

May 29, 2024



Cellecstar Biosciences and City of Hope Cancer Center Enter Collaboration to Evaluate Iopofosine I 131 in Mycosis Fungoides

Opportunity for Iopofosine Expansion Within Areas of High Unmet Need in Non-Hodgkin's Lymphoma

Establishes Partnership With One of the Largest Cancer Research and Treatment Organizations in the U.S.

FLORHAM PARK, N.J., May 29, 2024 (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 strategic partnership with City of Hope Cancer Center, one of the largest cancer research and treatment organizations in the United States. The collaboration will focus on the clinical development of Cellecstar's lead radioconjugate asset, Iopofosine I 131, in mycosis fungoides (MF), a rare form of non-Hodgkin's lymphoma (NHL) that affects the skin and, in some patients, internal organs and blood. Iopofosine is the first systemic targeted radiotherapeutic to be assessed for cutaneous T-cell lymphomas (CTCL). The investigator sponsored trial will evaluate approximately 10 patients; initiation is planned for late 2024 or early 2025.

"We are excited to partner with Cellecstar Biosciences to evaluate Iopofosine in patients with mycosis fungoides," said Dr. Steven T. Rosen, executive vice president and director emeritus, Comprehensive Cancer Center and Beckman Research Institute of City of Hope. "Its unique delivery platform targeting all tumor sites with systemic delivery may provide significant advantages over conventional external beam radiotherapy, which requires frequent and continuous therapy. Iopofosine's demonstrated efficacy in indolent non-Hodgkin's lymphoma may result in new treatment paradigms for these high-need patients. In addition, the ability of Iopofosine to target tumor cells beyond the skin may reduce the risk of systemic progression or transformation via targeting subclinical lesions and tumor stem cells. This treatment approach may be applicable to the variety of CTCLs beyond MF."

MF has a prevalence of approximately 30,000 patients and is the most common form of CTCL. It is a slow-growing form of blood cancer in which some of the body's white blood cells become malignant and has no curable treatment options. The most common presentation is skin rash, plaques and tumors on the skin resulting in disfigurement, severe and debilitating pruritis, and in some cases involves blood and internal organs that may lead to death.

"City of Hope is a world-renowned cancer research center with extensive clinical expertise

and Dr. Steven Rosen is a recognized global leader in oncology research, development and clinical care,” said Dr. Andrei Shustov, Cellectar’s senior vice president, medical. “This collaboration further substantiates iopofosine as a potential treatment for a wide variety of cancers. Iopofosine’s unique qualities may translate into significant clinical benefit and change the MF treatment paradigm for patients with no available curative options and limited benefit from available treatments.”

The U.S. Food and Drug Administration (FDA) has granted iopofosine I 131, a small-molecule Phospholipid Drug Conjugate™ (PDC) designed to provide targeted delivery of iodine-131 (radioisotope), Orphan Drug and Fast Track Designation for relapsed/refractory (r/r) Waldenstrom’s macroglobulinemia (WM), r/r multiple myeloma and r/r diffuse large B-cell lymphoma (DLBCL).

Cellectar is preparing to submit a New Drug Application (NDA) to the FDA based on its [CLOVER WaM](#) pivotal study in WM in the second half of 2024. The company previously announced [topline data](#) from its CLOVER WaM pivotal study earlier this year and plans to announce updated results in June.

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 or join the conversation by liking and following us on the company’s social media channels: [Twitter](#), [LinkedIn](#), and [Facebook](#).

About City of Hope

City of Hope was founded in 1913 and has grown into one of the largest cancer research and treatment organizations in the U.S. City of Hope research has been the basis for [numerous breakthrough cancer medicines](#). With an independent, National Cancer Institute-designated comprehensive cancer center at its core, City of Hope brings a uniquely integrated model to patients spanning cancer care, research and development, academics and training, and innovation initiatives. City of Hope’s growing national system includes its Los Angeles campus, a network of clinical care locations across Southern California, a new cancer center in Orange County, California, and cancer treatment centers and outpatient facilities in the Atlanta, Chicago and Phoenix areas. City of Hope’s affiliated group of organizations includes [Translational Genomics Research Institute](#) and [AccessHope™](#). For more information about City of Hope, follow us on [Facebook](#), [X](#), [YouTube](#), [Instagram](#) and [LinkedIn](#).

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 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, 2023, and our Form 10-Q for the quarter ended March 31, 2024. These forward-looking statements are made only as of the date hereof, and we disclaim any obligation to update any such forward-looking statements.

Contacts

MEDIA:

Claire LaCagnina

Bliss Bio Health

315-765-1462

clacagnina@blissbiohealth.com

INVESTORS:

Chad Kolean

Chief Financial Officer

investors@cellectar.com



Source: Cellectar Biosciences