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Cellecstar Initiates Pivotal Trial of CLR 131 in Waldenstrom's Macroglobulinemia

FLORHAM PARK, N.J., Jan. 12, 2021 (GLOBE NEWSWIRE) -- Cellecstar Biosciences, Inc. (NASDAQ: CLRB), a late-stage clinical biopharmaceutical company focused on the discovery, development, and commercialization of drugs for the treatment of cancer, today announced the initiation of a pivotal trial for CLR 131 in Waldenstrom's macroglobulinemia (WM).

The pivotal trial is designed as a global, non-comparator, single arm, expansion cohort of the currently ongoing Phase 2 CLOVER-1 study of CLR 131. This design is in alignment with the feedback received from the U.S. Food and Drug Administration (FDA) during the guidance meeting held in September 2020.

The study will enroll 50 WM patients who have failed first-line therapy and have failed to respond to, or have progressed while on treatment with a BTK inhibitor (i.e. ibrutinib). Patients in the trial will receive up to 4 doses of CLR 131 over 2 cycles (cycle one days 1, 15, and cycle two days 57, 71). The primary endpoint of the trial is response rate as defined as a partial response (a minimum of a 50% reduction in the biological marker IgM) or better in patients that receive a minimum total body dose of 60 mCi with secondary endpoints of treatment free survival, duration of response and progression free survival. An independent data monitoring committee (iDMC) will perform an interim safety and futility evaluation on the first 10 patients enrolled. The assessment will occur patient by patient and will conclude after the tenth patient is evaluated; there is no planned study stoppage. The trial has been initiated at select US cancer centers and will roll out to additional US and international sites in early 2021.

"CLR 131 has the potential to be an important therapeutic option for patients with Waldenstrom's macroglobulinemia, an indication with limited treatment alternatives. The 100% overall response rate achieved to date at comparable doses bodes well for CLR 131 to deliver meaningful outcomes for patients," said Jim Caruso, president and CEO of Cellecstar. "The company now possesses an accelerated route to commercialization with Fast Track and Orphan Drug designations further facilitating a clear regulatory pathway and a balance sheet to support development through NDA approval."

About Waldenstrom's macroglobulinemia

Waldenstrom's macroglobulinemia (WM) is a rare and incurable disease defined by specific genotypic subtypes that defines patient responses and long-term outcomes. The annual incidence is 6,500 with prevalence of approximately 60,000 patients globally. WM is a lymphoma, or cancer of the lymphatic system. The disease occurs in a type of white blood cell called a B-lymphocyte or B-cell, which normally matures into a plasma cell whose job is to manufacture immunoglobulins (antibodies) to help the body fight infection. In WM, there is a malignant change to the B-cell in the late stages of maturing, and it continues to proliferate into a clone of identical cells, primarily in the bone marrow but also in the lymph nodes and

other tissues and organs of the lymphatic system. These clonal cells over-produce an antibody of a specific class called IgM.

WM cells have characteristics of both cancerous B-lymphocytes (NHL) and plasma cells (multiple myeloma), and they are called lymphoplasmacytic cells. For that reason, WM is classified as a type of non-Hodgkin's lymphoma called lymphoplasmacytic lymphoma (LPL). About 95% of LPL cases are WM; the remaining 5% do not secrete IgM and consequently are not classified as WM.

There is no standard treatment for WM. Several drugs have demonstrated activity either alone or in combinations but only a single drug has received regulatory approval. Treatment is mainly focused on the control of symptoms and the prevention of organ damage. Front-line treatments for WM include rituximab alone or in combination with other agents. In the salvage therapy (second line or later) setting, ibrutinib, combinations of proteasome inhibitors and immunomodulatory drugs and stem cell transplantation are considered. Ibrutinib is the only drug to receive regulatory approval (2015) as a salvage therapy; in late 2019, it was approved for front-line treatment in combination with rituximab. Factors such as long-term cytopenias, age, hyper viscosity, the need for quick disease control, lymphadenopathy, co-morbidities, and IgM-related end-organ damage are key consideration in the choice of treatment.

About CLR 131

CLR 131 is a small-molecule Phospholipid Drug Conjugate™ designed to provide targeted delivery of iodine-131 (radioisotope) directly to cancer cells, while limiting exposure to healthy cells unlike many traditional on-market treatment options. The company's lead PDC therapeutic, CLR 131, is currently in two clinical studies. The CLOVER-1 Phase 2 study in hematologic malignancies and the Phase 1 pediatric safety study. The CLOVER-1 study met the primary efficacy endpoints from the Part A dose-exploration portions conducted in r/r B-cell malignancies and remains under further evaluation in highly refractory multiple myeloma patients. A global, pivotal expansion cohort was launched in December 2020 in BTK inhibitor failed or suboptimal response Waldenstrom's macroglobulinemia (WM) patients. The WM cohort will enroll up to 50 patients to evaluate the efficacy and safety of CLR 131 for marketing approval.

The U.S. Food and Drug Administration (FDA) granted CLR 131 Fast Track Designation and Orphan Drug Designation (ODD) for relapsed/refractory Waldenstrom's macroglobulinemia, multiple myeloma and diffuse large B-cell lymphoma. Rare Pediatric Disease Designations and ODDs were granted for the treatment of, neuroblastoma, rhabdomyosarcoma, Ewing's sarcoma and osteosarcoma. The European Commission granted an ODD for r/r multiple myeloma.

About Collectar Biosciences, Inc.

Collectar 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 product pipeline includes one preclinical PDC chemotherapeutic program (CLR 1900) and multiple 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 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, our Form 10-Q for the quarter ended March 31, 2020, our Form 10-Q for the quarter ended June 30, 2020 and our Form 10-Q for the quarter ended September 30, 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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