoglobulins (antibodies) to help the body fight infection. In WM, there is a malignant change to the B-cell

in the late stages of maturing, and it continues to proliferate into a clone of identical cells, primarily in the bone marrow but also in the lymph nodes and other tissues and organs of the lymphatic system. These clonal cells over-produce an antibody of a specific class called IgM.

WM cells have characteristics of both cancerous B-lymphocytes (NHL) and plasma cells (multiple myeloma), and they are called lymphoplasmacytic cells. For that reason, WM is classified as a type of non-Hodgkin's lymphoma called lymphoplasmacytic lymphoma (LPL). About 95% of LPL cases are WM; the remaining 5% do not secrete IgM and consequently are not classified as WM.

There is no standard treatment for WM. Several drugs have demonstrated activity either alone or in combinations, but only a single drug has received regulatory approval. Treatment is mainly focused on the control of symptoms and the prevention of organ damage. Front-line treatments for WM include rituximab alone or in combination with other agents. In the salvage therapy (second line or later) setting, ibrutinib, combinations of proteosome inhibitors and immunomodulatory drugs and stem cell transplantation are considered. Ibrutinib is the only drug to receive regulatory approval (2015) as a salvage therapy; in late 2019, it was approved for front-line treatment in combination with rituximab. Factors such as long-term cytopenias, age, hyper viscosity, the need for quick disease control, lymphadenopathy, co-morbidities, and IgM-related end-organ damage are key considerations in the choice of treatment.

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, 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.

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," their negatives or cognates, or language regarding potential future actions by FDA or other third parties. 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, 2021. These risks and uncertainties include the facts that regulatory and clinical trial requirements, interpretations or guidance may change, and that the FDA has substantial discretion in the approval process. 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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