August 13, 2024

Cellectar Biosciences Reports Financial Results for Q2 2024 and Provides a Corporate Update

Management to host a conference call today at 8:30 am ET

FLORHAM PARK, N.J., Aug. 13, 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 financial results for the quarter ended June 30, 2024, and provided a corporate update.

“With our recent positive data announcement from the CLOVER WaM pivotal study evaluating iopofosine I 131 in Waldenstrom’s macroglobulinemia, we remain focused on filing our WM NDA in the fourth quarter of this year,” said James Caruso, president and CEO of Cellectar. “We anticipate an accelerated six-month NDA review period and continue to prepare for a potential launch of iopofosine in 2025. We look forward to bringing this meaningful therapy to market and establishing iopofosine I 131 as the standard of care for the treatment of relapsed and refractory WM patients.”

Second Quarter and Recent Corporate Highlights

- Announced final data exceeded the primary endpoint in the company’s CLOVER WaM pivotal study evaluating iopofosine I 131, a potential first-in-class, targeted radiotherapeutic candidate for the treatment of relapsed/refractory Waldenstrom’s macroglobulinemia (WM) patients that received at least two prior lines of therapy, including Bruton tyrosine kinase inhibitors (BTKi’s). Data from the pivotal study demonstrated an 80% overall response rate (ORR), and a 56.4% major response rate (MRR) which exceeded the agreed-upon primary endpoint of a 20% MRR. The median number of prior lines of therapy was 4 (range, 2-14), with approximately 27% of patients’ refractory to all available therapies (BTKi, anti-CD20 antibody, chemotherapy), and 40% of patients dual-class refractory (BTKi and rituximab). Notably, comparable iopofosine I 131 ORRs were observed across all clinically challenging disease subgroups, including: MYD99-wt (81%; n=16), P53-mutated (80%; n=5), and clinical patient cohorts including post-BTKi (72%; n=39), as well as dual-class (59%; n=22), and triple-class (53%; n=15) refractory patients. Secondary endpoints of disease control rate (98.2%) and duration of response (DoR) presented evidence that iopofosine provided durable clinical benefit across all response categories. The median DoR in patients achieving major response and overall response were not reached as of the data cutoff, with 78% of major response patients and 72% of overall response patients remaining free from disease progression at 18 months, respectively.

- Announced a strategic partnership with City of Hope Cancer Center, one of the largest cancer research and treatment organizations in the United States, to evaluate iopofosine I 131 in mycosis fungoides, a rare form of non-Hodgkin's lymphoma (NHL) that affects the skin and, in some patients, internal organs and blood. The investigator-sponsored trial will evaluate approximately 10 patients with initiation planned for late 2024 or early 2025.

Second Quarter 2024 Financial Highlights

- **Cash and Cash Equivalents:** As of June 30, 2024, the company had cash and cash equivalents of $25.9 million, compared to $9.6 million as of December 31, 2023. Net cash used in operating activities during the three months ended June 30, 2024, was approximately $14.1 million. The company believes its cash balance as of June 30, 2024, when combined with the $19.4 million raised in July, is adequate to fund its basic budgeted operations into the second quarter of 2025.

- **Research and Development Expense:** R&D expense for the three months ended June 30, 2024, was approximately $8.2 million, compared to approximately $6.3 million for the three months ended June 30, 2023. The overall increase in R&D was primarily a result of expenditures for the company's WM pivotal trial, in addition to investments in product sourcing, manufacturing, and logistics infrastructure.

- **General and Administrative Expense:** G&A expense for the three months ended June 30, 2024, was $6.4 million, compared to $2.0 million for the same period in 2023. The increase in G&A was primarily driven by costs associated with the development of infrastructure necessary to support commercialization upon anticipated NDA approval, including the related marketing and personnel costs.

Conference Call & Webcast Details
Cellectar management will host a conference call for investors today, August 13, 2024, beginning at 8:30 am Eastern Time to discuss these results and answer questions. Stockholders and other interested parties may participate in the conference call by dialing 1-800-717-1738. The call will be available via webcast by clicking HERE or on the Events page of the company's website.

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 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.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 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:
Claire LaCagnina
Bliss Bio Health
315-765-1462
clacagnina@blissbiohealth.com

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

Source: Cellectar Biosciences