

# Cellectar Biosciences Announces INC Research as the CRO for the Phase II Trial of CLR 131 in Hematologic Malignancies; \$2M NCI Grant Covers Half of Study Cost, with Potential Option to Pursue Additional \$3M for Pivotal Trial

MADISON, Wis., Nov. 15, 2016 (GLOBE NEWSWIRE) -- Cellectar Biosciences, Inc. (Nasdaq:CLRB) (the "company"), an oncology-focused, clinical stage biotechnology company, today announced it has selected INC Research (Nasdaq:INCR), a leading global Phase I to IV contract research organization, to oversee its NCI-supported Phase II clinical trial of CLR 131 in patients with multiple myeloma and select hematologic malignancies. The company anticipates that its \$2M NCI grant will cover approximately 50 percent of the study's cost, and the terms of the grant allow Cellectar to pursue an additional \$3M for a pivotal Phase III trial of the company's lead radiotherapeutic compound.

Cellectar plans to leverage the results of its 80-patient, Phase II study to optimally design its pivotal trial of CLR 131 in multiple myeloma and other hematologic malignancies. The multi-armed study will include relapse/refractory patients with 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), who have been treated with standard therapy for their underlying malignancies. The company recently accelerated its guidance and announced plans to initiate the trial during the first quarter of 2017.

"INC Research has outstanding experience in cancer clinical research and a strong reputation within the hematology community. With strong investigator relationships, proven operational expertise and a commitment to high-quality data, they are the ideal partner for this important trial," said Jim Caruso, president and CEO of Cellectar. "Given the accelerated initiation of our Phase II study to the first quarter of 2017 and that we will utilize as many as 15 participating sites, we can confidently plan on providing initial efficacy data in the second half of 2017."

## **About CLR 131**

CLR 131 is an investigational compound under development for a range of hematologic malignancies. It is currently being evaluated in a Phase I clinical trial in patients with relapsed or refractory multiple myeloma. The company plans to initiate a Phase II clinical study to assess efficacy in a range of B-cell malignancies in the first quarter of 2017. Based upon preclinical and interim Phase I study data, treatment with CLR 131 provides a novel approach to treating hematological diseases and may provide patients with therapeutic

benefits, including overall response rate (ORR), an improvement in progression-free survival (PFS) 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 Cellectar an orphan drug designation for CLR 131 in the treatment of multiple myeloma.

## 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 company deliberately designed its phospholipid ether (PLE) carrier platform to be coupled with a variety of payloads to facilitate both therapeutic and diagnostic applications. The basis for selective tumor targeting of our PDC compounds lies in the differences between the plasma membranes of cancer cells compared to those of normal cells. Cancer cell membranes are highly enriched in lipid rafts, which are glycolipoprotein microdomains of the plasma membrane of cells that contain high concentrations of cholesterol and sphingolipids, and serve to organize cell surface and intracellular signaling molecules. PDCs have been tested in over 70 different xenograft models of cancer.

# **About Relapsed or Refractory Multiple Myeloma**

Multiple myeloma is the second most common blood or hematologic cancer with approximately 30,000 new cases in the United States every year. It affects a specific type of blood cells known as plasma cells. Plasma cells are white blood cells that produce antibodies to help fight infections. While treatable for a time, multiple myeloma is incurable and almost all patients will relapse or the cancer will become resistant/refractory to current therapies.

## About Cellectar Biosciences, Inc.

Cellectar Biosciences is developing phospholipid drug conjugates (PDCs) designed to provide cancer targeted delivery of diverse oncologic payloads to a broad range of cancers and cancer stem cells. Cellectar's PDC platform is based on the company's proprietary phospholipid ether analogs. These novel small-molecules have demonstrated highly selective uptake and retention in a broad range of cancers. Cellectar's PDC pipeline includes product candidates for cancer therapy and cancer diagnostic imaging. The company's lead therapeutic PDC, CLR 131, utilizes iodine-131, a cytotoxic radioisotope, as its payload. CLR 131 is currently being evaluated under an orphan drug designated Phase I clinical study in patients with relapsed or refractory multiple myeloma. In addition, the company plans to initiate a Phase II clinical study to assess efficacy in a range of B-cell malignancies in the first quarter of 2017. The company is also developing PDCs for targeted delivery of chemotherapeutics such as paclitaxel (CLR 1602-PTX), a preclinical stage product candidate, and plans to expand its PDC chemotherapeutic pipeline through both in-house and collaborative R&D efforts. For more information please visit www.cellectar.com.

### **About INC Research**

INC Research (Nasdaq:INCR) is a leading global contract research organization ("CRO") providing the full range of Phase I to Phase IV clinical development services for the biopharmaceutical and medical device industries. Leveraging the breadth of our service offerings and the depth of our therapeutic expertise across multiple patient populations, INC Research connects customers, clinical research sites and patients to accelerate the delivery

of new medicines to market. The Company was named "Best Contract Research Organization" in December 2015 by an independent panel for Scrip Intelligence, and ranked "Top CRO to Work With" among large global CROs in the 2015 CenterWatch Global Investigative Site Relationship Survey. INC Research is headquartered in Raleigh, NC, with operations across six continents and experience spanning more than 110 countries. For more information, please visit <a href="www.incresearch.com">www.incresearch.com</a> and connect with us on <a href="LinkedIn">LinkedIn</a> and <a href="Twitter @inc\_research">Twitter @inc\_research</a>.

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/A for the year ended December 31, 2015. 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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