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Cellecstar Reports Third Quarter 2019 Financial Results and Provides a Corporate Update

FLORHAM PARK, N.J., Nov. 12, 2019 (GLOBE NEWSWIRE) -- Cellecstar Biosciences, Inc. (NASDAQ: CLRB), a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of drugs for the treatment of cancer, today announced financial results for the third quarter ended September 30, 2019, and provided a corporate update.

Third Quarter and Recent Corporate Highlights

- Presented data from the DLBCL cohort in the company's Phase 2 CLOVER-1 study of CLR 131 in relapsed or refractory select B-cell malignancies at the European Society for Medical Oncology (ESMO) Congress 2019. The oral presentation featured data from 6 subjects, who received up to a single 30-minute intravenous (IV) dose of 25mCi/m² of CLR 131. Data showed durable responses with a mean of 312 days (ongoing) and includes a 33% overall response rate (ORR), a 16.6% complete response rate (CR) and a 50% clinical benefit rate (CBR). CLR 131 had activity in both DLBCL subtypes (germinal center B-cell and activated B-cell) and patients with highly resistant/aggressive cytogenetics (known as "dual hit"). All patients enrolled in the study received an average of 3 prior lines of systemic therapy, 5 of 6 patients were refractory to at least one prior line of therapy.
- Presented a poster entitled: "[Phospholipid ether delivery vehicle shows specificity for a broad range of tumor cells and provides a novel and improved approach for targeted therapy](#)," at the Cancer Research UK-AACR Joint Conference on Engineering and Physical Sciences in Oncology. The poster featured data demonstrating that phospholipid ether drug conjugates (PDCs) were capable of delivering small molecule cytotoxins selectively to tumor cells and were well tolerated in animal models.
- Presented [data from cohort 6 of its Phase 1 dose escalation study of CLR 131 in relapsed or refractory MM, in a late breaker poster](#) at the 17th International Myeloma Workshop. Data highlighted 4 subjects in cohort 6 who received a fractionated dose of 37.5mCi/m². Subjects in this cohort achieved a 50% ORR, with two subjects achieving partial responses (PR) and two subjects achieving minimal responses (39% and 48% reduction in M protein). CLR 131 was deemed safe and tolerated in all subjects with cytopenias being the only reported treatment emergent adverse events of grade 3 or higher. The majority (75%) of the subjects had high risk cytogenetics where median bone marrow plasma cell involvement was 25%. Patients' median age was 72.5 and they averaged 5 prior systemic therapies, with one patient being dual class refractory, one being quad-refractory, and two penta-refractory.

- Received a second FDA Fast Track Designation for CLR 131 for relapsed/refractory DLBCL. CLR 131 is currently being evaluated in patients with select B-cell lymphomas, including MM and DLBCL in the Phase 2 CLOVER-1 clinical study.
- Successfully completed the first cohort of malignant brain tumor patients in the ongoing Phase 1 study of CLR 131 in children and adolescents with select solid tumors, lymphoma, and malignant brain tumors, including relapsed or refractory neuroblastoma, rhabdomyosarcoma, Ewing's sarcoma, and osteosarcoma. The independent Data Monitoring Committee determined the 15mCi/m² single dose to be safe and tolerated and recommended the company progress to a second cohort utilizing a 30mCi/m² single dose of CLR 131.
- Received orphan drug designation from the European Commission for CLR 131 in the treatment of multiple myeloma. The designation provides ten years of market exclusivity for the treatment of multiple myeloma.
- Strengthened the management team with the appointment of Dov Elefant, Chief Financial Officer.

"We continue to effectively manage our financial resources to fund our budgeted operations into 2021 while advancing multiple clinical and preclinical programs. The third quarter proved to be highly productive for Cellectar with CLR 131 receiving FDA Fast Track Designation for DLBCL and Orphan Drug Designation for multiple myeloma from the European Commission. In addition, we presented incremental positive data at international scientific conferences," said Jim Caruso, CEO of Cellectar. "We continue to anticipate data from our ongoing clinical studies by the end of this year and in early 2020."

Third Quarter and Nine Months Summary of Financial Results

Cash and Cash Equivalents: As of September 30, 2019, cash and cash equivalents were approximately \$13.3 million compared to \$13.3 million as of December 31, 2018. The company believes the cash balance is adequate to fund its budgeted operations into the first quarter 2021. Cash used in operating activities was approximately \$9.0 million during the nine months ended September 30, 2019 as compared to \$8.7 million used during the nine months ended September 30, 2018.

Research and Development Expense: Research and development (R&D) expense for the three months ended September 30, 2019 was \$2.7 million compared to \$2.0 million in the three months ended September 30, 2018. The cumulative R&D spending for the first nine months of 2019 was \$6.8 million as compared to \$5.8 million for the first nine months of 2018. The majority of the company's R&D spend for year-to-date 2019 was dedicated to the start-up costs and support of our pediatric study. Clinical project costs and manufacturing expenses were \$2.1 million and \$5.0 million for the three and nine months ending September 30, 2019, respectively.

General and Administrative Expense: General and administrative (G&A) expense for the three months ended September 30, 2019 was approximately \$1.3 million compared to approximately \$1.1 million in the three months ended September 30, 2018. The cumulative G&A spending for the first nine months of 2019 were of \$4.0 million as compared to \$3.6 million for the first nine months of 2018.

Net Loss: Net loss attributable to common stockholders for the three months ended September 30, 2019 was \$(3.9) million, or a loss of \$(0.42) per diluted share, compared to a net loss of \$(5.3) million, or a loss of \$(1.65) per diluted share, in the three months ended September 30, 2018. Net loss attributable to common stockholders for the nine months ended September 30, 2019 was \$(10.7) million, or a loss of \$(1.51) per diluted share, compared to a net loss of \$(11.7) million, or a loss of \$(5.29) per diluted share, in the nine months ended September 30, 2018.

