

Cellecstar Presents Data from Cohort 6 of its CLR 131 Phase 1 Study in Patients with Relapsed or Refractory Multiple Myeloma

Data presented at the 17th International Myeloma Workshop

Patients in Cohort 6 achieved a meaningful clinical benefit with a 50% overall response rate and 100% disease control

FLORHAM PARK, N.J., Sept. 16, 2019 (GLOBE NEWSWIRE) -- Cellecstar 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 Mr. Jarrod Longcor, chief business officer of Cellecstar presented data from Cohort 6 of its Phase 1 dose escalation study of CLR 131 in relapsed or refractory multiple myeloma (R/R MM), in a late breaker poster at the 17th International Myeloma Workshop being held in Boston, MA from September 12-15, 2019.

The poster, entitled: "[CLR 131 Demonstrates High Rate of Activity in a Phase 1, Dose Escalation Study in Patients with Relapsed or Refractory Multiple Myeloma \(RRMM\)](#)" highlights data from 4 subjects in Cohort 6 who received a fractionated dose of 37.5 mCi/m². Subjects in this cohort achieved a 50% overall response rate, with two subjects achieving a partial response and two subjects achieving minimal responses (39% and 48% reduction in M protein). CLR 131 was deemed safe and tolerated in all subjects with cytopenias being the only reported treatment emergent adverse events of grade 3 or higher. The majority (75%) of the subjects had high risk cytogenetics where median bone marrow plasma cell involvement was 25%. Patients' median age was 72.5 and averaged 5 prior systemic therapies, with one patient being dual class refractory, one being quad-refractory, and two being penta-refractory.

The Phase 1 study employs the International Myeloma Working Group (IMWG) criteria for measuring responses. The IMWG defines a partial response as a 50% reduction in the marker of disease and a minimal response as a 25% to 49.9% reduction.

"Cohort 6's overall response rate of 50% with 100% disease control in highly chemo-refractory elderly patients highlights CLR 131's potential as a first-in-class targeted radiotherapeutic for relapsed or refractory multiple myeloma. We saw an encouraging dose response compared to prior cohorts and CLR 131 continues to demonstrate a favorable safety profile," said James Caruso, president and CEO of Cellecstar. "We have progressed to a higher 40 mCi/m² fractionated dose Cohort 7, with data expected in Q4 2019. Additionally, based on the positive results from Cohort 6, we are now allowed to use the 37.5 mCi/m² dosing level in our ongoing Phase 2 (CLOVER-1) study evaluating CLR 131 in patients with relapsed/refractory (R/R) B-cell malignancies and expect data from the Phase 2 trial in Q4 2019."

About the Phase 1 R/R MM Trial

The Phase 1 multicenter, open-label, dose-escalation study is designed to evaluate the safety and tolerability of CLR 131 administered as a 30-minute IV infusion, either as a single bolus dose or as two fractionated doses, in patients with R/R MM. All doses to date have been deemed safe and well tolerated by an independent Data Monitoring Committee (DMC). Based on the data and the recommendation of the DMC, the Company has initiated a Cohort 7 where patients will receive 40mCi/m² fractionated dose of CLR 131.

Based upon the encouraging activity from the 37.5 mCi/m² fractionated dose of CLR 131 in Cohort 6, the company is evaluating this dose level in a larger population in its Phase 2 (CLOVER-1) trial as well.

A copy of the poster presentation and materials can be accessed on the [Posters and Publications](#) section of the Cellecstar website.

About CLR 131

CLR 131 is a small-molecule, cancer-targeting radiotherapeutic Phospholipid Drug Conjugate™ (PDC) designed to deliver cytotoxic radiation directly and selectively to cancer cells and cancer stem cells. CLR 131 is the company's lead therapeutic PDC product candidate and is currently being evaluated in both Phase 2 and Phase 1 clinical

studies. The FDA granted orphan drug designation for CLR 131 for the treatment of multiple myeloma as well as orphan drug and rare pediatric disease designations for CLR 131 for the treatment of neuroblastoma, rhabdomyosarcoma, Ewing's sarcoma and osteosarcoma. In addition to the ongoing Phase 1 dose-escalation study and the Phase 2 (CLOVER-1) trial, the company recently initiated a Phase 1 open-label, dose-escalating study in pediatric solid tumors and lymphoma to evaluate the safety and tolerability of a single intravenous administration of CLR 131 in up to 30 children and adolescents with cancers including neuroblastoma, sarcomas, lymphomas (including Hodgkin's lymphoma) and malignant brain tumors.

About Collectar Biosciences, Inc.

Collectar 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 (R&D) 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 three clinical studies – a Phase 2 study, and two Phase 1 studies. The Phase 2 clinical study (CLOVER-1) is in relapsed/refractory (R/R) B-cell malignancies, including multiple myeloma (MM), chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL), lymphoplasmacytic lymphoma (LPL), marginal zone lymphoma (MZL), mantle cell lymphoma (MCL), and diffuse large B-cell lymphoma (DLBCL). The company is also conducting a Phase 1 dose escalation study in patients with R/R multiple myeloma (MM) and a Phase 1 study in pediatric solid tumors and lymphoma.

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

For more information, please visit www.collectar.com.

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. 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, the completion of clinical trials, the FDA review process and other government regulation, 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, 2018 and Form 10-Q for the quarters ended March 31, 2019 and June 30, 2019. 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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