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Cellecstar Biosciences' CLR 131 Achieves Overall Survival of Greater Than 22 Months in Advanced Multiple Myeloma Patients

MADISON, Wis., Aug. 08, 2017 (GLOBE NEWSWIRE) -- Cellecstar Biosciences, Inc. (Nasdaq:CLRB), an oncology-focused, clinical stage biotechnology company (the "company"), today announces its lead PDC compound, CLR 131 has achieved a median overall survival of 22.5 months to date after a single dose infusion of 12.5mCi/m² in patients with multiple myeloma. Patients in the first cohort of the company's Phase 1 clinical trial had an average of 5.8 prior lines of treatment and therefore were considered to be heavily pretreated.

It is important to note that the trial remains ongoing, and the overall survival could continue to increase over time. While there have been no head-to-head studies, for comparison, this ongoing overall survival length from the company's Phase 1 clinical trial exceeds historic published outcomes of currently marketed second and third line treatment modalities for multiple myeloma.

Phase 1 Clinical Trial Results

The fourth cohort of the company's Phase 1 clinical trial of CLR 131 in multiple myeloma is fully enrolled. Patients in this cohort received a single infusion providing a dose of 31.25 mCi/m², and Cellecstar expects to report initial results from this cohort by the close of the third quarter 2017, in line with previous guidance. In addition to the patients from the first cohort achieving a median overall survival (mOS) of 22.5 months to date, patients from the second and third cohorts (who received single doses of 18.75 mCi/m² and 25 mCi/m²) have experienced mOS of 13.2 months and 6.7 months, respectively. As with Cohort One, these cohorts remain ongoing and the overall survival could continue to increase over time. As a result, the company continues to collect overall survival data on all evaluable trial participants and will provide timely updates, as appropriate.

NCI-Supported Phase 2 Trial

The company's Phase 2 study of CLR 131 in multiple myeloma and other hematologic malignancies was initiated on March 30, 2017 and remains actively enrolling. The study is being conducted at approximately 10-15 cancer centers in the United States for patients with a variety of orphan-designated relapse or refractory hematologic cancers. The study's primary endpoint is clinical benefit rate (CBR), with additional endpoints of overall response rate (ORR), progression free survival (PFS), median overall survival (mOS) and other markers of efficacy following a single infusion of CLR 131 providing a dose of 25.0 mCi/m², with the option for a second 25.0 mCi/m² dose approximately 75-180 days later.

The hematologic cancers studied in the trial include multiple myeloma (MM), chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL), lymphoplasmacytic lymphoma (LPL), marginal zone lymphoma (MZL), mantle cell lymphoma (MCL), and potentially diffuse large B-cell lymphoma (DLBCL).

In addition to the CLR 131 infusion(s), MM patients will receive 40 mg oral dexamethasone weekly for up to 12 weeks. Efficacy responses will be determined by the latest International Multiple Myeloma Working Group criteria. Efficacy for all lymphoma patients will be determined according to Lugano criteria.

More information about the trial, including eligibility requirements, can be found at www.clinicaltrials.gov, reference NCT02952508.

"We continue to make meaningful progress on our CLR 131 program and are encouraged by the observed clinical outcomes to date. We look forward to reporting data from the fourth cohort of our Phase 1 trial as well as the single and multi-dose Phase 2 study when available," said Jim Caruso, president and CEO of Cellecstar Biosciences. "We also continue to make progress evaluating the clinical utility of CLR 131 in both liquid and solid tumor orphan designated cancers that have potential for accelerated regulatory pathways."

About CLR 131

CLR 131 is an investigational compound under development for a range of hematologic malignancies. It is currently being evaluated as a single-dose treatment in a Phase 1 clinical trial in patients with relapsed or refractory (R/R) multiple myeloma (MM) as well as in a Phase 2 clinical trial for R/R MM and select R/R lymphomas with either a one- or two-dose treatment. CLR 131 represents a novel approach to treating hematological diseases and based upon preclinical and interim Phase 1

study data may provide patients with therapeutic benefits including, overall survival, an improvement in progression-free survival, and overall quality of life. CLR 131 utilizes the company's patented PDC tumor targeting delivery platform to deliver a cytotoxic radioisotope, iodine-131, directly to tumor cells. The FDA has granted Collectar an orphan drug designation for CLR 131 in the treatment of multiple myeloma.

About Phospholipid Drug Conjugates (PDCs)

Collectar's product candidates are built upon its patented cancer cell-targeting delivery and retention platform of optimized phospholipid ether-drug conjugates (PDCs). The company deliberately designed its phospholipid ether (PLE) carrier platform to be coupled with a variety of payloads to facilitate both therapeutic and diagnostic applications. The basis for selective tumor targeting of our PDC compounds lies in the differences between the plasma membranes of cancer cells compared to those of normal cells. Cancer cell membranes are highly enriched in lipid rafts, which are glycolipoprotein microdomains of the plasma membrane of cells that contain high concentrations of cholesterol and sphingolipids, and serve to organize cell surface and intracellular signaling molecules. PDCs have been tested in more than 80 different xenograft models of cancer.

About Collectar Biosciences, Inc.

Collectar Biosciences is developing phospholipid drug conjugates (PDCs) designed to provide cancer targeted delivery of diverse oncologic payloads to a broad range of cancers and cancer stem cells. Collectar's PDC platform is based on the company's proprietary phospholipid ether analogs. These novel small-molecules have demonstrated highly selective uptake and retention in a broad range of cancers. Collectar's PDC pipeline includes product candidates for cancer therapy and cancer diagnostic imaging. The company's lead therapeutic PDC, CLR 131, utilizes iodine-131, a cytotoxic radioisotope, as its payload. CLR 131 has been designated as an orphan drug by the US FDA and is currently being evaluated in a Phase 1 clinical study in patients with relapsed or refractory multiple myeloma and a Phase 2 clinical study to assess efficacy in a range of B-cell malignancies. The company is also developing proprietary PDCs for targeted delivery of chemotherapeutics and has several preclinical stage product candidates, and plans to expand its PDC chemotherapeutic pipeline through both in-house and collaborative R&D efforts. For more information please visit www.collectar.com.

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 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, 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, 2016. 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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