

June 1, 2020



Cellecstar Granted SME Status by the European Medicines Agency

Designation Comes with Financial and Scientific Incentives

FLORHAM PARK, N.J., June 01, 2020 (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 it has been granted Small and Medium-Sized Enterprise (SME) status by the European Medicines Agency's (EMA) Micro, Small and Medium-sized Enterprise (SME) office.

The newly granted SME status allows Cellecstar to participate in significant financial incentives that include a 90% to 100% EMA fee reduction for scientific advice, clinical study protocol design, endpoints and statistical considerations, quality inspections of facilities and fee waivers for selective EMA pre and post-authorization regulatory filings, including orphan drug and PRIME designations. Cellecstar is also eligible to obtain EMA certification of quality and manufacturing data prior to review of clinical data. Other financial incentives include EMA-provided translational services of all regulatory documents required for market authorization, further reducing the financial burden of the market authorization process.

"The receipt of our SME status is timely as we prepare to engage the EMA for discussions to harmonize CLR 131's pivotal study," stated James Caruso, president and chief executive officer. "SME status from the EMA, will allow Cellecstar to pursue EU marketing authorization in a more efficient and cost-effective manner and will greatly benefit our company as we advance CLR 131 to commercialization."

The EMA plays a central role in facilitating the development and authorization of medicines across Europe. The SME initiative promotes innovation from smaller companies like Cellecstar to ensure Europe continues to be a favorable environment for preclinical and clinical development of promising new therapeutic options like CLR 131. Detailed information on SME status can be found [here](#).

About Cellecstar Biosciences, Inc.

Cellecstar 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 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 two clinical studies. The CLOVER-1 Phase 2 study completed the Part A dose-exploration portion, conducted in relapsed/refractory (r/r) B-cell malignancies, and is now enrolling in the Part B expansion cohorts evaluating an approximate 100mCi total body dose of CLR 131 in relapsed/refractory (r/r) multiple myeloma (MM) and lymphoplasmacytic lymphoma/Waldenstrom's macroglobulinemia (LPL/MM). The data from the Part A portion was announced on February 19, 2020. The company is also conducting a Phase 1 dose-escalation study in pediatric solid tumors and lymphomas.

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

For more information, please visit www.cellectar.com or join the conversation by liking and following us on the company's social media channels: [Twitter](#), [LinkedIn](#), and [Facebook](#).

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 including our expectations of the impact of the recent COVID-19 pandemic. 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, patient enrollment and the completion of clinical studies, the FDA review process and other government regulation, our ability to maintain orphan drug designation in the United States for CLR 131, 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, 2019 and our Form 10-Q for the quarter ended March 31, 2020. These forward-looking statements are made only as of the date hereof, and we disclaim any obligation to update any such forward-looking statements. 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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