



Fractionated Dosing Improves Tolerability and Safety of Cellecstar's CLR 131 in R/R Multiple Myeloma Patients

August 20, 2018

Positive Results from Cohort 5 of Phase 1b Trial Company Intends to Initiate a Sixth Cohort and Transition Ongoing Phase 2 Trial to a Fractionated Dose

MADISON, Wis., Aug. 20, 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, announces data from Cohort 5 of the company's ongoing Phase 1b clinical trial evaluating CLR 131 for the treatment of relapsed/refractory (R/R) multiple myeloma (MM).

Unlike prior cohorts that used single doses of CLR 131, Cohort 5 utilized a fractionated two-dose regimen of 15.625 mCi/m² given approximately one week apart. This dosing schedule provides higher average drug exposure but lower peak serum levels than non-fractionated dosing potentially reducing adverse events and improving efficacy. The independent Data Monitoring Committee (DMC) determined the fractionated dose used in Cohort 5 to be safe and well tolerated and recommended advancement to a higher dose cohort.

Results from Cohort 5 indicate enhanced tolerability and safety in comparison to Cohort 4 despite an 18% increase in total average dose from 55.29 mCi to 65.15 mCi of CLR 131. Patients in Cohort 5 required less supportive care such as transfusions of platelets or packed red blood cells than seen in previous cohorts. Based on the results and DMC recommendation, the company plans to initiate a sixth cohort using a fractionated dose regimen of two doses of 18.75 mCi/m² administered one week apart and to modify the dosing regimen of its ongoing Phase 2 trial of R/R hematologic malignancies to use fractionated dosing.

In addition to the improved safety profile demonstrated in Cohort 5, the company also monitored signals of efficacy. Despite Cohort 5 patients averaging 5 lines of prior systemic therapies, all patients experienced clinical benefit with two patients achieving minimal responses and two stable disease. Furthermore, looking at surrogate markers, patients in Cohort 5 monitored by M-protein showed a nearly 50% further reduction in M-protein than seen in Cohort 4.

"We are encouraged with the potential for improving the CLR 131 profile with the fractionated dose regimen. These results point to the promise of this dosing strategy to increase efficacy and improve clinical outcomes," said James Caruso, president and chief executive officer of Cellecstar Biosciences. "In the fight against cancer, dose-limiting toxicities are a critical challenge to achieving therapeutic efficacy. We believe the fractionated dose regimen and our targeted drug delivery may overcome this challenge and we plan to incorporate it into current and future trial designs."

About Phospholipid Drug Conjugates™

Cellecstar's product candidates are built upon a patented delivery and retention platform that utilizes optimized phospholipid ether-drug conjugates (PDCs™) to target cancer cells. The PDC platform selectively delivers diverse oncologic payloads to cancerous cells and cancer stem cells, including hematologic cancers and solid tumors. This selective delivery allows the payloads' therapeutic window to be modified, which may maintain or enhance drug potency while reducing the number and severity of adverse events. This platform takes advantage of a metabolic pathway utilized by all tumor cell types in all cell cycle stages. Compared with other targeted delivery platforms, the PDC platform's mechanism of entry does not rely upon specific cell surface epitopes or antigens. In addition, PDCs can be conjugated to molecules in numerous ways, thereby increasing the types of molecules selectively delivered. Cellecstar believes the PDC platform holds potential for the discovery and development of the next generation of cancer-targeting agents.

About CLR 131

CLR 131 is Cellecstar'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 R/R MM and a range of B-cell malignancies and a Phase 1b clinical study in patients with R/R MM exploring fractionated dosing. The objective of the multicenter, open-label, Phase 1b dose-escalation study is the characterization of safety and tolerability of CLR 131 in patients with R/R MM. Patients in Cohorts 1-4 received single doses of CLR 131 ranging from 12.5 mCi/m² to 31.25 mCi/m². All study doses have been deemed safe and well tolerated by an independent Data Monitoring Committee. 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 Cellecstar Biosciences, Inc.

Cellecstar 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 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.cellecstar.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, 2017 and our Form 10-Q for the quarterly period ended June 30, 2018. 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

 [Primary Logo](#)

Source: Cellectar Biosciences, Inc.