

**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 (Date of earliest event reported): **July 12, 2019**

MACROGENICS, INC.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-36112
(Commission
File Number)

06-1591613
(IRS Employer
Identification No.)

**9704 Medical Center Drive,
Rockville, Maryland**
(Address of Principal Executive Offices)

20850
(Zip Code)

Registrant's telephone number, including area code: **(301) 251-5172**

Not applicable

(Former Name or Former Address, if Changed Since Last Report)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.01 per share	MGNX	Nasdaq Global Select Market

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 or Rule 12b-2 of the Securities Exchange Act of 1934.

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 1.02 Termination of a Material Definitive Agreement

On July 12, 2019, MacroGenics, Inc. (the “Company”) received written notice from Les Laboratoires Servier and Institut de Recherches Internationales Servier (collectively, “Servier”), informing the Company of Servier's intention to terminate the Option for a License Agreement dated September 19, 2012, as amended, between Servier and the Company (the “Agreement”). The anticipated effective date of the termination is January 15, 2020 in accordance with the terms of the Agreement, unless sooner agreed to by the parties. As a result of this termination, the Company will regain full exclusive, worldwide commercialization rights to develop and market flotetuzumab, which is the Company's investigational, bispecific DART[®] molecule that recognizes both CD123 and CD3.

A summary of the material terms of the Agreement is included in the Company's Annual Report on Form 10-K filed on February 26, 2019 (the “2019 Form 10-K”), which is qualified in its entirety by reference to the full text of the Agreement and amendments, which are filed as Exhibit 10.20 to the Company's Form S-1 (333-190994) filed on October 4, 2013 and Exhibits 10.18 and 10.19 to the 2019 Form 10-K.

On July 17, 2019, the Company issued a press release including an announcement of Servier's notice of its intention to terminate the Agreement. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits.

99.1 [Press Release, dated July 17, 2019.](#)

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.

Date: July 17, 2019

MACROGENICS, INC.

By: /s/ Jeffrey Peters
Jeffrey Peters
Vice President and General Counsel

MacroGenics Provides Update on Flotetuzumab Program in Acute Myeloid Leukemia

- *Enrollment of Phase 1 monotherapy expansion cohort completed; presentation of data expected 2H2019*
- *End of Phase 1 meeting requested with FDA to discuss program and future development plans*
- *Initiation of enrollment of combination study with anti-PD-1 is imminent*
- *MacroGenics will regain full global rights to flotetuzumab in connection with Servier's termination of license and collaboration agreement*

ROCKVILLE, Md., July 17, 2019 (GLOBE NEWSWIRE) -- MacroGenics, Inc. (NASDAQ: MGNX), a clinical-stage biopharmaceutical company focused on discovering and developing innovative monoclonal antibody-based therapeutics for the treatment of cancer, today announced that it plans to advance the development of flotetuzumab, its investigational bispecific CD123 x CD3 DART® molecule, in patients with primary refractory acute myeloid leukemia (AML), a difficult-to-treat patient population.

To date, MacroGenics has enrolled 50 patients at the recommended Phase 2 dose (RP2D) in the Phase 1 monotherapy study, including 30 patients with primary refractory AML. The updated clinical data from this study will be submitted for presentation at the 2019 American Society for Hematology (ASH) Annual Meeting. MacroGenics plans to meet with the FDA in the third quarter to discuss future development of flotetuzumab, and to define a potential registration path for this molecule as monotherapy.

In parallel, MacroGenics plans to initiate a study in relapsed or refractory AML patients combining flotetuzumab with MGA012, a proprietary anti-PD-1 antibody, as a potential means to both broaden and lengthen the duration of response of AML patients on flotetuzumab. The combination is supported by a strong scientific rationale based on data previously reported by MacroGenics. The Company is positioned to begin to enroll patients imminently.

