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Cellecstar Biosciences Partners with Florida Cancer Specialists & Research Institute to Support the Treatment of Waldenstrom's Macroglobulinemia in the Community Setting

Strategic collaboration to advance patient care and further define the U.S. treatment landscape

First of several planned community-based cancer care network collaborations for Cellecstar to facilitate future patient access and clinical success with iopofosine I 131

FLORHAM PARK, N.J., Oct. 25, 2023 (GLOBE NEWSWIRE) -- Cellecstar Biosciences, Inc. (NASDAQ: CLRB), a late-stage clinical biopharmaceutical company focused on the discovery, development and commercialization of targeted drugs for the treatment of cancer, announced today a partnership with [Florida Cancer Specialists & Research Institute, LLC \(FCS\)](#), a world-class cancer care organization serving oncology patients throughout the state of Florida. Through this partnership, Cellecstar and FCS will evaluate and further define unmet needs that exist across the Waldenstrom's macroglobulinemia (WM) treatment landscape within the community oncology setting to advance patient care.

"WM is a rare type of lymphoma with limited treatment options and no established standard of care in relapsed refractory disease. This collaboration will help to provide insight into the management of the relapsed WM population and how to optimize the promise of novel therapies as treatment alternatives for patients," said Dr. Lucio Gordan, president and managing physician of FCS. "We view radioligands as a rapidly emerging treatment alternative, especially for WM patients and have established clinics with the capabilities to provide these treatments throughout our entire Florida-based network. Each location is equipped with advanced, state-of-the-art technologies that ensure the effective, safe and convenient delivery of a comprehensive range of radiation oncology therapies."

FCS is one of the largest community-based cancer centers in the United States with over 250 physicians, 220 nurse practitioners and nearly 100 locations within their network. As leaders in medical oncology and hematology, FCS currently manages over 1,000 Waldenstrom's macroglobulinemia patients.

"We are extremely pleased to be partnering with FCS, which shares our patient-centric vision and alignment on the unique benefits and significant potential of radiotherapeutics. This collaboration will help us to better understand patients' and health care providers' needs across the WM treatment landscape as we prepare for the potential launch of iopofosine I 131," said James Caruso, president and CEO of Cellecstar. "This partnership with FCS represents the first of several strategic collaborations we plan to establish with leading

community based cancer care networks to facilitate and ensure patient access and clinical success with iopofosine.”

The company expects to release top-line data from its CLOVER-WaM pivotal trial in WM ([NCT02952508](https://clinicaltrials.gov/ct2/show/study/NCT02952508)) in 4Q 2023 and assuming an FDA Priority Review and NDA approval, remains on target for a 2024 US product launch.

The U.S. Food and Drug Administration (FDA) has granted Collectar’s iopofosine I 131, a small-molecule Phospholipid Drug Conjugate™ (PDC) designed to provide targeted delivery of iodine-131 (radioisotope), Fast Track Designation for relapsed/refractory WM patients.

WM is a rare type of non-Hodgkin lymphoma that begins in the white blood cells. It is estimated that 26,000 people are living with WM in the US and greater than 10,000 are in a second-line plus stage of treatment. Currently there are limited treatment options with only one approved class of drugs and no established standard of care beyond second-line therapy.

About Collectar Biosciences, Inc.

Collectar Biosciences is a late-stage clinical biopharmaceutical company focused on the discovery and development of proprietary drugs for the treatment of cancer, independently and through research and development collaborations. The company’s core objective is to leverage its proprietary Phospholipid Drug Conjugate™ (PDC) delivery platform to develop the next-generation of cancer cell-targeting treatments, delivering improved efficacy and better safety as a result of fewer off-target effects.

The company’s product pipeline includes lead asset iopofosine I 131, a small-molecule PDC designed to provide targeted delivery of iodine-131 (radioisotope), proprietary preclinical PDC chemotherapeutic programs and multiple partnered PDC assets.

For more information, please visit www.collectar.com and www.wmclinicaltrial.com or join the conversation by liking and following us on the company’s social media channels: [Twitter](#), [LinkedIn](#), and [Facebook](#).

About Florida Cancer Specialists & Research Institute, LLC (FLCancer.com)

Florida Cancer Specialists & Research Institute (FCS) offers patients access to more clinical trials than any private oncology practice in Florida. The majority of new cancer drugs recently approved for use in the U.S. were studied in clinical trials with FCS participation.* Recognized for their research, FCS is a recipient of the national Clinical Trials Participation Award presented by the American Society of Clinical Oncology (ASCO). FCS physicians, trained in prestigious medical schools and research institutes, are consistently ranked nationally as Top Doctors by U.S. News & World Report.

Founded in 1984, FCS has built a national reputation for excellence that is reflected in exceptional and compassionate patient care, driven by innovative clinical research, cutting-edge technologies and advanced treatments, including targeted therapies genomic-based treatment and immunotherapy. Our highest values are embodied by our outstanding team of highly trained and dedicated physicians, clinicians and staff.

**Prior to approval*

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 including our expectations regarding the WM CLOVER-WaM pivotal trial. 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 disruptions at our sole source supplier of iopofosine, the ability to attract and retain partners for our technologies, the identification of lead compounds, the successful preclinical development thereof, patient enrollment and the completion of clinical studies, the FDA review process and other government regulation, our ability to maintain orphan drug designation in the United States for iopofosine, 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, 2022, and our Form 10-Q for the quarter ended June 30, 2023. 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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