
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Date of Report: February 25, 2019
(Date of earliest event reported)

CELLECTAR BIOSCIENCES, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

1-36598
(Commission
File Number)

04-3321804
(IRS Employer
Identification Number)

100 Campus Drive, Florham Park, New Jersey 07932
(Address of principal executive offices)

(608) 441-8120
(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

ITEM 7.01 REGULATION FD DISCLOSURE

On February 25, 2019, we issued a press release announcing additional positive top-line results from our ongoing Phase 2 clinical study of CLR 131, our lead product candidate. A copy of the press release is furnished as Exhibit 99.1 and is incorporated by reference herein.

ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS

(d) Exhibits

Number	Title
<u>99.1</u>	<u>Press release dated February 25, 2019, titled “Celleckta Reports Positive Top-line Response Rate of 30% from R/R Multiple Myeloma Cohort in Ongoing Phase 2 Study of CLR 131”</u>

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: February 25, 2019

CELLECTAR BIOSCIENCES, INC.

By: /s/ Brian M. Posner

Name: Brian M. Posner

Title: Chief Financial Officer



Collectar Reports Positive Top-line Response Rate of 30% from R/R Multiple Myeloma Cohort in Ongoing Phase 2 Study of CLR 131

Company's lead product candidate previously demonstrated positive top-line results from the diffuse large B-cell lymphoma cohort of this study

Dosing in multiple tumor types is ongoing; Collectar intends to report additional data this year

FLORHAM PARK, N.J., Feb. 25, 2019 (GLOBE NEWSWIRE) -- Collectar 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 additional positive top-line results from its ongoing Phase 2 clinical study of CLR 131, the company's lead product candidate. In the relapse refractory multiple myeloma cohort, CLR 131 achieved a 30% overall response rate in the first 10 evaluable patients. All patients reported here were administered one, single 30-minute infusion of 25mCi/m², which is approximately 25% less drug than the newly adopted fractionated dose of 15.625mCi/m² on days 1 and 8. The company previously announced an overall response rate of 33% in patients with R/R diffuse large B-cell lymphoma (DLBCL) also receiving the single, 25mCi/m² dose of CLR 131.

In the R/R multiple myeloma cohort, one patient achieved a very good partial response (a 90% or greater decrease in surrogate marker) and two had partial responses (a 50% to 89% decrease in surrogate marker) as defined by the International Myeloma Working Group. The patients in this cohort averaged five lines of systemic therapies prior to treatment with CLR 131. All patients in this cohort demonstrated at least stable disease. Collectar continues to dose additional patients at higher fractionated doses, and the company intends to announce further data from additional cohorts later this year.

"We are encouraged by the 30% response rate and continued positive results in our ongoing Phase 2 study of CLR 131," said James Caruso, president and CEO of Collectar. "This represents the second cohort of patients who have demonstrated encouraging responses to our lead drug candidate while receiving sub-optimal single doses. We look forward to the availability of additional data this year and will continue to aggressively enroll patients and dose at higher levels that have the potential to generate increased efficacy."

Natalie Callender, M.D., Associate Professor of Medicine, Director University of Wisconsin Carbone Cancer Center Myeloma Clinical Program and a lead investigator added, "The results from this cohort are impressive. Historically, patients receiving 4th line chemotherapy treatment show a 15% response rate, and patients receiving 5th line chemotherapy show an 8% response rate, whether dosed as monotherapy or in combination. The high response rates, combined with a significant reduction in surrogate markers of disease with a single, one-time infusion of CLR 131, have the potential to make this drug attractive to patients in later lines of therapy. Additionally, the ability of CLR 131 to achieve a minimum of stable disease in 100% of subjects dosed with minimal hematologic toxicities in the study to date is meaningful for these late-line patients."

About the Phase 2 Study of CLR 131

The Phase 2 study is being conducted in approximately 10 leading cancer centers in the United States in patients with relapsed or refractory B-cell hematologic cancers. The hematologic cancers being studied in the trial include multiple myeloma (MM), chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL), lymphoplasmacytic lymphoma (LPL), marginal zone lymphoma (MZL), mantle cell lymphoma (MCL), and potentially diffuse large B-cell lymphoma (DLBCL).

The study's primary endpoint is clinical benefit response (CBR), with additional endpoints of overall response rate (ORR), progression free survival (PFS), median overall survival (OS) and other markers of efficacy following a single 25.0 mCi/m² dose of CLR 131, with the option for a second 25.0 mCi/m² dose approximately 75-180 days later.

Based on the performance results from Cohort 5 of our Phase 1 study in patients with relapse or refractory MM, reviewed below, the Company has modified the dosing regimen of this trial to a fractionated dose of 15.625 mCi/m² administered on day 1 and day 8.

In addition to the CLR 131 infusion(s), MM patients will receive 40 mg oral dexamethasone weekly for up to 12 weeks. Efficacy responses will be determined by the latest International Multiple Myeloma Working Group criteria. Efficacy for all lymphoma patients will be determined according to Lugano criteria. Cellectar was awarded approximately \$2 million in non-dilutive grant funding from the National Cancer Institute to help fund the trial. More information about the trial, including eligibility requirements, can be found at www.clinicaltrials.gov, reference NCT02952508.

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 to 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, as well as a second Phase 1 study in combination with external beam radiation for head and neck cancer.

The company's product pipeline also includes one preclinical PDC chemotherapeutic program (CLR 1900) and partnered assets including 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 September 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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