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Cellecstar Biosciences Presents Compelling Efficacy Data from Phase 2b CLOVER WaM Subset Analysis of Iopofosine I 131 in Patients Relapsed/Refractory to BTK Inhibitor Therapy at the International Workshop for Waldenström Macroglobulinemia

Subgroup analysis of patients who received Bruton Tyrosine Kinase inhibitor (BTKi) treatment immediately prior to iopofosine I 131 achieved 87.5% ORR, 79.2% MRR and 100% CBR with median DOR of 16 months

Initiation and site selections for Phase 3 confirmatory randomized clinical trial in post-first line, post-BTKi population evaluating Progression-Free Survival as primary endpoint underway; dosing of first patients expected in 1Q27 and application for U.S. accelerated market approval anticipated in 1H27

FLORHAM PARK, N.J., Oct. 15, 2026 (GLOBE NEWSWIRE) -- Cellecstar Biosciences, Inc. (NASDAQ: CLRB), a late-stage clinical biopharmaceutical company focused on the discovery and development of drugs for the treatment of cancer, today announced that efficacy results from a subset of patients treated with iopofosine I 131 immediately post-Bruton Tyrosine Kinase inhibitor (BTKi) therapy in the company's Phase 2b CLOVER WaM clinical trial of iopofosine I 131 to treat relapsed or refractory (r/r) Waldenström macroglobulinemia (WM) were presented today at the International Workshop for Waldenström Macroglobulinemia (IWM) taking place October 14 to October 16, 2026, in Palm Springs, California.

The poster highlighted data from a subgroup (n=24) of patients treated with a BTKi immediately prior to iopofosine I 131 from the CLOVER WaM trial in WM. This subgroup analysis is derived from the [CLOVER WaM clinical trial 12-month follow-up data set](#) previously reported.

"These compelling data further strengthen the growing body of evidence supporting the potential of iopofosine I 131 to address a critical unmet need and offers something WM patients rarely get after BTK inhibitors: deep, durable responses from a short, fixed course of treatment. Because its targeted radiation works independently of the BTK pathway and other pathways currently targeted or attempting to be targeted, we believe it has the potential to remain effective as patients become refractory to today's targeted therapies, and those still to come," said Jarrod Longcor, chief operating officer of Cellecstar Biosciences. "Patients in the immediate post-BTKi setting often face limited treatment options and increasingly

refractory disease, making the robust response rates, durable clinical benefit, and favorable tolerability profile observed in this analysis especially encouraging. With Breakthrough Therapy Designation, a mature and expanding CLOVER WaM dataset, and plans underway to dose patients in our confirmatory clinical trial in early 2027, we believe iopofosine I 131 is well positioned to become a meaningful new treatment option for these patients, and we remain focused on advancing the program toward potential regulatory approval.”

Summary of Results in Subgroup Immediately post-BTKi treatment (n=24)

The patients included in this subset analysis were enrolled in the CLOVER WaM clinical trial and were treated with iopofosine I 131 immediately after receiving a regimen containing BTKi. Seventy-five percent were BTKi refractory and more than 54% had received multiple BTKi therapies. Patients had a median of three prior lines of therapy (range 2-7) with 17% being TP53 mutated and 29% being MYD88 wild type, both of which confer greater resistance and rapid progression. Key findings included:

- Overall Response Rate (ORR): 87.5%
- Major Response Rate (MRR): 79.2%
- Median Duration of Response (DoR): 16.0 months
- Treatment Free Survival (TFS): 19.1 months
- Clinical Benefit Rate (CBR): 100%
- Safety: Treatment emergent adverse events (TEAE) occurred in less than 10% of patients, with the only Grade 3 or higher TEAE being cytopenias

Cellectar is advancing plans to dose the first patients in the confirmatory Phase 3 randomized clinical trial in a post-first line, post-BTKi population. The registration-directed trial is expected to evaluate progression-free survival (PFS) as the primary endpoint, consistent with regulatory guidance.

The company is also preparing to submit a New Drug Application for accelerated approval with the U.S. Food and Drug Administration (FDA) in the first half of 2027, supported by the strength and maturity of the CLOVER WaM dataset.

About Accelerated Approval and Confirmatory Study Initiation

The CLOVER WaM dataset incorporates key elements aligned with regulatory expectations for accelerated approval as requested by the FDA, including:

- Use of surrogate endpoints (MRR supported by DoR) reasonably likely to predict clinical benefit
- Demonstration of durable responses in a high unmet need population
- Completion of ≥12-month follow-up across all 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 iopofosine I 131, which is a PDC designed to provide targeted delivery of iodine-131 (radioisotope). Iopofosine I 131 has been tested in Phase 2b trials as a treatment for relapsed or refractory Waldenström Macroglobulinemia

(WM), in relapsed or refractory multiple myeloma (MM) and central nervous system (CNS) lymphoma. The CLOVER-2 Phase 1b study is evaluating iopofosine I 131 in pediatric patients with high-grade gliomas, for which Cellestar is eligible to receive a Pediatric Review Voucher from the FDA upon approval. The FDA has granted iopofosine I 131 Breakthrough, six Orphan Drug, four Rare Pediatric Drug and two Fast Track Designations for various cancer indications, and the EMA has granted iopofosine I 131 PRiority MEdicines (PRIME) designation.

Cellestar is also developing CLR 121125 (CLR 125), an iodine-125 Auger-emitting program targeted for solid tumors, such as triple negative breast (TNBC), lung, and colorectal cancer, and is currently being evaluated in a Phase 1b study for TNBC, which will determine the recommended dose for the subsequent Phase 2 trial. CLR 125 has been well tolerated *in vivo* and has demonstrated strong preclinical data showing reduction or inhibition of solid tumor growth.

In addition to these assets, the Cellestar team is developing CLR 121225 (CLR 225), an actinium-225 based program targeting solid tumors in indications with significant unmet need, such as pancreatic cancer, as well as proprietary preclinical PDC chemotherapeutic programs and multiple partnered PDC assets.

For more information, please visit <https://www.cellestar.com/> or join the conversation by liking and following us on the company's social media channels: [X](#), [LinkedIn](#), and [Facebook](#).

Forward Looking Statements

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. 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 FDA and EMA regulatory pathways, ability to execute strategic alternatives, identify suitable collaborators, partners, licensees or purchasers for our product candidates and, if we are able to do so, to enter into binding agreements with regard to any of the foregoing, or to raise additional capital to support our operations, or our ability to fund our operations if we are unsuccessful with any of the foregoing. 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, 2025, and our Form 10-Q for the quarterly period ending June 30, 2026. 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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