
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: January 7, 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 January 7, 2019, we issued a press release announcing median overall survival (mOS) in Cohorts 1-4 of our ongoing Phase 1 clinical trial evaluating CLR 131 for the treatment of relapsed/refractory (R/R) multiple myeloma (MM). 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 January 7, 2019, titled “Cellestar Provides Update on Phase 1 Trial of CLR 131 in Relapsed/Refractory Multiple Myeloma”</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: January 7, 2019

CELLECTAR BIOSCIENCES, INC.

By: /s/ Brian M. Posner

Name: Brian M. Posner

Title: Chief Financial Officer

Collectar Provides Update on Phase 1 Trial of CLR 131 in Relapsed/Refractory Multiple Myeloma

Median overall survival of 22.0 months observed in Cohorts 1-4

FLORHAM PARK, N.J. (January 7, 2019) – Collectar Biosciences (Nasdaq: CLRB), a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of drugs for the treatment of cancer, today announced median overall survival (mOS) in Cohorts 1-4 of the company's ongoing Phase 1 clinical trial evaluating CLR 131 for the treatment of relapsed/refractory (R/R) multiple myeloma (MM). The results showed mOS of 22.0 months among 15 patients, all of whom were heavily pretreated, averaging five prior lines of systemic therapy. Each patient in Cohorts 1-4 of this dose-escalation study received a single 30-minute infusion of CLR 131.

All patients enrolled in Cohorts 1 through 4 were previously treated with both proteasome inhibitors and immunomodulatory drugs, and experienced disease progression with greater than one-third dual refractory. While no head-to-head studies have been conducted between CLR 131 and other therapies in this heavily pretreated population, for background purposes, a 2016 article published in the journal *Bone Marrow Transplantation* refractory to both proteasome inhibitors and immunomodulatory drugs achieve mOS of 9 months.¹ Additionally, mOS for R/R MM patients receiving treatment in third line averages approximately 12 months of survival, including several recently approved drugs.^{2,3}

"The median overall survival of 22 months in this heavily pretreated patient population is very encouraging. These are patients with limited therapeutic options and, unfortunately, face poor prognoses," said James Caruso, president and chief executive officer of Collectar Biosciences. "The convenience afforded by CLR 131 delivered in only one or two doses as currently administered in our ongoing hematology studies makes it a far less intrusive regimen than other treatments that must be administered at regular dosing intervals. We believe extending mOS with a more patient-friendly dosing regimen provides both a distinctive product profile and the potential to provide beneficial patient outcomes even in later lines of therapy."

1. R.F Cornell and A.A. Kassim (2016). Evolving paradigms in the treatment of relapsed/refractory multiple myeloma: increased options and increased complexity. *Journal of Bone Marrow Transplantation*

2. Jurczynszyn et al (2014). New drugs in multiple myeloma – role of carfilzomib and pomalidomide. *Contemporary Oncology*

3. Dimopolous et al (2016). Safety and efficacy of pomalidomide plus low-dose dexamethasone in STRATUS (MM-010): a phase 3b study in refractory multiple myeloma. *Blood Review*

About the Phase 1 R/R MM Trial

The objective of this multicenter, open-label, Phase 1 dose-escalation study is the characterization of safety and tolerability of CLR 131 administered either as a single-dose or split-dose, 30-minute infusion(s) in patients with R/R MM. In Cohorts 1-4, patients received doses of 12.5 mCi/m² up to 31.25 mCi/m². All doses were deemed safe and well tolerated by an independent Data Monitoring Committee (DMC). All 15 patients were heavily pretreated, receiving an average of five previous lines of multidrug therapy including anti-CD38, immunomodulating drugs and proteasome inhibitors. All patients were relapsed or refractory to at least one proteasome inhibitor and IMiD. Most patients presented with advanced stage 2 or 3 disease and 67% had previously received at least one stem cell transplant.

Data from Cohort 5, released in August 2018, evaluated a split or fractionated dose of 31.25 mCi/m² for tolerability and safety. The dosing schedule provided higher average drug exposure but lower peak serum levels than non-fractionated dosing, potentially reducing adverse events and improving efficacy. The DMC determined the fractionated dose used in Cohort 5 to be safe and well tolerated, and recommended advancement to a higher dose cohort.

In December 2018, Cohort 6 was initiated. Cohort 6 will evaluate up to four patients with each receiving two doses of 18.75 mCi/m² of CLR 131 administered one week apart. This fractionated dosing regimen will result in each patient being treated with a total of approximately 75.0 mCi of CLR 131, representing an increase in average total exposure of greater than 15% over Cohort 5.

About CLR 131

CLR 131 is Cellectar's investigational radioiodinated phospholipid ether-drug conjugate (PDC™) therapy that exploits the tumor-targeting properties of the company's proprietary phospholipid ether (PLE) and PLE analogs to selectively deliver radiation to malignant tumor cells, thus minimizing radiation exposure to normal tissues. CLR 131 is in a Phase 2 clinical study in R/R MM and a range of B-cell malignancies, and a Phase 1 clinical study in patients with R/R MM exploring fractionated dosing.

The objective of the multicenter, open-label, Phase 1 dose-escalation study is the characterization of safety and tolerability of CLR 131 in patients with R/R MM. Patients in Cohorts 1-4 received single doses of CLR 131 ranging from 12.5 mCi/m² to 31.25 mCi/m², as well as a fractionated dose of 15.625 mCi/m² given twice over seven days in Cohort 5. Cohort 6 will evaluate up to four patients with each receiving two doses of 18.75 mCi/m² of CLR 131 administered one week apart. This fractionated dosing regimen will result in each patient being treated with a total of approximately 75.0 mCi of CLR 131, representing an increase in average total exposure of greater than 15% over Cohort 5. All study doses and regimens have been deemed safe and well tolerated by an independent DMC. 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.

About Phospholipid Drug Conjugates™

Collectar's product candidates are built upon a patented delivery and retention platform that utilizes optimized PDCs to target cancer cells. The PDC platform selectively delivers diverse oncologic payloads to cancerous cells and cancer stem cells, including hematologic cancers and solid tumors. This selective delivery allows the payloads' therapeutic window to be modified, which may maintain or enhance drug potency while reducing the number and severity of adverse events. This platform takes advantage of a metabolic pathway utilized by all tumor cell types in all cell cycle stages. Compared with other targeted delivery platforms, the PDC platform's mechanism of entry does not rely upon specific cell surface epitopes or antigens. In addition, PDCs can be conjugated to molecules in numerous ways, thereby increasing the types of molecules selectively delivered. Collectar believes the PDC platform holds potential for the discovery and development of the next generation of cancer-targeting agents.

About Collectar Biosciences, Inc.

Collectar 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 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.collectar.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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