About CLR 131

CLR 131 is a small-molecule, targeted Phospholipid Drug Conjugate™ (PDC) designed to deliver cytotoxic radiation directly to cancer cells, while limiting exposure to healthy cells. CLR 131 is the company's lead product candidate and is currently being evaluated in a Phase 2 study in B-cell lymphomas, and two Phase 1 dose-escalating clinical studies, one in multiple myeloma and one in pediatric solid tumors and lymphoma. CLR 131 was granted Orphan Drug designation for the treatment of multiple myeloma, and was granted Orphan Drug and Rare Pediatric Disease designations for the treatment of neuroblastoma, rhabdomyosarcoma, Ewing's sarcoma and osteosarcoma.

About Cellectar Biosciences, Inc.

Cellectar Biosciences is focused on the discovery, development and commercialization of drugs for the treatment of cancer. The company is developing proprietary drugs independently and through research and development (R&D) 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, delivering 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 lead PDC therapeutic, CLR 131, is currently in three clinical studies - one Phase 2 study, and two Phase 1 studies. The Phase 2 clinical study (CLOVER-1) is in relapsed/refractory (R/R) B-cell malignancies, including multiple myeloma (MM), chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL), lymphoplasmacytic lymphoma (LPL), marginal zone lymphoma (MZL), mantle cell lymphoma (MCL), and diffuse large B-cell lymphoma (DLBCL). The company is also conducting a Phase 1 dose escalation study in patients with R/R multiple myeloma (MM) and a Phase 1 study in pediatric solid tumors and lymphomas.

The company's product pipeline also includes one preclinical PDC chemotherapeutic program (CLR 1900) and several 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. 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 CLR 131, the ability to attract and retain partners for our technologies, the identification of lead compounds, the successful preclinical development thereof, the completion of clinical studies, the FDA review process and other government regulation, 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, 2018 and Form 10-Q for the quarters ended March 31, 2019, June 30, 2019 and September 30, 2019. 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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CELLECTAR BIOSCIENCES, INC. CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2019 (Unaudited)	December 31, 2018
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 13,301,612	\$ 13,255,616
Restricted cash	—	55,000
Prepaid expenses and other current assets	1,450,364	641,218
Total current assets	14,751,976	13,951,834
Fixed assets, net	461,940	543,339
Right-of-use asset, net	363,861	—
Long-term assets	75,000	540,823
Other assets	6,214	18,086
TOTAL ASSETS	\$ 15,658,991	\$ 15,054,082
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	\$ 2,875,342	\$ 1,543,819
Derivative liability	—	43,000
Capital lease obligations, current portion	—	2,213
Deferred rent	—	33,090

Lease liability	102,597	—
Total current liabilities	<u>2,977,939</u>	<u>1,622,122</u>
LONG-TERM LIABILITIES:		
Deferred rent, less current portion	—	170,999
Lease liability	<u>449,632</u>	<u>—</u>
Total long-term liabilities	<u>449,632</u>	<u>170,999</u>
TOTAL LIABILITIES	<u>3,427,571</u>	<u>1,793,121</u>
COMMITMENTS AND CONTINGENCIES (Note 7)		
STOCKHOLDERS' EQUITY:		
Series C preferred stock: 215 and 473 issued and outstanding as of September 30, 2019 and December 31, 2018, respectively	1,148,204	2,526,049
Common stock, \$0.00001 par value; 80,000,000 shares authorized; 9,386,703 and 4,732,387 shares issued and outstanding as of September 30, 2019 and December 31, 2018, respectively	94	47
Additional paid-in capital	119,384,474	108,323,208
Accumulated deficit	<u>(108,301,352)</u>	<u>(97,588,343)</u>
Total stockholders' equity	<u>12,231,420</u>	<u>13,260,961</u>
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 15,658,991	\$ 15,054,082

CELLECTAR BIOSCIENCES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(UNAUDITED)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
COSTS AND EXPENSES:				
Research and development	\$ 2,703,831	\$ 1,995,571	\$ 6,821,775	\$ 5,798,526
General and administrative	<u>1,260,048</u>	<u>1,091,921</u>	<u>3,972,275</u>	<u>3,647,412</u>
Total costs and expenses	<u>3,963,879</u>	<u>3,087,492</u>	<u>10,794,050</u>	<u>9,445,938</u>
LOSS FROM OPERATIONS	<u>(3,963,879)</u>	<u>(3,087,492)</u>	<u>(10,794,050)</u>	<u>(9,445,938)</u>
OTHER INCOME:				
Gain on revaluation of derivative warrants	46,000	66,000	43,000	19,050
Interest income, net	<u>14,072</u>	<u>6,558</u>	<u>38,041</u>	<u>15,440</u>
Total other income, net	<u>60,072</u>	<u>72,558</u>	<u>81,041</u>	<u>34,490</u>
NET LOSS	(3,903,807)	(3,014,934)	(10,713,009)	(9,411,448)
DEEMED DIVIDEND ON PREFERRED STOCK	—	(2,241,795)	—	(2,241,795)
NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS	<u>\$ (3,903,807)</u>	<u>\$ (5,256,729)</u>	<u>\$ (10,713,009)</u>	<u>\$ (11,653,243)</u>

BASIC AND DILUTED NET LOSS PER COMMON SHARE	\$	(0.42)\$	(1.65)\$	(1.51)\$	(5.29)
SHARES USED IN COMPUTING BASIC AND DILUTED NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS PER COMMON SHARE		9,386,703	3,184,856	7,098,285	2,204,554



Source: Cellestar Biosciences