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Cellecstar Receives Orphan Drug Designation from the European Commission for CLR 131 in Multiple Myeloma

FLORHAM PARK, N.J., Sept. 24, 2019 (GLOBE NEWSWIRE) -- Cellecstar Biosciences, Inc. (NASDAQ: CLRB), a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of drugs for the treatment of cancer, today announced that the European Commission has awarded CLR 131 orphan designation for the treatment of multiple myeloma.

Orphan designation is given to medicinal products that represent a significant benefit over existing treatments; are intended for the treatment, prevention or diagnosis of a disease that is life-threatening or chronically debilitating; and where prevalence of the condition in the EU is less than 5 in 10,000 persons.

“We are very pleased to receive Orphan Drug Designation from the European Commission as it is another important acknowledgement of the potential benefits of CLR 131 in multiple myeloma,” said James Caruso, president and CEO of Cellecstar Biosciences. “This designation complements our U.S. orphan drug designation and U.S. fast track designation already granted by the FDA. CLR 131 has shown encouraging results to date in the treatment of late line relapsed/refractory multiple myeloma as demonstrated in our recent presentation at the International Myeloma Workshop. We look forward to sharing additional data from our clinical trials later this year.”

The European Medicines Agency (EMA) plays a central role in facilitating the development and authorization of medicines for rare diseases. Orphan designation benefits include protocol assistance, reduced EU regulatory filing fees and 10 years of market exclusivity. Designated orphan medicines are also eligible for conditional marketing authorization. Detailed information on orphan designation can be found [here](#).

About CLR 131

CLR 131 is a small-molecule, cancer-targeting radiotherapeutic Phospholipid Drug ConjugateTM (PDC) designed to deliver cytotoxic radiation directly and selectively to cancer cells and cancer stem cells. CLR 131 is the company's lead therapeutic PDC product candidate and is currently being evaluated in both Phase 2 and Phase 1 clinical studies. The FDA granted orphan drug designation for CLR 131 for the treatment of multiple myeloma as well as orphan drug and rare pediatric disease designations for CLR 131 for the treatment of neuroblastoma, rhabdomyosarcoma, Ewing's sarcoma and osteosarcoma. In addition to the ongoing Phase 1 dose-escalation study and the Phase 2 (CLOVER-1) trial, the company recently initiated a Phase 1 open-label, dose-escalating study in pediatric solid tumors and lymphoma to evaluate the safety and tolerability of a single intravenous administration of

CLR 131 in up to 30 children and adolescents with cancers including neuroblastoma, sarcomas, lymphomas (including Hodgkin's lymphoma) and malignant brain tumors.

About Cellerar Biosciences, Inc.

Cellerar Biosciences is focused on the discovery, development and commercialization of drugs for the treatment of cancer. The company is developing proprietary drugs independently and through research and development (R&D) collaborations. The company's core objective is to leverage its proprietary Phospholipid Drug Conjugate™ (PDC) delivery platform to develop PDCs that specifically target cancer cells, delivering improved efficacy and better safety as a result of fewer off-target effects. The company's PDC platform possesses the potential for the discovery and development of the next-generation of cancer-targeting treatments, and it plans to develop PDCs independently and through research and development collaborations.

The company's lead PDC therapeutic, CLR 131, is currently in three clinical studies – a Phase 2 study, and two Phase 1 studies. The Phase 2 clinical study (CLOVER-1) is in relapsed/refractory (R/R) B-cell malignancies, including multiple myeloma (MM), chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL), lymphoplasmacytic lymphoma (LPL), marginal zone lymphoma (MZL), mantle cell lymphoma (MCL), and diffuse large B-cell lymphoma (DLBCL). The company is also conducting a Phase 1 dose escalation study in patients with R/R multiple myeloma (MM) and a Phase 1 study in pediatric solid tumors and lymphoma.

The company's product pipeline also includes one preclinical PDC chemotherapeutic program (CLR 1900) and several partnered PDC assets.

For more information, please visit www.cellerar.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, 2018 and Form 10-Q for the quarters ended March 31, 2019 and June 30, 2019. 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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