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Cellectar Receives Orphan Drug Designation from the European Commission for CLR 131 in Waldenstrom's Macroglobulinemia

Benefits include 10 years of market exclusivity in the European Union

FLORHAM PARK, N.J., Jan. 27, 2021 (GLOBE NEWSWIRE) -- Cellectar 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 that the European Medicines Agency has adopted a positive opinion for CLR 131 orphan designation for the treatment of Waldenstrom's Macroglobulinemia (WM).

European orphan designation is given to medicinal products that are deemed to provide a clinically relevant advantage or make a major contribution to patients' care, compared with existing methods to treat the condition; 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.

"WM is an incurable disease with treatment options restricted to one approved drug and various salvage therapies. The 100% overall response rate and durability of these responses after four 15 minute infusions spread over 80 days seen to date with CLR 131, supports our belief that CLR 131 can be an important therapy for WM patients," said James Caruso, president and CEO of Cellectar. "Receipt of European orphan drug designation provides Cellectar with significant regulatory benefits and further validates the clinical potential of CLR 131 in WM. In addition, the European orphan designation complements our U.S. orphan drug and U.S. fast track designations previously granted by the FDA."

Cellectar has initiated a pivotal trial evaluating CLR 131 in Waldenstrom's macroglobulinemia patients that have failed or had a suboptimal response to a Bruton's tyrosine kinase inhibitor at select US cancer centers and intends to expand the trial to additional US and international sites in the first quarter of the year. Additional information can be found at www.ClinicalTrials.gov.

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 European market exclusivity which protects CLR 131 from competition from similar medicines with similar indications, which cannot be marketed during the exclusivity period. Designated orphan medicines are also eligible for conditional marketing authorization which is a pragmatic tool for the fast-track approval of a medicine that fulfills an unmet medical need. Detailed information on orphan designation can be found here.

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.

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 proteosome 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 ODD for r/r multiple myeloma and Waldenstrom's macroglobulinemia.

About Cellectar Biosciences, Inc.

Cellectar 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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