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Cellecstar Reports Financial Results for Year Ended December 2021 and Provides a Corporate Update

FLORHAM PARK, N.J., March 21, 2022 (GLOBE NEWSWIRE) -- Cellecstar Biosciences, Inc. (NASDAQ: CLRB), a late-stage clinical biopharmaceutical company focused on the discovery, development and commercialization of targeted drugs for the treatment of cancer, today announced financial results for the year ended December 31, 2021 and provided a corporate update.

Fourth Quarter and Recent Corporate Highlights

- Presented data from 11 multiple myeloma patients from the company's ongoing Phase 2 CLOVER-1 study of iopofosine I-131 (iopofosine) at the 63rd ASH Annual Meeting and Exposition. The patients included in this report were triple class refractory had a median 7.2 prior lines of therapy, 50% classified as high risk, showed a mean overall response rate (ORR) of 45.5%, clinical benefit rate (CBR) of 72.7% and disease control rate (DCR) of 100% were observed. A subset of 5 quad/penta drug refractory patients had an ORR of 80%, a CBR and DCR of 100%. Median progression free survival (PFS) for all 11 patients was 3.4 months. Treatment emergent adverse events were mostly limited to bone marrow suppression in line with prior observations. No patients experienced a treatment emergent adverse event of neuropathy, arrhythmia, cardiovascular event, bleeding, ocular toxicities, renal function, alterations in liver enzymes, or infusion-site reactions.
- Announced initial responses from patients in the company's Phase 1 study of iopofosine in children and adolescents with relapsed and refractory high-grade gliomas (HGGs) and soft tissue sarcomas, with patients exhibiting positive changes in various tumor parameters. Patients received doses up to 60 mCi/m² and initial response and tumor uptake were confirmed by further therapeutic responses as evidenced by changes in tumor parameters. These include patients with relapsed HGGs experiencing over 5 months of PFS. The independent data monitoring committee advised that based upon the initial data, the study could initiate the 75 mCi/m² dosing cohort.

"The data presented from our ongoing trials continue to be very encouraging, and we believe iopofosine has the potential to provide a meaningful therapeutic benefit for patients with Waldenstrom's macroglobulinemia (WM) and other treatment refractory B-cell lymphomas. We continue to make significant strides in our clinical trials as we enroll patients in our ongoing pivotal trial in WM and our Phase 2 CLOVER-1 study," said James Caruso, president and CEO of Cellecstar. "We look forward to sharing our planned interim data safety

monitoring assessment from our WM pivotal trial. In the near-term our efforts are supported by a strong balance sheet that will fund our expected clinical and regulatory milestones into the second half of 2023.”

2021 Financial Highlights

- **Cash and Cash Equivalents:** As of December 31, 2021, the company had cash and cash equivalents of \$35.7 million, compared to \$57.2 million at December 31, 2020. Cash used in operating activities during the twelve months ended December 31, 2021 was approximately \$22.6 million. The company believes its cash on hand is adequate to fund basic budgeted operations for at least 12 months from the filing of the 2021 financial statements.
- **Research and Development Expense:** R&D expense for the year ended December 31, 2021 was approximately \$17.6 million, compared to approximately \$10.1 million for year ended December 31, 2020. The overall increase in R&D expense of approximately \$7.5 million was a result of an increase in planned clinical project costs primarily related to the company’s WM pivotal study. Manufacturing and related costs remained relatively consistent year over year.
- **General and Administrative Expense:** G&A expense for year ended December 31, 2021 was \$6.6 million compared to approximately \$5.2 million for the year ended December 31, 2020. The increase of \$1.4 million in G&A costs was primarily a result of an increase in professional fees and insurance, personnel costs and stock-based compensation expense.
- **Net Loss:** The net loss attributable to common stockholders for the year ended December 31, 2021 was (\$24.1) million, or (\$0.43) per share, compared to (\$15.1) million, or (\$0.76) per share, in 2020.

About Collectar Biosciences, Inc.

