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Cellecstar Initiates DLBCL Cohort in Phase 2 Trial of CLR 131 in Refractory B-Cell Hematologic Cancers

MADISON, Wis., Jan. 29, 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 that it has enrolled the first patient in the diffuse large B-cell lymphoma (DLBCL) cohort of its Phase 2 clinical trial of CLR 131, its lead radiotherapeutic Phospholipid Drug Conjugate™ (PDC™). This group represents the fourth and final cohort of the company's Phase 2 study for patients with relapsed or refractory B-cell hematologic cancers. The Company expects to enroll up to 10 patients with DLBCL into this cohort prior to conducting an interim analysis. If these interim data are positive, the DLBCL cohort could be expanded by an additional 10-20 patients.

"DLBCL is a rare hematologic cancer with few treatment options and the expansion of the Phase 2 trial provides the opportunity to further explore the broad treatment potential of CLR 131 in an area of significant unmet need. We are now exploring CLR 131 in six hematologic malignancies and we expect to initiate Phase 1 studies in head & neck cancer and pediatric tumors in 2018," stated James Caruso, president and chief executive officer of Cellecstar Biosciences. "Importantly, we are able to undertake our development plans with modest shareholder investment as our Phase 2 study is partially funded through a National Cancer Institute (NCI) Small Business Innovation Research grant. In addition, the Phase 1 head & neck study will be predominantly funded through a NCI Specialized Programs of Research Excellence grant and costs for the pediatric study will be shared with our partners at the University of Wisconsin."

About the Phase 2 Study of CLR 131

We are conducting the Phase 2 study for patients with relapsed or refractory B-cell hematologic cancers in approximately 10 leading cancer centers in the United States. These hematologic cancers include multiple myeloma (MM), chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL), lymphoplasmacytic lymphoma (LPL), marginal zone lymphoma (MZL), mantle cell lymphoma (MCL), and DLBCL.

The study's primary endpoint is clinical benefit response (CBR), with additional secondary 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 in accordance with the latest International Multiple Myeloma Working Group criteria. Efficacy for all lymphoma patients will be determined according to Lugano criteria. 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 CLR 131

CLR 131 is an investigational compound under development for a range of orphan designated cancers. It is currently being

evaluated as a single-dose treatment in a Phase I clinical trial in patients with relapse or refractory (R/R) MM as well as in a Phase II clinical trial for R/R MM and select R/R lymphomas with either a one- or two-dose treatment. Based upon preclinical and interim Phase I study data, treatment with CLR 131 provides a novel approach to treating solid and hematological tumors and may provide patients with therapeutic benefits, including overall survival, an improvement in progression-free survival, surrogate efficacy marker response rate, and overall quality of life. CLR 131 utilizes the company's patented PDC tumor targeting delivery platform to deliver a cytotoxic radioisotope, iodine-131, directly to tumor cells. The FDA has granted orphan drug designation for CLR 131 in the treatment of MM.

About Phospholipid Drug Conjugates™ (PDCs™)

Cellectar's product candidates are built upon its patented cancer cell-targeting delivery and retention platform of optimized phospholipid ether-drug conjugates (PDCs). The PDC platform provides selective delivery of a diverse range of oncologic payloads to cancerous cells, whether a hematologic cancer or solid tumor, the primary tumor, a metastatic tumor or cancer stem cells. The selective delivery of oncologic payloads allows for the modification of the payloads' therapeutic window which may maintain or enhance drug potency while reducing the number and severity of adverse events. The PDC platform takes advantage of a metabolic pathway utilized by all tumor cell types in all stages of the tumor "cycle." This property allows the PDC molecules to gain access to the intracellular compartment of the tumor cells and for the PDCs to continue to accumulate over time, which enhances drug efficacy. The PDC platform's mechanism of entry does not rely upon specific cell surface epitopes or antigens as are required by other targeted delivery platforms. In addition to the benefits provided by the mechanism of entry, PDCs offer the potential advantage of having the ability to be conjugated to molecules in numerous ways, thereby increasing the types of molecules selectively delivered via the PDC. The PDC platform possesses the potential for the discovery and development of the next generation of cancer-targeting agents.

About Cellectar Biosciences, Inc.

Cellectar Biosciences is a biopharmaceutical company 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 phospholipid drug conjugate™ (PDCs™) platform to develop oncologic 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 therapeutic PDC, CLR 131 is currently being evaluated in a Phase 1 clinical study in patients with relapsed or refractory (R/R) multiple myeloma (MM) and a Phase 2 clinical study to assess efficacy in R/R MM and a range of B-cell malignancies. In 2018, the Company plans to initiate a Phase 1 study of CLR 131 for Pediatric Solid Tumors and Lymphoma and a second Phase 1 study of CLR 131 used in combination with external beam radiation for the treatment of Head and Neck Cancer. The companies' proprietary pipeline also includes two pre-clinical chemotherapeutic PDC programs (CLR 1700 and 1900) and partnered assets include PDC's 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, 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, 2016. 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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