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Cellecstar Reports Positive Phase 2 Interim Data for CLR 131 in Relapsed/Refractory DLBCL Patients

33% Overall Response Rate Observed in DLBCL Patient Cohort

MADISON, Wis., July 18, 2018 (GLOBE NEWSWIRE) -- Cellecstar Biosciences (Nasdaq:CLRB), a clinical stage biopharmaceutical company focused on the discovery, development and commercialization of drugs for the treatment of cancer, today announces positive interim results from the company's Phase 2 clinical trial for its lead product candidate CLR 131, in patients with diffuse large B-cell lymphoma (DLBCL). After a single 25.0 mCi/m² IV administration of CLR 131, patients with relapsed/refractory DLBCL were assessed for response. These interim data show a 33% overall response rate (ORR) and a 50% clinical benefit response (CBR). In addition, the observed responses to date show overall tumor reduction ranged from 60% to greater than 90%. As a result of these favorable outcomes, the company has expanded this cohort to include up to 30 additional patients.

"We are very encouraged by the strong response rates and meaningful reductions in tumor volumes seen in the trial to date in this very sick and heavily pretreated relapsed/refractory DLBCL patient population," stated James Caruso, president and chief executive officer of Cellecstar Biosciences. "We believe these data combined with the activity seen to date in other hematologic malignancies further validate the continued development of CLR 131."

The DLBCL cohort of this Phase 2 trial was initiated in January 2018 and represents the fourth B-cell hematologic cancer to be studied in the trial. All DLBCL patients enrolled are required to have relapsed or refractory disease to multidrug chemotherapy regimens containing rituximab and an anthracycline. Part of the funding for this study is provided by a multimillion-dollar NCI Fast Track SBIR grant.

About the Phase 2 Study of CLR 131

The Phase 2 study is being conducted in approximately 10 leading cancer centers in the United States for patients with relapsed or refractory B-cell hematologic cancers. The hematologic cancers being studied in the trial include multiple myeloma (MM), chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL), lymphoplasmacytic lymphoma (LPL), marginal zone lymphoma (MZL), mantle cell lymphoma (MCL), and potentially diffuse large B-cell lymphoma (DLBCL).

The study's primary endpoint is clinical benefit response (CBR), with additional endpoints of progression free survival (PFS), median overall survival (OS) and other markers of efficacy following a single 25.0 mCi/m² dose of CLR 131, with the option for a second 25.0 mCi/m² dose approximately 75-180 days later.

In addition to the CLR 131 infusion(s), MM patients will receive 40 mg oral dexamethasone weekly for up to 12 weeks. Efficacy responses will be determined by the latest International Multiple Myeloma Working Group criteria. Efficacy for all lymphoma patients will be determined according to Lugano criteria. Cellectar has been awarded approximately \$2 million in a non-dilutive grant from the National Cancer Institute to help fund the trial. More information about the trial, including eligibility requirements, can be found at www.clinicaltrials.gov, reference NCT02952508.

About Diffuse Large B-Cell Lymphoma

According to the Lymphoma Research Foundation, diffuse large B-cell lymphoma (DLBCL) is an aggressive form of non-Hodgkin's lymphoma (NHL), accounting for about 30 percent of newly diagnosed cases of NHL in the United States.

The American Cancer Society's most recent estimates for NHL for 2018 project approximately 74,680 people (41,730 males and 32,950 females) will be diagnosed with NHL including both adults and children. They estimate that approximately 19,910 people will die from this cancer (11,510 males and 8,400 females).

DLBCL occurs in both men and women, although it is slightly more common in men. Although DLBCL can occur in childhood, its incidence generally increases with age, and roughly half of patients are over the age of 60.

DLBCL is an aggressive (fast-growing) lymphoma that can arise in lymph nodes or outside of the lymphatic system, in the gastrointestinal tract, testes, thyroid, skin, breast, bone, or brain. Often, the first sign of DLBCL is a painless, rapid swelling in the neck, underarms, or groin that is caused by enlarged lymph nodes. For some patients, the swelling may be painful. Other symptoms may include night sweats, fever, and unexplained weight loss. Patients may notice fatigue, loss of appetite, shortness of breath, or pain.

About Phospholipid Drug Conjugates™ (PDCs)

Cellectar's product candidates are built upon a patented delivery and retention platform that utilizes optimized PDCs to target cancer cells. The PDC platform selectively delivers diverse oncologic payloads to cancerous cells and cancer stem cells, including hematologic cancers and solid tumors. This selective delivery allows the payloads' therapeutic window to be modified, which may maintain or enhance drug potency while reducing the number and severity of adverse events. This platform takes advantage of a metabolic pathway utilized by all tumor cell types in all cell cycle stages. Compared with other targeted delivery platforms, the PDC platform's mechanism of entry does not rely upon specific cell surface epitopes or antigens. In addition, PDCs can be conjugated to molecules in numerous ways, thereby increasing the types of molecules selectively delivered. Cellectar believes the PDC platform holds potential for the discovery and development of the next generation of cancer-targeting agents.

About CLR 131

CLR 131 is Cellectar's investigational radioiodinated PDC therapy that exploits the tumor-targeting properties of the company's proprietary phospholipid ether (PLE) and PLE analogs to selectively deliver radiation to malignant tumor cells, thus minimizing radiation exposure to normal tissues. CLR 131, is in a Phase 2 clinical study in relapsed or refractory (R/R) MM and a range of B-cell malignancies and a Phase 1 clinical study in patients with (R/R) MM exploring fractionated dosing. The company is currently initiating a Phase 1 study with CLR 131 in pediatric solid tumors and lymphoma, and is planning a second Phase 1 study in combination with external beam radiation for head and neck cancer.

About Cellectar Biosciences, Inc.

Cellectar Biosciences is focused on the discovery, development and commercialization of drugs for the treatment of cancer. The company plans to develop proprietary drugs independently and through research and development (R&D) collaborations. The core drug development strategy is to leverage our PDC platform to develop therapeutics that specifically target treatment to cancer cells. Through R&D collaborations, the company's strategy is to generate near-term capital, supplement internal resources, gain access to novel molecules or payloads, accelerate product candidate development and broaden our proprietary and partnered product pipelines.

The company's lead PDC therapeutic, CLR 131, is in a Phase 1 clinical study in patients with relapsed or refractory (R/R) MM and a Phase 2 clinical study in R/R MM and a range of B-cell malignancies. The company is currently initiating a Phase 1 study with CLR 131 in pediatric solid tumors and lymphoma, and is planning a second Phase 1 study in combination with external beam radiation for head and neck cancer. The company's product pipeline also includes two preclinical PDC chemotherapeutic programs (CLR 1700 and 1900) and partnered assets include PDCs from multiple R&D collaborations.

For more information please visit www.cellectar.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 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, 2017. These forward-looking statements are made only as of the date hereof, and we disclaim any obligation to update any such forward-looking statements.

CONTACT:

LHA Investor Relations
Miriam Weber Miller
212-838-3777
mmiller@lhai.com



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