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Cellectar Reports Third Quarter 2018 Financial Results and Provides Business Update

FLORHAM PARK, N.J., Nov. 13, 2018 (GLOBE NEWSWIRE) -- Cellectar Biosciences, Inc. (Nasdaq: CLRB) ("Cellectar" or "the Company"), a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of drugs for the treatment of cancer, today reported financial results for the three and nine months ended September 30, 2018 and provided a business update.

Third Quarter 2018 and Recent Highlights

- Announced that the U.S. Food and Drug Administration has granted an exemption to the Import Alert for CLR 131 in all hematology indications, effective immediately. The company continues to work with the appropriate division of the FDA to obtain an exemption for its pediatric program, evaluating CLR 131 in multiple childhood cancers with significant unmet medical need.

- Reported positive results from the ongoing Phase 1 clinical trial evaluating CLR 131 for the treatment of relapsed/refractory ("R/R") multiple myeloma ("MM").
    - Announced that cohort 5 fractionated dosing results demonstrated nearly 50% further reduction in M-protein than seen in cohort 4 and an improvement in tolerability and safety despite patients averaging five lines of prior therapy. Unlike previous cohorts that used single doses, cohort 5 patients received a fractionated, two-dose CLR-131 regimen of 15.625 mCi/m^2 administered one week apart. The Company announced plans to initiate a sixth cohort using a fractionated dose regimen of 18.75 mCi/m^2.
    - Announced updated pooled, single-dose (cohorts 1-4) overall survival ("OS") of 19.4 months and reported that median OS had not been reached. All 15 patients from the single-dose cohorts received an average of five lines of multidrug therapy.

- Reported positive interim data from the ongoing Phase 2 clinical trial evaluating CLR 131 for the treatment of R/R hematologic malignancies.
    - Announced that the diffuse large B-cell lymphoma cohort showed a 33% overall response rate, approximately 17% complete response rate and a 50% clinical benefit response rate.
    - Provided a case study from the CLR 131 Phase 2 clinical trial for a patient with advanced Waldenstrom macroglobulinemia who experienced a 94% reduction in tumor burden and complete resolution in four of five targeted tumor masses.

- Received orphan drug designations ("ODD") and rare pediatric disease designations

("RPDD") from the U.S. Food and Drug Administration ("FDA") for CLR 131 to treat pediatric osteosarcoma and Ewing's sarcoma.
    - Cellectar has received an ODD and RPDD for CLR 131 to treat rhabdomyosarcoma, neuroblastoma, Ewing's sarcoma and osteosarcoma and plans to evaluate all four indications in the Phase 1 pediatric clinical trial.

- Closed an underwritten public offering, realizing net proceeds of approximately $15.0 million.

"Yesterday, we were pleased to share that the FDA granted an Import Alert exemption for our CLR 131 hematology programs which allows for immediate patient enrollment in our Phase 1 and 2 clinical trials for relapsed/refractory multiple myeloma and hematology malignancies" said James Caruso, president and CEO of Cellectar Biosciences. "In this past quarter we announced positive data from both our Phase 1 and 2 hematology trials including results from the first fractionated dose cohort of our Phase 1 trial and an increase in patient overall survival in our single-dose cohorts to 19.4 months and counting. We were similarly pleased to report positive interim data observed from the Phase 2 trial for DLBCL and exciting efficacy results from a challenging LPL case study."

2018 Third Quarter and Nine Month Financial Results

Research and development expenses for the third quarter of 2018 were $2.0 million, compared with $2.3 million for the third quarter of 2017. Research and development expenses for the first nine months of 2018 were $5.8 million, compared with $6.4 million for the first nine months of 2017. The year-over-year decreases are attributable to lower clinical project costs and lower manufacturing-related costs. Research and development expenses for the three and nine months ended September 30, 2018 included a charge of approximately $0.3 million in in connection with the decommissioning of the Company's former manufacturing facility.

General and administrative expenses for the third quarter of 2018 were $1.1 million, compared with $1.2 million for the third quarter of 2017, and were $3.6 million for the first nine months of 2018, compared with $3.1 million for the first nine months of 2017. The year-over-year increases are attributable to higher consulting expenses.

The net loss attributable to common stockholders for the third quarter of 2018 was $5.3 million, or $1.65 per share, compared with a net loss attributable to common stockholders for the third quarter of 2017 of $3.5 million, or $2.58 per share. The net loss attributable to common stockholders for the first nine months of 2018 was $11.7 million, or $5.29 per share, compared with a net loss attributable to common stockholders for the first nine months of 2017 of $9.5 million, or $7.30 per share.

Cash and cash equivalents as of September 30, 2018 were $16.4 million, compared with $10.0 million as of December 31, 2017. During the third quarter the Company raised net proceeds of approximately $15.0 million in connection with a public offering. Consistent with prior guidance, the Company believes its cash on hand is adequate to fund operations into the first quarter of 2020.

About Cellectar Biosciences, Inc.
Cellectar Biosciences is focused on the discovery, development and commercialization of drugs for the treatment of cancer. The Company plans to develop proprietary drugs independently and through research and development ("R&D") collaborations. The core drug development strategy is to leverage our PDC platform to develop therapeutics that specifically target treatment to cancer cells. Through R&D collaborations, the Company's strategy is to generate near-term capital, supplement internal resources, gain access to novel molecules or payloads, accelerate product candidate development and broaden our proprietary and partnered product pipelines.

The Company's lead PDC therapeutic, CLR 131, is in a Phase 1 clinical study in patients with R/R MM and a Phase 2 clinical study in R/R MM and a range of B-cell malignancies. The Company plans to initiate a Phase 1 study with CLR 131 in pediatric solid tumors and lymphoma and is planning a second Phase 1 study in combination with external beam radiation for head and neck cancer. The Company's product pipeline also includes two preclinical PDC chemotherapeutic programs (CLR 1700 and 1900) and partnered assets include PDCs from multiple R&D collaborations.

For more information please visit www.cellectar.com.

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 trials, 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, 2017 and our Form 10-Q for the quarterly period ended June 30, 2018. 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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