

October 31, 2016



# **Cellecstar Biosciences Announces Design for NCI-Supported Phase II Study of CLR 131 in Multiple Myeloma and Other Hematologic Malignancies**

## **Company Accelerates Guidance for Initiation of Trial; Anticipates Preliminary Data as Early as Second Half of 2017**

MADISON, Wis., Oct. 31, 2016 (GLOBE NEWSWIRE) -- Cellecstar Biosciences, Inc. (Nasdaq:CLRB) (the "company"), an oncology-focused, clinical stage biotechnology company, today announces the study design of its Phase II clinical trial of CLR 131 in patients with relapsed or refractory multiple myeloma (MM), chronic lymphocytic lymphoma/small lymphocytic lymphoma (CLL/SLL), lymphoplasmacytic lymphoma (LPL), marginal zone lymphoma (MZL), mantle cell lymphoma (MCL), and potentially diffuse large B-cell lymphoma (DLBCL), who have been treated with standard therapy for their underlying malignancies. The company previously provided guidance for study initiation in the first half of 2017 and now anticipates initiating the trial during the first quarter of 2017.

The Phase II study, for which the company has received a \$2 million non-dilutive grant from the National Cancer Institute, will be conducted in up to 15 centers across the United States. The company expects that all patients will receive a single dose of CLR 131 at 25.0 mCi/m<sup>2</sup> infused over approximately 30 minutes, with the option of a second dose approximately 80-160 days later, based upon physician assessment. Concurrently, patients in the trial with MM will be receiving 40mg oral dexamethasone weekly for up to 12 weeks. The primary endpoint for the study is Objective Response Rate (ORR). Secondary endpoints include Progression-Free Survival and other measures of efficacy. In MM patients, efficacy responses will be determined according to the latest International Multiple Myeloma Working Group criteria, while in lymphomas, efficacy will be determined according to the Lugano criteria. The company anticipates initial efficacy data as early as the second half of 2017.

"We continue to see consistently positive outcomes with CLR 131 and this study will further define its clinical benefits in a single and multi-dose regimen for the treatment of multiple myeloma, the results of which will be instrumental in the design of a pivotal trial," said Jim Caruso, president and CEO of Cellecstar. "We believe CLR 131 may also provide therapeutic benefits in a number of orphan-designated hematologic cancers and we designed the Phase 2 study to optimize our understanding of the drug's clinical utility."

In order to be eligible for the study, multiple myeloma patients must have received prior treatment with a proteasome inhibitor as well as an immunomodulatory drug. Patients with lymphomas, CLL/SLL, LPL, and MZL, including patients with mucosa associated lymphoid

tissue, must have received treatment with at least two prior lines of therapy. Patients with MCL require treatment with at least one prior line of therapy.

### **About CLR 131**

CLR 131 is an investigational compound under development for a range of hematologic malignancies. It is currently being evaluated in a Phase I clinical trial in patients with relapsed or refractory multiple myeloma. The company plans to initiate a Phase II clinical study to assess efficacy in a range of B-cell malignancies in the first quarter of 2017. Based upon pre-clinical and interim Phase I study data, treatment with CLR 131 provides a novel approach to treating hematological diseases and may provide patients with therapeutic benefits, including overall response rate (ORR), an improvement in progression-free survival (PFS) 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 Cellectar an orphan drug designation for CLR 131 in the treatment of multiple myeloma.

### **About Phospholipid Drug Conjugates (PDCs)**

Cellectar's product candidates are built upon its patented cancer cell-targeting delivery and retention platform of optimized phospholipid ether-drug conjugates (PDCs). Its phospholipid ether (PLE) carrier platform was deliberately designed 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 over 70 different xenograft models of cancer.

### **About Relapsed or Refractory Multiple Myeloma**

Multiple myeloma is the second most common blood or hematologic cancer with approximately 30,000 new cases in the United States every year. It affects a specific type of blood cells known as plasma cells. Plasma cells are white blood cells that produce antibodies to help fight infections. While treatable for a time, multiple myeloma is incurable and almost all patients will relapse or the cancer will become resistant/refractory to current therapies.

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

Cellectar 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. Cellectar'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. Cellectar'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 is currently being evaluated under an orphan drug designated Phase I clinical study in patients with relapsed or refractory multiple myeloma. The company is also developing PDCs for targeted delivery of chemotherapeutics such as paclitaxel (CLR 1602-PTX), a preclinical stage product candidate, and plans to expand its PDC chemotherapeutic pipeline through both in-house and collaborative R&D efforts. For additional information please visit [www.cellectar.com](http://www.cellectar.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/A for the year ended December 31, 2015. 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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Source: Cellestar Biosciences, Inc.