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Cellectar Biosciences Reports Positive 12-Month Follow-Up Data from Phase 2b CLOVER WaM Study Demonstrating Durable Responses and Efficacy of Iopofosine I 131 in r/r Waldenström Macroglobulinemia

83.6% ORR and 61.8% MRR achieved in heavily pretreated population with median duration of response of 17.8 months

FDA-requested dataset with ≥12-month follow-up on all patients strengthens regulatory positioning for accelerated approval and supports initiation of confirmatory trial in 4Q26

Compelling efficacy observed in post-BTKi patients, including ~64% MRR and durable responses exceeding 18 months

Recently Announced Oversubscribed Financing of up to $140 Million with Leading Healthcare Institutional Investors Supports Confirmatory Study and NDA Filing for Accelerated Approval of Iopofosine I 131 in Waldenström Macroglobulinemia with the FDA

FLORHAM PARK, N.J., May 05, 2026 (GLOBE NEWSWIRE) -- Cellectar Biosciences, Inc. (NASDAQ: CLRB), a late-stage clinical biopharmaceutical company focused on the discovery and development of targeted oncology therapies, today announced updated and mature 12-month follow-up data from its Phase 2b CLOVER WaM clinical trial evaluating iopofosine I 131 in patients with relapsed or refractory (r/r) Waldenström macroglobulinemia (WM). The updated dataset includes a minimum of 12 months of follow-up for all enrolled patients, as requested by the U.S. Food and Drug Administration (FDA), and the durability data presented here, further strengthen the previously reported efficacy results. The Company also reports subset analyses from CLOVER WaM showing iopofosine I 131 demonstrated strong and consistent efficacy in both BTKi-exposed and BTKi-refractory patients.

“The depth, durability, and consistency of responses observed across both the total population and BTKi-treated subsets underscore iopofosine’s potential as a meaningful new treatment option in WM and differentiate it from currently available therapies,” said Jarrod Longcor, chief operating officer of Cellectar Biosciences. “With the completion of at least 12-month follow-up on all patients, we believe this dataset meets key regulatory expectations for an accelerated approval submission and positions us well as we advance toward initiating our confirmatory study.”

Patients enrolled in the CLOVER WaM clinical trial had a median of four prior lines of therapy (range 2-15), with refractory rates running from 77% in Bruton tyrosine kinase inhibitors (BTKi)-exposed patients to 60% in chemotherapy-exposed patients and 58% in patients exposed to both BTKi and rituximab, making this one of the most heavily pretreated and refractory WM populations studied to date. Updated 12-month data demonstrated high response rates and sustained durability, supporting its accelerated regulatory pathway and potential role as a differentiated treatment option.

Summary of Efficacy Results in per Protocol Study Population (n=55):

- Overall Response Rate (ORR): 83.6%
- Major Response Rate (MRR): 61.8% *(primary endpoint achieved)*
- Median Duration of Response (DoR): 17.8 months *(secondary endpoint achieved)*
- Median Progression-Free Survival (PFS): 13.5 months
- Very Good Partial Response/Complete Response Rate (VGPR/CR): 14.5%
- Disease Control Rate (DCR): 98.2%

During the follow-up period, responses deepened and remained durable, underscoring the strength of the data, especially considering that treatment with iopofosine I 131 is a fixed-dosed regimen containing four ~30-minute infusions. This further highlights its potential for meaningful clinical benefit without the need for continuous therapy.

“These mature 12-month follow-up data, as required by the FDA, further strengthen the compelling clinical profile of iopofosine I 131,” said James Caruso, president and chief executive officer. “Importantly, the durability of response continues to improve over time, and the consistency of activity in post-BTKi patients reinforces the potential of iopofosine to address a critical unmet need in the second line setting and beyond. We remain committed to providing iopofosine I 131 to the thousands of patients who can benefit from treatment and plan to initiate our confirmatory study in fourth quarter of this year.”

Iopofosine I 131 continues to demonstrate a predictable and manageable safety profile:

- Adverse events were transient and unlike other therapies approved for WM there were no significant bleeding events and low rates of infection (<10%)
- Cytopenias were the most common treatment-emergent adverse events
- Non-hematologic toxicities were primarily low grade (Grade $\leq$2)

Compelling Activity in BTKi-Exposed and Refractory Patients
BTKi therapies have become the standard of care in frontline treatment of WM, outcomes in post-BTKi patients are of increasing importance. Iopofosine I 131 demonstrated strong and consistent efficacy in both BTKi-exposed and BTKi-refractory patients, populations that are among the most difficult to treat.

Summary of Efficacy Results in BTKi-Exposed Patients (n=39):

- MRR: 64.1%
- Median DoR: 18.2 months
- Median PFS: 15.9 months

Summary of Efficacy Results in BTKi-Refractory Patients (n=33):

- MRR: 63.6%
- Median DoR: 18.2 months
- Median PFS: 14.8 months

These results demonstrate durability and depth of response comparable to, or exceeding, the overall study population, reinforcing the consistency of iopofosine's activity across treatment-resistant subgroups. Furthermore, comparative assessments with published datasets suggest that iopofosine I 131 delivers superior efficacy across key endpoints relative to currently available salvage therapies in similar patient populations.

Efficacy and safety results from r/r WM patients treated with iopofosine I 131 immediately following BTKi therapy have been accepted for presentation at the upcoming American Society of Clinical Oncology (ASCO) Annual Meeting taking place from May 29-June 2, 2026 in Chicago, Illinois.

The company also plans to present the full data sets at upcoming medical congresses or scientific meetings.

About Accelerated Approval and Confirmatory Study Initiation
The CLOVER WaM dataset incorporates key elements aligned with regulatory expectations for accelerated approval, 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, as requested by the FDA

Cellectar is advancing plans to initiate a confirmatory randomized study in a post-first line, post-BTKi population. The study is expected to evaluate progression-free survival (PFS) as the primary endpoint, consistent with regulatory guidance.

The company is also preparing for potential regulatory submissions in the United States and Europe, supported by the strength and maturity of the CLOVER WaM dataset.

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 U.S. 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 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 salvage 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 treatments, such as iopofosine I 131, that may 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 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 Cellectar 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.

Cellectar 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 Cellectar 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.cellectar.com/or join the conversation by liking and following us on the company's social media channels: X, LinkedIn, and Facebook.

Forward Looking Statements 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. 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 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. 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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