

January 9, 2026



Cellestar Biosciences to Highlight Strategic Initiatives for 2026 at Upcoming Biotech Showcase during 44th Annual JP Morgan Healthcare Conference

Following Guidance from the European Medicines Agency's (EMA) Scientific Advice Working Party (SAWP) Regarding Iopofosine I 131 for the Treatment of Waldenström's Macroglobulinemia (WM), Expects to Submit for Conditional Marketing Approval in Europe in 3Q 2026

Plans to Present Final Results and Subset Analysis of WM Patients from the Phase 2 CLOVER WaM Clinical Study of Iopofosine I 131

Anticipates Dosing of First Patients in Phase 1b Study of CLR 125 for the Treatment of Triple Negative Breast Cancer in 1Q26 with Interim Data Mid-2026

FLORHAM PARK, N.J., Jan. 09, 2026 (GLOBE NEWSWIRE) -- Cellestar Biosciences, Inc. (NASDAQ: CLRB), a late-stage clinical biopharmaceutical company focused on the development of targeted radiotherapeutics for cancer, today announces plans to highlight the company's 2026 strategic initiatives at the upcoming Biotech Showcase, taking place January 12-15, 2026, in San Francisco during the 44th Annual JP Morgan Healthcare Conference. James Caruso, president and CEO of Cellestar, will present a corporate update on Tuesday, January 14, 2025, at 1:30 pm Pacific Time.

2025 Achievements

- Received feedback from the SAWP supporting a Conditional Marketing Authorization (CMA) filing for iopofosine I 131 in WM based upon our CLOVER WaM study
- U.S. Food and Drug Administration (FDA) granted Break Through Designation (BTD) for iopofosine I 131 in relapsed/refractory WM
- Confirmed traditional accelerated approval pathway with the FDA for iopofosine I 131 in WM
- Presented compelling data from the CLOVER-2 Phase 1b study in relapsed/refractory pediatric high-grade glioma (pHGG), demonstrating extended progression-free survival and favorable safety profile
- Initiated a Phase 1b clinical study for CLR 125, an Auger-emitting iodine-125 program for the treatment of triple-negative breast cancer (TNBC)
- Strengthened supply chain through strategic supply agreements for our next generation Auger- and alpha-emitting radiotherapeutics
- Raised approximately \$15.2 million through financings and warrant exercises to support pipeline development and regulatory milestones

CEO Commentary

“Our priorities are clear: secure European conditional marketing approval for iopofosine I 131 for WM in early 2027 with commercialization to follow, further validate our PDC platform by executing on our Phase 1b study evaluating CLR 125 for TNBC, and advance our regulatory strategy with the FDA for iopofosine I 131 approval in the U.S. With an established iopofosine I 131 regulatory strategy for both EMA and FDA, and promising data across our pipeline, we are entering 2026 with strong momentum and multiple opportunities,” said James Caruso, president and CEO of Collectar. “We believe these initiatives position Collectar to deliver meaningful therapies for patients and create significant value for shareholders.”

2026 Strategic Initiatives

- **Regulatory Milestones:**
 - Submit CMA application to EMA for iopofosine I 131 in WM in 3Q 2026, with potential European market approval in early 2027
 - Advance NDA preparations for U.S. accelerated approval
- **Clinical Development:**
 - Enroll patients in the Phase 1b study of CLR 125 in TNBC with interim data expected in mid-2026
 - Present final findings and subset analysis from the CLOVER WaM Phase 2 study of iopofosine I 131
 - Prepare actinium-based CLR 225 for first-in-human trials in pancreatic cancer
- **Pipeline Expansion:**
 - Progress additional PDC-based radiotherapeutics into preclinical and IND-enabling studies
- **Partnerships:**
 - Evaluate strategic collaborations for commercialization of iopofosine I 131
- **Financial Strategy:**
 - Continue disciplined capital management and explore non-dilutive funding opportunities

“Looking ahead, we are focused on receiving a conditional marketing approval in 2027 from the EMA impacting approximately thirty countries, which collectively possess a larger WM population than the U.S. In parallel, we remain committed to advancing our regulatory strategy with the FDA fully understanding the tremendous incremental value it potentially represents for all Collectar stakeholders. The FDA-recommended post-BTKi indication positions iopofosine I 131 as a treatment option as early as the second line, substantially expanding the available patients in the U.S. market. Additionally, we are actively recruiting patients for our Phase 1b study evaluating CLR 125, our Auger-based radiotherapeutic for the treatment of TNBC, which builds on strong preclinical data showing growth inhibition and tumor volume reduction in this challenging-to-treat cancer,” concluded Mr. Caruso.

Mr. Caruso’s Biotech Showcase presentation will be live webcast and can be accessed [HERE](#). A replay of the presentation will be available on the [Events](#) section of the company’s [Investor Relations](#) website.

About Collectar Biosciences, Inc.

Collectar Biosciences is a late-stage clinical radiopharmaceutical company focused on the discovery and development of proprietary drugs for the treatment of cancer. 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 that deliver improved efficacy and better safety.

The company's product pipeline includes its lead assets: iopofosine I 131, a PDC designed to provide targeted delivery of iodine-131 (radioisotope) for the treatment of hematologic and solid tumor cancers such as Waldenstrom's macroglobulinemia (WM) and pediatric high grade gliomas; CLR 121125 (CLR 125), an iodine-125 Auger-emitting program targeting solid tumors, such as triple negative breast, lung and colorectal cancers; CLR 121225 (CLR 225), an actinium-225 based program targeting solid tumors with significant unmet need, such as pancreatic cancer; and proprietary preclinical PDC chemotherapeutic programs and multiple partnered PDC assets.

Iopofosine I 131 has been studied in Phase 2b trials for relapsed or refractory WM and multiple myeloma (MM), non-Hodgkin's lymphomas and central nervous system (CNS) lymphoma, and the CLOVER-2 Phase 1b study, targeting 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 Therapy, six Orphan Drug, five Rare Pediatric Drug and two Fast Track Designations for various cancer indications. The European Medicines Agency (EMA) has also granted PRIME and orphan drug designations for the treatment of WM.

For more information, please visit 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. We will require additional funding to fully execute our strategy. 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, 2024, and our Form 10-Q for the quarterly period ended September 30, 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.

INVESTORS:

Anne Marie Fields

Precision AQ

212-362-1200

annemarie.fields@precisionaq.com



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