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Cellestar Biosciences Announces Positive Data From Phase 1 Therapeutic Trial of CLR 131 in Multiple Myeloma

Safety and Activity Data Reviewed From First Cohort of Patients; CLR 131 Performance Triggers Advancement Into Second Cohort at Higher Dose

MADISON, Wis., Jan. 05, 2016 (GLOBE NEWSWIRE) -- Cellestar Biosciences, Inc. (NASDAQ:CLRB), an oncology-focused biotechnology company, today announces data from the first cohort of patients enrolled in its orphan drug-designated Phase 1 study of CLR 131 in patients with relapsed or refractory multiple myeloma. Based on safety and efficacy data from the first cohort, the trial's Data Monitoring Committee approved enrollment of the second cohort of patients with a 50 percent escalation in dose level of CLR 131.

The primary objective of the multi-center, open label, Phase 1 dose escalation study is to characterize the safety and tolerability of CLR 131 in patients with relapsed or refractory multiple myeloma. Secondary objectives include establishment of the recommended Phase 2 dose, both with and without dexamethasone, as well as an assessment of therapeutic activity.

Prior to their participation in this study, patients in the first cohort had received a minimum of three systemic regimens and up to 12 lines of therapy.

"Judging by the results of the first cohort, I believe there is significant potential for CLR 131 as a safe and tolerable treatment modality for relapsed or refractory multiple myeloma," stated Sikander Ailawadhi, MD, senior associate consultant, Division of Hematology/Oncology, Department of Medicine, The Mayo Clinic, Jacksonville, Florida, and the site's lead investigator. "I believe initiating the second cohort of the trial will provide additional useful information, both in terms of establishing an appropriate treatment dose, as well as further understanding the compound's potential in this indication."

Data from the first cohort of patients in the Phase 1 study demonstrated safety and tolerability with a favorable adverse event profile. Additionally, stable disease was achieved in four of five treated patients with two of these patients maintaining stable disease throughout the 85-day study monitoring period.

"Importantly, these data collectively demonstrate safety and tolerability in heavily pre-treated multiple myeloma patients as well as provide promising signals of activity," said Jim Caruso, president and CEO of Cellestar Biosciences. "These early outcomes and feedback from the investigators are encouraging and we look forward to further evaluating CLR 131 in the second cohort to determine optimal dose and regimen. More globally, these results provide us with further confirmation on the utility of our PDC delivery platform, which we believe is instrumental to these outcomes."

The company is developing CLR 131, its lead radiotherapeutic phospholipid drug conjugate (PDC), for the treatment of multiple myeloma through the targeted delivery of iodine-131 to myelomatous cells.

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 1 study in patients with relapsed or refractory multiple myeloma. The company is also developing PDCs for targeted delivery of chemotherapeutics such as paclitaxel (CLR 1603-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.cellectarbiosciences.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, 2014. 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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