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Cellestar Biosciences Announces Partnership with Radiopharmaceutical Specialists, CPDC, to Establish Manufacturing Capacity in Anticipation of CLR 131 Pivotal Trial and Commercial Production

MADISON, Wis., Nov. 28, 2016 (GLOBE NEWSWIRE) -- Cellestar Biosciences, Inc. (Nasdaq:CLRB) (the “company”), an oncology-focused, clinical stage biotechnology company, today announced it has selected Hamilton, Ontario-based Centre for Probe Development and Commercialization (CPDC), a well-respected GMP manufacturing organization specializing in radiopharmaceuticals, as a supplier of the company’s lead phospholipid drug conjugate (PDC), CLR 131.

The company believes that CPDC will provide a cost-effective and long-term manufacturing solution. The partnership establishes manufacturing capacity at a level sufficient for both a pivotal trial and future large-scale commercial production. CPDC’s development of further production capability for CLR 131 will significantly enhance the company’s ability to support the anticipated clinical trial activity as it progresses through 2017 while also preparing for a pivotal study and, ultimately, commercialization.

“This partnership with CPDC signals an important milestone in the development of CLR 131; it reflects our confidence in the potential clinical utility of our lead compound and establishes an additional supply source as well as pivotal trial and commercial scale production,” said Jim Caruso, president and CEO of Cellestar Biosciences. “As we prepare to initiate our NCI-supported Phase II trial of CLR 131 in multiple myeloma and other hematologic malignancies, it is imperative that we continue to identify optimal pathways to accelerate and further support its development.”

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 Cellestar 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 CPDC

CPDC discovers, develops, and distributes radiopharmaceuticals. The CPDC was founded in 2008 as a Centre of Excellence for Commercialization and Research (CECR) in Canada, specializing in radiopharmaceutical research, development and commercialization. Since its inception, CPDC has gained recognition as one of a select few R&D centres that has the full range of scientific, technical, regulatory and business expertise combined with the full specialized infrastructure required to translate radiopharmaceuticals to the clinic and provide them to the marketplace. Through its outstanding staff, and working with academic and industry partners, CPDC has completed over 50 radiopharmaceutical discovery, development, and manufacturing programs. It has brought over a dozen radiopharmaceuticals into clinical development, and currently supports more than 25 clinical trials that are being run in Canada, the United-States, and Europe.

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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