Collectar Biosciences is focused on the discovery and development of drugs for the treatment of cancer. The company is developing proprietary drugs 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 PDCs that specifically target cancer cells to deliver improved efficacy and better safety as a result of fewer off-target effects. The company’s PDC platform possesses the potential for the discovery and development of the next-generation of cancer-targeting treatments, and it plans to develop PDCs independently and through research and development collaborations.

The company’s product pipeline includes iopofosine, a small-molecule PDC designed to provide targeted delivery of iodine-131 (radioisotope), proprietary preclinical PDC chemotherapeutic programs and multiple partnered PDC assets. The company is currently investigating iopofosine in a global, pivotal expansion cohort in relapsed or refractory WM patients who have received at least two prior lines of therapy, including those who have failed or had a suboptimal response to Bruton tyrosine kinase inhibitors. The WM cohort will enroll up to 50 patients to evaluate the efficacy and safety of iopofosine for marketing approval. The company is also evaluating iopofosine in highly refractory multiple myeloma

patients in its Phase 2 CLOVER-1 study and relapsed/refractory pediatric cancer patients with sarcomas or brain tumors in the Phase 1 CLOVER-2 study.

The Phase 1 pediatric study is an open-label, sequential-group, dose-escalation study to evaluate the safety and tolerability of iopofosine in children and adolescents with relapsed or refractory cancers, including malignant brain tumors, neuroblastoma, sarcomas, and lymphomas (including Hodgkin's lymphoma). The Phase 1 study is being conducted internationally at seven leading pediatric cancer centers.

For more information, please visit www.cellectar.com and www.wmclinicaltrial.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 of the impact of the COVID-19 pandemic. 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, 2020, and our Form 10-K for the year ended December 31, 2021, when filed. 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

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	December 31, 2021	December 31, 2020
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 35,703,975	\$ 57,165,377
Prepaid expenses and other current assets	867,485	774,432
Total current assets	36,571,460	57,939,809
Fixed assets, net	344,491	355,982
Right-of-use asset, net	204,644	282,365
Long-term assets	75,000	75,000
Other assets	6,214	6,214
TOTAL ASSETS	\$ 37,201,809	\$ 58,659,370
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	\$ 3,854,914	\$ 3,443,197
Lease liability	135,449	119,904
Total current liabilities	3,990,363	3,563,101
Lease liability, net of current portion	166,292	301,740
TOTAL LIABILITIES	4,156,655	3,864,841
COMMITMENTS AND CONTINGENCIES (Note 10)		
STOCKHOLDERS' EQUITY:		
Preferred stock, \$0.00001 par value; 7,000 shares authorized; Series C preferred stock: 0 and 215 shares issued and outstanding as of December 31, 2021 and 2020, respectively	—	1,148,204
Series D preferred stock: 111 and 1,519 shares issued and outstanding as of December 31, 2021 and 2020, respectively	1,382,023	18,887,645
Common stock, \$0.00001 par value; 160,000,000 and 80,000,000 shares authorized; 61,101,263 and 45,442,729 shares issued and outstanding as of December 31, 2021 and 2020, respectively	611	454
Additional paid-in capital	182,560,309	161,533,653
Accumulated deficit	(150,897,789)	(126,775,427)
Total stockholders' equity	33,045,154	54,794,529
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 37,201,809	\$ 58,659,370

CELLECTAR BIOSCIENCES, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

	Year Ended December 31,	
	2021	2020
COSTS AND EXPENSES:		
Research and development	\$ 17,586,469	\$ 10,140,681
General and administrative	6,544,811	5,149,668
Total costs and expenses	24,131,280	15,290,349
LOSS FROM OPERATIONS	(24,131,280)	(15,290,349)
OTHER INCOME:		
Other income	6,634	—
Gain on extinguishment of debt	—	185,280
Interest income, net	2,284	10,897
Total other income, net	8,918	196,177
NET LOSS	\$ (24,122,362)	\$ (15,094,172)
BASIC AND DILUTED NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS PER COMMON SHARE	\$ (0.43)	\$ (0.76)
SHARES USED IN COMPUTING BASIC AND DILUTED NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS PER COMMON SHARE	55,515,727	19,812,659



Source: Cellestar Biosciences