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Cellectar Receives FDA Fast Track Designation for CLR 131 in Lymphoplasmacytic Lymphoma/ Waldenstrom's Macroglobulinemia

FLORHAM PARK, N.J., May 26, 2020 (GLOBE NEWSWIRE) -- Cellectar Biosciences, Inc. (NASDAQ: CLRB), a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of drugs for the treatment of cancer, today announced the U.S. Food and Drug Administration (FDA) has granted Fast Track Designation for CLR 131 in lymphoplasmacytic lymphoma (LPL)/Waldenstrom's macroglobulinemia (WM) in patients having received two prior treatment regimens or more. CLR 131 is the company's small-molecule, cancer-targeting radiotherapeutic Phospholipid Drug Conjugate™ (PDC™) designed to deliver cytotoxic radiation directly and selectively to cancer cells and cancer stem cells. It is currently being evaluated in Cellectar's ongoing Phase 2 CLOVER-1 clinical study in patients with relapsed or refractory multiple myeloma and lymphoplasmacytic lymphoma/Waldenstrom's macroglobulinemia.

"LPL/WM patients that do not respond optimally or are intolerant of ibrutinib, currently have limited treatment options and poor survival rates. Fast Track Designation for LPL/WM further supports our clinical development strategy to quickly and efficiently provide these patients with an effective therapeutic alternative," said James Caruso, president and CEO of Cellectar. "All four LPL/WM patients treated in our CLOVER-1 Phase 2 study to date achieved a 100% overall response rate and a 25% complete response rate. This strong response rate may represent an important improvement in the treatment of relapsed/refractory LPL/WM as no approved or late-stage development treatments for relapsed or refractory patients have reported complete responses."

Cellectar announced that it had received Orphan Drug Designation (ODD) for CLR 131 in LPL earlier this year. In addition to the variety of benefits derived from the ODD, the company will also receive increased engagement and assistance from the FDA in support of the regulatory approval pathway for LPL/WM.

Fast Track Designation

Fast Track Designation is granted to drugs being developed for the treatment of serious or life-threatening diseases or conditions where there is an unmet medical need. The purpose of the Fast Track Designation provision is to help facilitate development and expedite the review and potential approval of drugs to treat serious and life-threatening conditions. Sponsors of drugs that receive Fast Track Designation have the opportunity for more frequent interactions with the FDA review team throughout the development program. These can include meetings to discuss study design, data required to support approval, or other

aspects of the clinical program. Additionally, products that have been granted Fast Track Designation may be eligible for priority review of a New Drug Application (NDA) Real Time Oncology Review (RTOR) by the FDA which allows the FDA to begin review of the data within weeks of concluding the pivotal study.

About LPL/WM

Waldenstrom's macroglobulinemia (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 B-lymphocytes and plasma cells, 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. WM is a very rare and incurable disease.

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 lymphoma. The company recently completed a Phase 1 dose-escalation clinical study in r/r multiple myeloma. The 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/Waldenstrom's macroglobulinemia, 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. Most recently, the European Commission granted an ODD for r/r multiple myeloma.

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 designed to 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 lead PDC therapeutic, CLR 131, is currently in two clinical studies. The CLOVER-1 Phase 2 study completed the Part A dose-exploration portion conducted in relapsed/refractory (r/r) B-cell malignancies and is now enrolling in the Part B expansion

cohorts evaluating an approximate 100mCi total body dose of CLR 131 in relapsed/refractory (r/r) multiple myeloma (MM) and lymphoplasmacytic lymphoma/Waldenstrom's macroglobulinemia (LPL/WM). The data from the Part A portion was announced on February 20, 2020. The company is also conducting a Phase 1 dose-escalation study in pediatric solid tumors and lymphomas.

The company's product pipeline includes one preclinical PDC chemotherapeutic program (CLR 1900) and several 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 recent 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 quarter ended March 31, 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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