September 9, 2020

Cellectar Reports Data on CLR 131 Phase 2 CLOVER-1 Study in Triple Class Refractory Multiple Myeloma Patients

40% overall response rate (ORR) with a total administered dose of 60 mCi or greater

FLORHAM PARK, N.J., Sept. 09, 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 that a clinically meaningful 40% overall response rate (ORR) was observed in the subset of refractory multiple myeloma patients deemed triple class refractory who received a total administered dose of 60 mCi or greater. Triple class refractory is defined as patients refractory to immunomodulatory, proteasome inhibitors and anti-CD38 antibody drug classes.

The 40% ORR (6/15 patients) represents triple class refractory patients enrolled in Part A of Cellectar's CLOVER-1 study and additional patients enrolled in Part B from March through May 2020. As a reminder, all patients being enrolled in Part B are required to be triple class refractory. The additional six patients were heavily pre-treated with an average of 9 prior multi-drug regimens. Three patients received a total administered dose of greater than 60 mCi and three received less than 60 mCi. Consistent with the data released in February 2020, patients receiving greater than 60 mCi exhibit strong responses. Patients continue to tolerate CLR 131 well, with the most common and almost exclusive treatment emergent adverse events being cytopenias and importantly, no unexpected adverse events have been reported.

"We remain encouraged by the consistency of CLR 131's efficacy and tolerability data in these extremely challenging to treat triple class refractory multiple myeloma patients," said Dr. John Friend, CMO of Cellectar Biosciences. "A 40% ORR is a clinically meaningful outcome. For reference purposes, two recently approved drugs received a 25% and 31% ORR in triple class refractory patients. We look forward to the further development of CLR 131, a first in class phospholipid radio conjugate that may provide a significant benefit to patients and treatment alternative for clinicians."

About CLOVER-1
The Phase 2 CLOVER-1 study is an open-label study designed to determine the efficacy and safety of CLR 131 in select B-cell malignancies. 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 ≥ 60 mCi total body dose and 2 cycle doses as patients have demonstrated a clinically meaningful response and predictable safety profile of CLR 131 in r/r multiple myeloma (MM) and

lymphoplasmacytic lymphoma/Waldenstrom's macroglobulinemia (LPL/WM). Patients with LPL/WM must have received at least two prior treatment regimens, unless ineligible to receive standard agents, and have measurable disease, as defined by either a nodal lesion of >15 mm, an extranodal lesion of >10 mm, or measurable IgM. Prior external beam radiation therapy was allowed. The median age of the four LPL/WM patients enrolled in the study was 70 (range 54-81) and included 2 females and 2 males who had a median of two prior regimens (range 1-5). CLR 131 was administered intravenously, up to 30 minutes.

Cellectar was awarded approximately $2 million in non-dilutive grant funding from the National Cancer Institute to help fund the study. More information about the study, including eligibility requirements, can be found at www.clinicaltrials.gov, reference NCT02952508.

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 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. Earlier this year, the European Commission granted an ODD for r/r multiple myeloma and most recently, the U.S. Food and Drug Administration 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.

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 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 a two cycle dosing regimen that provides approximately 100 mCi total body dose of CLR 131 in r/r multiple myeloma (MM) and lymphoplasmacytic lymphoma/Waldenstrom's macroglobulinemia (LPL/WM). The data from the Part A portion was 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 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 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.

Contacts

Investors:

Monique Kosse
Managing Director
LifeSci Advisors
212-915-3820
monique@lifesciadvisors.com

CELLECTAR BIOSCIENCES

Source: Cellectar Biosciences