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Cellectar Reports 2018 Second Quarter Financial Results and Provides Business Update

MADISON, Wis., Aug. 10, 2018 (GLOBE NEWSWIRE) -- Cellectar Biosciences (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 six months ended June 30, 2018 and provided a business update.

Second quarter 2018 and recent highlights:

- Closed a public offering raising gross proceeds of $16.56 million including the full exercise of the underwriters’ over-allotment option.
- Received orphan drug designations and rare pediatric disease designations from the U.S. Food and Drug Administration (FDA) for CLR 131 to treat rhabdomyosarcoma and neuroblastoma, both rare pediatric cancers.
- Received orphan drug designation from the FDA for CLR 131 to treat Ewing’s sarcoma, a rare pediatric cancer.
- Expanded patient enrollment in the relapsed/refractory (R/R) diffuse large B-cell lymphoma (DLBCL) cohort of the company’s Phase 2 clinical trial of CLR 131 and reported interim results showing a 33% overall response rate and a 50% clinical benefit response.
- Provided an update on a patient with advanced Waldenstrom macroglobulinemia in the CLR 131 Phase 2 trial who experienced a 94% reduction in tumor burden and complete resolution in four of five targeted tumor masses.
- Entered into a collaboration with Orano Med for the development of novel PDCs utilizing Orano Med’s unique alpha emitter, lead-212 (^{212}Pb), conjugated to Cellectar’s phospholipid ether (PLE); the companies intend to evaluate the new Phospholipid Drug Conjugates (PDC™) in up to three oncology indications.
- Strengthened intellectual property with the issuance of a U.S. patent entitled “Alkylphosphocholine analogs for multiple myeloma imaging and therapy” covering the use of CLR 131 in multiple (MM), the issuance of a U.S. patent entitled “Ether and Alkyl Phospholipid Compounds for Treating Cancer and Imaging Detection of Cancer Stem Cells” enhancing coverage for the use of CLR 131 as a treatment for various cancers and cancer stem cells. In addition, the company was issued a composition-of-matter patent for CLR 131 in Japan.

- Presented two late-breaking poster presentations at the AACR Annual Meeting that highlighted the potential benefits of fractionated dosing regimens of CLR 131 and the ability of the company's PDCs to provide improved targeting of tumor cells and the intracellular trafficking of these molecules.

CLR 131 Supply Update

On August 7, 2018, the Company was informed by Centre for Probe Development and Commercialization ("CPDC"), the Company's sole supplier of CLR 131, that it is subject to an Import Alert 66-40 (the "Import Alert") by the United States Food and Drug Administration ("FDA"). While the basis for the Import Alert was not related to CLR 131, or CPDC's production facility associated with CLR 131, CPDC informed the Company on August 8, 2018 that CPDC would not be able to supply CLR 131 to the Company until the Import Alert is lifted or alternative agreements are reached with the FDA. The Company intends to work with CPDC to resolve this issue as soon as practical. As a result of the supply disruption, the Company expects delays in enrollment in its ongoing clinical trials. At this time, the Company is not able to assess the extent of the delays or what impact the supply disruption will have on the Company, but the inability of CPDC to supply CLR 131 on a prolonged basis would result in further delayed patient enrollment in current and planned clinical trials for CLR 131.

"The second quarter was highly productive for the company as we executed on our corporate plan and achieved multiple clinical, regulatory and financial milestones. However, due to our supplier being placed on an import alert for activities unrelated to CLR 131 we are experiencing an unexpected interruption in drug supply and are working to resolve this as rapidly as possible" said James Caruso, president and CEO of Cellectar Biosciences. "On the clinical front, we announced positive DLBCL interim data from our Phase 2 trial and expanded the cohort. We received important FDA designations that underscore the potential of our rare pediatric disease portfolio. Also, in late July we raised capital that materially strengthened our balance sheet which we believe provides a runway into the first quarter of 2020".

2018 Second Quarter and First Half Financial Results

Research and development expenses for the second quarter of 2018 were $1.7 million, compared with $2.2 million for the second quarter of 2017. Research and development expenses for the first half of 2018 were $3.8 million, compared with $4.0 million for the first half of 2017. The year-over-year decrease in both periods is attributable to lower clinical project costs and manufacturing-related costs.

General and administrative expenses for the second quarter of 2018 were $1.2 million, compared with $1.0 million for the second quarter of 2017, and were $2.6 million for the first half of 2018, compared with $2.0 million for the first half of 2017. The year-over-year increase in both periods is attributable to higher consulting, legal and marketing expenses, as well as one-time personnel costs incurred in connection with the decision to outsource manufacturing.

The net loss attributable to common stockholders for the second quarter of 2018 was $2.9 million, or $1.69 per share, compared with a net loss attributable to common stockholders for the second quarter of 2017 of $3.1 million, or $2.32 per share. The net loss attributable to common stockholders for the first half of 2018 was $6.4 million, or $3.75 per share,

compared with a net loss attributable to common stockholders of $6.0 million, or $4.72 per share, for the first half of 2017.

Cash and cash equivalents as of June 30, 2018 were $4.2 million, compared with $10.0 million as of December 31, 2017. As noted above, subsequent to the close of the second quarter the company raised gross proceeds of $16.56 million from an underwritten public offering. The Company expects net proceeds from this financing, after deducting underwriting discounts and commissions and estimated offering expenses, will be approximately $14.9 million. The Company's pro forma cash balance at June 30, 2018 was approximately $19.1 million.

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 relapsed or refractory (R/R) MM and a Phase 2 clinical study in R/R MM and a range of B-cell malignancies. The company is currently initiating 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 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. 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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