

August 26, 2024



Iopofosine I 131 Featured in Two Separate Presentations at 12th International Workshop on Waldenstrom's Macroglobulinemia

Jorge Castillo, M.D. to Present Iopofosine I 131 Activity in Bing-Neel Syndrome

Andrei Shustov, M.D. to Review CLOVER WaM Pivotal Study

FLORHAM PARK, N.J., Aug. 26, 2024 (GLOBE NEWSWIRE) -- Cellecstar Biosciences, Inc. (NASDAQ: CLRB), a late-stage clinical biopharmaceutical company focused on the discovery, development and commercialization of drugs for the treatment of cancer, today announced two presentations: one regarding the treatment of a patient with Bing-Neel Syndrome (BNS), and a review of the company's CLOVER WaM pivotal study of iopofosine I 131 at the 12th International Workshop on Waldenstrom's Macroglobulinemia being held October 17-19, 2024, in Prague, Czech Republic.

BNS is a rare, life-threatening complication of WM that manifests in the central nervous system (CNS). It typically translates into various neurological sequelae, such as neuropathy, headaches, visual disturbances, changes in gait, partial paralysis and is associated with poor outcomes. Up to 30% of patients diagnosed with BNS die within the first three years of diagnosis.

Cellecstar's lead product candidate, iopofosine I 131, is a potential first-in-class, novel cancer targeting agent utilizing a phospholipid ether radioconjugate. Iopofosine has demonstrated the ability to cross the blood brain barrier with clinical activity in multiple hematologic malignancies that involve or occur within the CNS. This includes relapsed/refractory primary CNS lymphoma, which is most often the result of diffuse large B cell lymphoma infiltrating the CNS.

At IWWM, a case study report will be presented by Jorge Castillo MD, associate professor of medicine, Harvard Medical School, and clinical director, Bing Center for Waldenstrom's Macroglobulinemia Dana Farber Cancer Institute, demonstrating complete central nervous system clearance in a relapsed/refractory BNS patient treated with iopofosine I-131.

In addition, Andrei Shustov MD, Cellecstar's senior vice president of medical, will review topline data from the fully enrolled and completed CLOVER WaM pivotal study, the first and largest WM study to date in a highly refractory patient population.

"I look forward to Cellecstar providing top line data on the activity of iopofosine in relapsed or refractory patients with Waldenstrom's Macroglobulinemia at the 12th International Workshop on Waldenstrom's Macroglobulinemia in Prague next month," commented Steven P. Treon

MD, MA, MS, PhD, FACP, FRCP, professor of medicine, Harvard Medical School, director, Bing Center for Waldenstrom's Macroglobulinemia Dana Farber Cancer Institute, and chair of IWWM, "Iopofosine represents a novel therapeutic approach for treating patients with Waldenstrom's Macroglobulinemia, particularly for those who have received multiple prior lines of therapy."

Details for the presentations are as follows:

Title: Treatment With Iopofosine I-131 in a Patient with Bing-Neel Syndrome, A Rare Manifestation of Waldenstrom Macroglobulinemia: A Case Report

Presenter: Jorge Castillo MD, associate professor of medicine, Harvard Medical School, and clinical director, Bing Center for Waldenstrom's Macroglobulinemia Dana Farber Cancer Institute

Date/Time: Friday, October 18, 2024, 4:30-6:30 p.m.

Session: Poster Presentations (Session XVI)

Location: Moravia Hall, Prague Marriott

Title: Multi-center Trial of Iopofosine in Relapsed/Refractory WM

Speaker: Andrei Shustov, MD, senior vice president, Medical, Cellectar Biosciences

Date/Time: Saturday, October 19, 2024, 4:00-5:00 p.m.

Session: Clinical Trials in Progress for WM II (Session XXII)

Location: Moravia Hall, Prague Marriott

**Iopofosine I 131 is an investigational agent and has not been approved for use in any country, for any indication.*

About Waldenstrom's Macroglobulinemia

Waldenstrom's Macroglobulinemia (WM) is a B-cell malignancy characterized by bone marrow infiltration with clonal lymphoplasmacytic cells that produce a monoclonal immunoglobulin M (IgM) that remains incurable with available treatments. The prevalence in the US is approximately 26,000 with 1,500-1,900 patients being diagnosed annually. Approximately 11,500 patients require treatment in the relapsed or refractory setting and there are an estimated 4,700 patients requiring 3rd line or greater therapy. There are approximately 1,000 patients that have exhausted all current treatment options by 3rd line because they are ineligible or intolerant to those existing therapies. Therefore, the total addressable market for 3rd line or greater therapy is approximately 5,700 patients. There are no FDA approved treatment options for patients progressing on BTKi therapy. BTKi therapies do not demonstrate complete response rates and require continuous treatment. Approximately 50% of 3rd line patients not receiving treatment are likely to consider new treatment options because greater than 50% of patients are treated with the same or similar treatment from prior lines of therapy. Greater than 60% of treatments utilized are non-FDA-approved therapies. There is an established unmet need for new FDA-approved treatments that provide a novel mechanism of action, increased deep durable responses, and time limited treatment, especially in heavily pretreated WM patients.

About Bing Neel Syndrome

Bing-Neel syndrome (BNS) is a rare presentation of WM developing in about 1% of patients during the course of their disease. While the syndrome can occur at any time after the WM diagnosis, in 40-50% of BNS cases it is the first manifestation of WM. BNS occurs when

lymphoma cells gain access to the CNS and results in neurologic deficits and other sequelae, significantly affecting patients' quality of life. Cancer cells can afflict both brain parenchyma and cerebral fluid with meninges. Patients with BNS have compromised outcomes with up to 40% of patients dying within 2-3 years after the diagnosis and the majority of deaths resulting from the BNS. Treatment of BNS requires the use of agents capable of penetrating the blood-brain-barrier and typically in doses that are hard to tolerate in this elderly patient population. There are currently no curative options for BNS.

About Celectar Biosciences, Inc.

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

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:

Christy Maginn
Bliss Bio Health
703-297-7194
cmaginn@blissbiohealth.com

INVESTORS:
Chad Kolean
Chief Financial Officer
investors@collectar.com



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