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Cellestar Biosciences Partners with MiBA, a Data Subsidiary of American Oncology Network, to Advance the Treatment of Waldenstrom's Macroglobulinemia in the Community Setting

Partnership to Provide Key Data on WM Treatment Landscape and Community Clinic Access to Support Iopofosine I 131 Commercialization Strategy

FLORHAM PARK, N.J., Jan. 11, 2024 (GLOBE NEWSWIRE) -- Cellestar 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 to advance the treatment of Waldenstrom's macroglobulinemia (WM) in the community setting with American Oncology Network (AON), a leading oncology platform with an innovative model of physician-led, community-based oncology management, and its data arm subsidiary Meaningful Insights-BioTech Analytics (MiBA), a healthcare AI technology company on a mission to close the feedback loop between physicians, patients, and industry partners.

"AON is currently managing over 650 Waldenstrom's macroglobulinemia patients," said Dr. Fred Divers, chief medical officer of AON. "We are committed to providing promising new radiotherapies, starting with Cellestar's iopofosine I 131, a novel phospholipid radiotherapeutic conjugate, throughout our nationwide network of clinics. It is critical for patients to have access to advances in the treatment of this rare cancer, where there is currently no standard of care for those with relapsed or refractory disease. The pivotal topline data for iopofosine demonstrating an overall response rate of 76.5% and 100% disease control rate utilizing a four dose fixed course of therapy in a heavily pretreated relapse/refractory WM patient population is very compelling when compared to response rates of other therapeutic options in this setting."

Positive topline data from the pivotal Clover WaM study for iopofosine I 131 was reported on January 8, achieving the primary endpoint with a 61% major response rate (MRR) and exceeding the protocol statistical hurdle of 20%. This was the largest study to date in relapsed or refractory WM patients post-BTKi therapy and represents the most refractory population ever tested in clinical studies based upon a review of published literature. Iopofosine I 131 was well tolerated and its toxicity profile was consistent with the Company's previously reported safety data.

"We are extremely pleased to be partnering with AON and MiBA to support our collective goal to enrich the WM treatment paradigm for patients and providers," said James Caruso,

president and CEO of Cellectar. “This collaboration will provide additional insight to patients’ and health care providers’ needs across the WM treatment landscape and the learnings will be incorporated into the launch strategy for iopofosine I 131. Following achievement of the primary endpoint in the CLOVER WaM pivotal study, this partnership with AON represents another strategically important collaboration to ensure patient access and optimize outcomes with iopofosine therapy upon FDA approval.”

AON is one of the fastest growing networks of community oncology practices with 85 sites of care across the U.S. focused on delivering high-quality cancer care. The partnership with AON and MiBA is a key addition to Cellectar’s planned collaborations with leading U.S. community-based cancer care networks to identify unmet WM patient needs and opportunities to optimize the potential commercial launch for iopofosine I 131.

“We are very excited to be able to support the efforts of all involved in this project with MiBA’s technical and analytical capabilities,” said Mark Moch, Executive Manager at MiBA. “Data identification, curation and advanced analytics are essential in moving treatments forward. Keeping our patient at the center and working in close association with AON and Cellectar, gives us the ability to positively affect outcomes and contribute to future standards of care.”

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

WM is a rare type of B-cell lymphoma that originates from the bone marrow lymphocytes. It is estimated that 26,000 people are living with WM in the U.S. 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 Cellectar Biosciences, Inc.

Cellectar 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.cellectar.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 American Oncology Network

Since its inception in 2018, American Oncology Network, Inc. (Nasdaq: AONC) has offered an innovative model of physician-led, community-based oncology management. AONC preserves and elevates community oncology by helping its physicians navigate the complex healthcare landscape, providing them an efficient platform to work autonomously and thrive,

and most importantly, improving the quality of patient care that is being delivered. The network is an alliance of physicians and veteran healthcare leaders partnering to ensure the long-term success and viability of oncology diagnosis and treatment in community-based settings. As of September 30, 2023, AONC has more than 200 providers across 85 locations in 19 states and the District of Columbia. AONC's robust platform provides oncology practices with comprehensive support, access to revenue- diversifying adjacent services and practice management expertise to empower physicians to make cancer care better for every patient.

About MiBA

MiBA is a healthcare AI technology company on a mission to close the feedback loop between physicians, patients and industry partners. The technology and data insights that MiBA generates will support pharmaceutical companies, research organizations, payers, biotech, health systems and providers to advance the quality of patient care.

MiBA's culture is one of empathy. The heart of the mission is every patient deserves the best care possible- period. Putting the power of data into the hands of industry stakeholders to enable to drive informed decisions.

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 September 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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