



Cellecstar Granted Orphan Drug Designation for CLR 131 to Treat Rhabdomyosarcoma

May 9, 2018

MADISON, Wis., May 09, 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 the U.S. Food and Drug Administration (FDA) Office of Orphan Products Development has granted Orphan Drug Designation to CLR 131, the company's lead Phospholipid Drug Conjugate™ (PDC) product candidate, for the treatment of rhabdomyosarcoma, a rare pediatric cancer.

"Rhabdomyosarcoma is the most common type of tissue sarcoma in children. While initial response to treatment is generally favorable, there is an important need for new treatments, especially in children who experience relapse," said John Friend, M.D., chief medical officer of Cellecstar. "Cellecstar is committed to working closely with the FDA to fully evaluate the potential for targeted delivery of CLR 131 to address this currently unmet medical need."

Orphan drug designation provides seven-year market exclusivity, increased engagement and assistance from the FDA, tax credits for certain research, research grants and a waiver of the New Drug Application user fee. Rhabdomyosarcoma is recognized by the FDA as an orphan disease, usually defined as a condition that affects fewer than 200,000 people nationwide.

About Rhabdomyosarcoma

Rhabdomyosarcoma (RMS), a malignant tumor of mesenchymal origin, is the most common soft tissue sarcoma in children, accounting for approximately 40% of childhood soft tissue sarcomas in the United States. The incidence is about 4.5 cases per 1 million per year in children younger than 15 years and more than 50% are younger than 10 years at diagnosis. Approximately 340 new cases are diagnosed each year in North America and the prognosis is favorable with a 64% 5-year survival in children aged birth to 19 years [Ward 2014]. At least one-third of all patients will experience disease progression or relapse, and 95% of all failures occur within 3 years. The median progression free survival following the first recurrence or progression is approximately nine months.

About CLR 131

CLR 131 is Cellecstar'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. In 2018 the company plans to initiate a Phase 1 study with CLR 131 in pediatric solid tumors and lymphoma, and a second Phase 1 study in combination with external beam radiation for head and neck cancer.

About Cellecstar Biosciences, Inc.

Cellecstar 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. In 2018 the company plans to initiate a Phase 1 study with CLR 131 in pediatric solid tumors and lymphoma, and 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.cellecstar.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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Source: Cellecstar Biosciences, Inc.