November 7, 2024

Cellectar Selected to Present New Data from Phase 2 CLOVER-WaM Study in Oral Session at ASH 2024

Ailawadhi, Sikander, M.D., Lead Investigator, to Present Iopofosine I 131 Efficacy and Safety Results from Phase 2 CLOVER-WaM Study

Highlights Company's Leadership and Progress in Developing Iopofosine I 131 as Treatment for Waldenstrom's Macroglobulinemia

FLORHAM PARK, N.J., Nov. 07, 2024 (GLOBE NEWSWIRE) -- Cellectar 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 that new data from the company's open-label Phase 2 CLOVER-WaM study of iopofosine I 131 as a potential treatment for Waldenstrom's macroglobulinemia (WM) will be highlighted in an oral presentation at the 66th American Society of Hematology Annual Meeting and Exposition (ASH 2024) taking place from December 7–10, 2024, in San Diego, California.

Cellectar's lead product candidate, iopofosine I 131, is a potential first-in-class, novel cancer targeting agent utilizing a phospholipid ether as a radioconjugate. Iopofosine I 131 is an investigational agent and has not been approved for use in any country, for any indication.

WM is the dominant subtype lymphoplasmacytic lymphoma that remains incurable with available therapies. Treatment options beyond initial therapy are limited, underscoring the need for new therapies with novel mechanisms of action.

The pivotal CLOVER-WaM (NCT02952508) trial assessed the efficacy and safety of iopofosine I 131 in relapsed and refractory patients with WM who received at least 2 prior therapies.

"We are honored to have the positive results from our CLOVER-WaM pivotal trial selected for oral presentation at ASH 2024. This highlights the need for novel class therapies for an often-overlooked patient population affected by this rare disease in which iopofosine I 131 has the potential to establish itself as the standard-of-care for relapsed/refractory patients," said James Caruso, president and CEO of Cellectar. "As previously announced, we plan to submit a New Drug Application with the U.S. Food and Drug Administration in the coming months and, given the limited effective therapeutic alternatives available for WM patients, will be seeking priority review."

Details for the presentations are as follows:

Presenter: Ailawadhi, Sikander, M.D., professor of medicine, Division of Hematology/Oncology, Departments of Medicine and Cancer Biology, Mayo Clinic
Title: Iopofosine I 131 in Previously Treated Patients with Waldenstrom Macroglobulinemia

(WM): Efficacy and Safety Results from the International, Multicenter, Open-Label Phase 2 Study (CLOVER-WaM™)
Session: Oral
Session Date: Monday, December 9, 2024
Session Time: 2:45 PM – 4:15 PM
Location: Marriott Marquis San Diego Marina, Marriott Grand Ballroom 11-13
Publication Number: 861

The complete abstract of the oral presentation can be accessed at the ASH 2024 website at 66th ASH Annual Meeting & Exposition - Hematology.org.

In-person participants at ASH 2024 may visit Cellectar Biosciences at Exhibit Booth #3300 in the Exhibit Hall (Halls B2-F at the San Diego Convention Center).

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 third line or greater therapy. There are also approximately 1,000 patients that have exhausted all current treatment options by third line because they are ineligible or intolerant to those existing therapies. Therefore, the total addressable market for third line or greater therapy is approximately 5,700 patients. There are no U.S. Food and Drug Administration (FDA) approved treatment options for patients progressing on BTKi therapy. BTKi therapies do not demonstrate complete response rates and require continuous treatment.

Non-FDA approved treatments are used in more than 60% of patients. Over 50% of patients are treated with the same or similar treatment from prior lines of therapy. There is an established unmet need for new FDA-approved treatment like Iopofosine I-131 that provide a novel mechanism of action, increased deep durable responses, and time limited treatment, especially in heavily pretreated WM patients.

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 PDC designed to provide targeted delivery of iodine-131 (radioisotope), proprietary preclinical PDC chemotherapeutic programs and multiple partnered PDC assets. Additional radiotherapeutics are in development utilizing alpha emitters and Auger to target solid tumors.

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.

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/A for the year ended December 31, 2023, and our Form 10-Q for the quarter ended June 30, 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.

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Source: Cellectar Biosciences