

July 17, 2018



# Cellecstar Reports 94% Reduction in Overall Tumor Volume in Waldenstrom Macroglobulinemia Patient in Phase 2 CLR 131 Clinical Study

MADISON, Wis., July 17, 2018 (GLOBE NEWSWIRE) -- Cellecstar Biosciences (Nasdaq:CLRB), a clinical stage biopharmaceutical company focused on the discovery, development and commercialization of drugs for the treatment of cancer, today announces that a patient in the lymphoplasmacytic lymphoma (LPL) arm with advanced Waldenstrom macroglobulinemia, enrolled in the CLR 131 Phase 2 trial, showed a 94% reduction in tumor burden and complete resolution in four of five targeted tumor masses.

Prior to study enrollment, this 67-year-old female patient was diagnosed with Waldenstrom macroglobulinemia and had received two lines of multi-drug therapy with the most recent treatment achieving a best response of disease progression. As part of Cellecstar's Phase 2 study in hematologic cancers, the patient received a single 25mCi/m<sup>2</sup> dose of CLR 131 over a 30-minute infusion period. On day 52 post infusion, a CT scan showed a >50% reduction in tumor volume and was classified as a partial response.

Based on this initial response and additional clinical factors, the treating physician, Sikander Ailawadhi, M.D., Associate Professor, Division of Hematology/Oncology, Department of Medicine, The Mayo Clinic, Jacksonville, Florida, administered a second dose of CLR 131 on day 123. A CT scan taken 64 days after the second dose, showed a 94% overall reduction in tumor burden and complete resolution in four of five targeted tumor masses. The total targeted tumor mass shrank from approximately 4700mm<sup>2</sup> prior to the first CLR 131 infusion to approximately 500mm<sup>2</sup> at last reading, and we continue to monitor the patient's progress.

"In addition to a robust clinical response, we were also happy to see resolution of symptoms that affected the patient's quality of life, including shortness of breath associated with moderately-sized pleural effusion shortly after the patient's first dose of CLR 131," stated Dr. Ailawadhi. "CLR 131 has shown good clinical response in LPL as well as other hematologic indications and could provide an excellent addition to the treatment armamentarium."

## **About Waldenstrom Macroglobulinemia**

Waldenstrom macroglobulinemia is a rare type of cancer that begins in the white blood cells, according to the Mayo Clinic. Patients with Waldenstrom macroglobulinemia, typically have bone marrow that produces too many abnormal white blood cells, crowding out healthy blood cells. The abnormal white blood cells produce a protein that accumulates in the blood, impairs circulation and causes complications. Waldenstrom macroglobulinemia is considered a type of non-Hodgkin's lymphoma and is sometimes called lymphoplasmacytic lymphoma or LPL.

## **About the Phase 2 Study of CLR 131**

The Phase 2 study is being conducted in approximately 10 leading cancer centers in the United States for patients with relapsed or refractory B-cell hematologic cancers. The hematologic cancers being 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).

The study's primary endpoint is clinical benefit response (CBR), with additional endpoints of progression free survival (PFS), median overall survival (OS) and other markers of efficacy following a single 25.0 mCi/m<sup>2</sup> dose of CLR 131, with the option for a second 25.0 mCi/m<sup>2</sup> dose approximately 75-180 days later.

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. Cellectar has been awarded approximately \$2 million in a non-dilutive grant from the National Cancer Institute to help fund the trial. More information about the trial, including eligibility requirements, can be found at [www.clinicaltrials.gov](http://www.clinicaltrials.gov), reference NCT02952508.

## **About CLR 131**

CLR 131 is Cellectar's investigational radioiodinated PDC therapy that exploits the tumor-targeting properties of the company's proprietary phospholipid ether (PLE) and PLE analogs to selectively deliver radiation to malignant tumor cells, thus minimizing radiation exposure to normal tissues. CLR 131, is in a Phase 2 clinical study in relapsed or refractory (R/R) MM and a range of B-cell malignancies and a Phase 1 clinical study in patients with (R/R) MM exploring fractionated dosing. The company is currently initiating a Phase 1 study with CLR 131 in pediatric solid tumors and lymphoma, and is planning a second Phase 1 study in combination with external beam radiation for head and neck cancer.

## **About Cellectar Biosciences, Inc.**

Cellectar Biosciences is focused on the discovery, development and commercialization of drugs for the treatment of cancer. The company plans to develop proprietary drugs independently and through research and development (R&D) collaborations. The core drug development strategy is to leverage our PDC platform to develop therapeutics that specifically target treatment to cancer cells. Through R&D collaborations, the company's strategy is to generate near-term capital, supplement internal resources, gain access to novel molecules or payloads, accelerate product candidate development and broaden our proprietary and partnered product pipelines.

The company's lead PDC therapeutic, CLR 131, is in a Phase 1 clinical study in patients with relapsed or refractory (R/R) MM and a Phase 2 clinical study in R/R MM and a range of B-cell malignancies. The company is currently initiating a Phase 1 study with CLR 131 in pediatric solid tumors and lymphoma, and is planning a second Phase 1 study in combination with external beam radiation for head and neck cancer. The company's product pipeline also includes two preclinical PDC chemotherapeutic programs (CLR 1700 and 1900) and partnered assets include PDCs from multiple R&D collaborations.

For more information please visit [www.collectar.com](http://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 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, 2017. These forward-looking statements are made only as of the date hereof, and we disclaim any obligation to update any such forward-looking statements.

### **CONTACT:**

LHA Investor Relations  
Miriam Weber Miller  
212-838-3777  
[mmiller@lhai.com](mailto:mmiller@lhai.com)



Source: Collectar Biosciences, Inc.