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

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**FORM 8-K**

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**CURRENT REPORT**

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

Date of Report: March 19, 2019
(*Date of earliest event reported*)

# CELLECTAR BIOSCIENCES, INC.

(*Exact name of registrant as specified in its charter*)

| **Delaware** | **1-36598** | **04-3321804** |
|---|---|---|
| *(State or other jurisdiction of incorporation)* | *(Commission File Number)* | *(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 March 19, 2019, we issued a press release announcing that the U.S. Food and Drug Administration (FDA) has granted an exemption to the Import Alert placed on the Centre for Probe Development and Commercialization (CPDC) for the use of CLR 131 in connection with our pediatric IND. A copy of the press release is furnished as Exhibit 99.1 and is incorporated by reference herein.

**ITEM 8.01 OTHER EVENTS**

As described above, the FDA notified us that it has granted an exemption to the Import Alert placed on CPDC for the use of CLR 131 in connection with our pediatric IND. This exemption will allow Cellectar to immediately begin enrolling patients in our Phase 1 pediatric study for the treatment of select relapsed or refractory solid tumors including neuroblastoma, lymphomas and malignant brain tumors.

On November 12, 2018, we announced that we had received FDA exemption to the CPDC Import Alert for our hematology IND. In February 2019, we announced that a single, 25mCi/m2, 30-minute intravenous infusion of CLR 131 in the first 10 patients with R/R MM were assessed. We are currently enrolling patients in our Phase 1 and Phase 2 multiple myeloma and select B-cell lymphoma studies of CLR 131.

**ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS**

(d) Exhibits

| Number | Title |
|---|---|
| 99.1 | Press release dated March 19, 2019, titled "FDA Grants Exemption to Import Alert for Cellectar's CLR 131 in Pediatric and Adolescent Patients" |

**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: March 19, 2019

**CELLECTAR BIOSCIENCES, INC.**

By: */s/ Charles T. Bernhardt*
Name: Charles T. Bernhardt
Title: Interim Chief Financial Officer

**Exhibit 99.1**

# FDA Grants Exemption to Import Alert for Cellectar's CLR 131 in Pediatric and Adolescent Patients

*Company to initiate Phase 1 study in pediatric and adolescent patients with select relapsed or refractory solid tumors, lymphomas and malignant brain tumors*

FLORHAM PARK, N.J., Mar. 19, 2019 -- Cellectar 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 that the U.S. Food and Drug Administration (FDA) has granted an exemption to the Import Alert placed on the Centre for Probe Development and Commercialization (CPDC) for the use of CLR 131 in connection with the company's pediatric IND. This exemption will allow Cellectar to immediately begin enrolling patients in its Phase 1 pediatric study for the treatment of select relapsed or refractory solid tumors including neuroblastoma, lymphomas and malignant brain tumors.

Cellectar is already enrolling patients in its Phase 1 and Phase 2 multiple myeloma and select B-cell lymphoma studies of CLR 131 after having received FDA exemption to the CPDC Import Alert in November 2018 for its hematology IND.

"We are grateful that the FDA has granted this additional exemption for CLR 131, which allows us to immediately initiate our pediatric clinical study in children battling life-threatening cancers," said James Caruso, president and CEO of Cellectar. "These patients have a very poor prognosis and low rates of survival as a result of limited effective treatment options. Based on our preclinical and ongoing clinical studies, we are optimistic that CLR 131 has the potential to provide a meaningful treatment option for children suffering from cancers with high unmet medical needs."

**About the Phase 1 Pediatric Study of CLR 131**
The Phase 1 pediatric study will be an open-label, sequential-group, dose-escalation study to evaluate the safety and tolerability of a single intravenous administration of CLR 131 in up to 30 children and adolescents with cancers, including neuroblastoma, sarcomas, lymphomas (including Hodgkin's lymphoma) and malignant brain tumors. Secondary objectives of the study are to identify the recommended Phase 2 dose of CLR 131 and to determine preliminary antitumor activity (treatment response) of CLR 131 in children and adolescents. We plan to initiate this Phase 1 study at 5-7 pediatric cancer centers, within and possibly outside the US.

**About CLR 131**
CLR 131 is a small-molecule, cancer-targeting radiotherapeutic PDC designed to deliver cytotoxic radiation directly and selectively to cancer cells and cancer stem cells. CLR 131 is our lead therapeutic PDC product candidate and is currently being evaluated in both Phase 2 and Phase 1 clinical studies. In December 2014, the FDA granted orphan drug designation for CLR 131 for the treatment of multiple myeloma. In 2018, the FDA granted orphan drug and rare pediatric disease designations for CLR 131 for the treatment of neuroblastoma, rhabdomyosarcoma, Ewing's sarcoma and osteosarcoma. The FDA previously accepted our IND application for a Phase 1 open-label, dose-escalating study to evaluate the safety and tolerability of a single intravenous administration of CLR 131 in up to 30 children and adolescents with cancers including neuroblastoma, sarcomas, lymphomas (including Hodgkin's lymphoma) and malignant brain tumors.

**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 2 clinical study in R/R MM and select B-cell malignancies, as well as a dose escalation Phase 1 study in patients with R/R MM. The company is initiating a Phase 1 study with CLR 131 in pediatric solid tumors and lymphoma.

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.

**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, 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.

**Contacts**

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