MacroGenics and Laboratoires Servier will terminate their collaboration and license agreement, with an effective date of January 15, 2020, unless sooner agreed to by the parties. As a result, MacroGenics will regain full global rights to develop and commercialize flotetuzumab. MacroGenics entered into an agreement with Servier in September 2012 to develop and commercialize flotetuzumab and other earlier stage DART molecules, in all regions other than North America, Japan, South Korea and India. Servier recently informed MacroGenics of its intention to terminate the agreement.

“We have made significant progress to advance flotetuzumab during our collaboration with Servier and we thank them for their participation,” said Scott Koenig, M.D., Ph.D., President and CEO of MacroGenics. “As MacroGenics has been leading the ongoing multi-national clinical effort, we anticipate no disruption or impact to our continued development of flotetuzumab and are excited about the potential of the program going forward.”

About Flotetuzumab

Flotetuzumab is a clinical-stage bispecific DART molecule that recognizes both CD123 and CD3. CD123, the interleukin-3 receptor alpha chain, is over-expressed on cancer cells in a wide range of hematological malignancies, including AML and myelodysplastic syndromes (MDS). The primary mechanism of action of flotetuzumab is believed to be its ability to redirect T lymphocytes to kill CD123-expressing cells. To achieve this, the DART molecule combines a portion of an antibody recognizing CD3, an activating molecule expressed by T cells, with an arm that recognizes CD123 on the target cancer cells.

Flotetuzumab is currently being evaluated in the U.S. and Europe in a Phase 1/2 dose expansion study designed to assess the safety, tolerability, and initial anti-leukemic activity of the molecule in patients with relapsed/refractory AML. Data from 31 patients were presented at the ASH Annual Meeting in December 2018, demonstrating anti-leukemic activity in patients with relapsed/refractory AML. In 27 response evaluable patients, the overall response rate (ORR) was 26% (7/27), with a complete response (CR) rate (a composite of both CR and CRi responses) of 19% (5/27). Notably, in primary refractory patients, an extremely challenging population to treat, the ORR was 35% (6/17) with a CR rate of 29% (5/17). The most common treatment-related adverse event (TRAE) was infusion-related reaction/cytokine release syndrome (IRR/CRS), and occurred in 93% (29/31) of patients. Grade 3 or greater IRR/CRS was observed in 13% (4/31) of patients.

The U.S. Food and Drug Administration has granted orphan drug designation to flotetuzumab for the treatment of AML.

About MacroGenics, Inc.

MacroGenics is a clinical-stage biopharmaceutical company focused on discovering and developing innovative monoclonal antibody-based therapeutics for the treatment of cancer. The Company generates its pipeline of product candidates primarily from its proprietary suite of next-generation antibody-based technology platforms, which have applicability across broad therapeutic domains. The combination of MacroGenics' technology platforms and protein engineering expertise has allowed the Company to generate promising product candidates and enter into several strategic collaborations with global pharmaceutical and biotechnology companies. For more information, please see the Company's website at www.macrogenics.com. MacroGenics, the MacroGenics logo, and DART are trademarks or registered trademarks of MacroGenics, Inc.

Cautionary Note on Forward-Looking Statements

Any statements in this press release about future expectations, plans and prospects for the Company, including statements about the Company's strategy, future operations, clinical development of the Company's therapeutic candidates, milestone or opt-in payments from the Company's collaborators, the Company's anticipated milestones and future expectations and plans and prospects for the Company and other statements containing the words "subject to", "believe", "anticipate", "plan", "expect", "intend", "estimate", "project", "may", "will", "should", "would", "could", "can", the negatives thereof, variations thereon and similar expressions, or by discussions of strategy constitute forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the uncertainties inherent in the initiation and enrollment of future clinical trials, expectations of expanding ongoing clinical trials, availability and timing of data from ongoing clinical trials, expectations for regulatory approvals, other matters that could affect the availability or commercial potential of the Company's product candidates and other risks described in the Company's filings with the Securities and Exchange Commission. In addition, the forward-looking statements included in this press release represent the Company's views only as of the date hereof. The Company anticipates that subsequent events and developments will cause the Company's views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so, except as may be required by law. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date hereof.

Contacts:

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