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): January 23, 2018

MACROGENICS, INC.

(Exact Name of Registrant as Specified in Charter)

Delaware	**001-36112**	**06-1591613**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

9704 Medical Center Drive, Rockville, Maryland	**20850**
(Address of Principal Executive Offices)	(Zip Code)

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

Not applicable

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

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 7.01. Regulation FD Disclosure.

On January 23, 2018, the Company issued a press release announcing completion of a pre-planned interim futility analysis of the Phase 3 SOPHIA trial. SOPHIA is a randomized, controlled, multi-center study that compares margetuximab plus chemotherapy to trastuzumab plus chemotherapy in subjects with metastatic breast cancer. Based on the results from the futility analysis, an independent data safety monitoring committee has recommended that the SOPHIA trial continue as planned. In addition, the Company also announced in the same press release that the U.S. FDA has granted Fast Track designation of margetuximab for treatment of patients with metastatic or locally advanced HER-2 positive breast cancer who have previously been treated with anti-HER2-targeted therapy. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and incorporated by reference herein.

The information furnished pursuant to this Item 7.01 of this Report, including Exhibit 99.1 attached hereto, shall not be deemed "filed" for purposes of Section 18 of the Exchange Act or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or under the Exchange Act, regardless of any general incorporation language in any such filing, unless the Company expressly sets forth in such filing that such information is to be considered "filed" or incorporated by reference therein.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits.

99.1 Press Release, dated January 23, 2018

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: January 23, 2018

MACROGENICS, INC.

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

MacroGenics Announces Continuation of SOPHIA Study of Margetuximab Based on Completion of Interim Futility Analysis

FDA grants Fast Track designation to margetuximab for treatment of metastatic breast cancer

Rockville, MD, Jan. 23, 2018 (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 completion of a pre-planned interim futility analysis of the Phase 3 SOPHIA trial. This randomized, multi-center clinical study compares margetuximab plus chemotherapy to trastuzumab plus chemotherapy in subjects with metastatic breast cancer. Based on results from the futility analysis, an independent data safety monitoring committee (DSMC) has recommended that the SOPHIA study continue as planned without modification. This analysis was based on a pre-specified assessment of progression-free survival (PFS) as determined by independent central review. The futility analysis did not allow for early stopping due to efficacy.

MacroGenics also announced today that the U.S. FDA has granted Fast Track designation for the investigation of margetuximab for treatment of patients with metastatic or locally advanced HER2 positive breast cancer who have previously been treated with anti-HER2-targeted therapy. Fast Track designation is designed to facilitate the development and expedite the review of new therapies for serious conditions and unmet medical needs. With Fast Track designation, early and frequent communications between the FDA and the sponsor are encouraged to help enable rapid development of the candidate molecule.

"We are encouraged with the DSMC's determination that there were no safety concerns and that the analysis of PFS data support continuation of the Phase 3 SOPHIA trial. Recruitment of patients into the SOPHIA study is progressing well. We remain on track to complete enrollment by the end of 2018 and we look forward to sharing top-line results after the trial has read out in 2019," commented Scott Koenig, M.D., Ph.D., President and Chief Executive Officer of MacroGenics. "Also, we are very pleased to receive Fast Track designation for margetuximab, as this may potentially expedite future regulatory interactions on this product candidate. Furthermore, the gastric cancer data recently presented at ASCO GI for margetuximab in combination with anti-PD-1 may provide additional opportunities to address unmet medical needs in other HER2+ indications."

About the SOPHIA Study

MacroGenics continues to enroll patients in the pivotal Phase 3 SOPHIA clinical study of margetuximab at approximately 200 trial sites across North America, Europe and Asia. The 530-patient study is designed to evaluate the efficacy of margetuximab plus chemotherapy compared to that of trastuzumab plus chemotherapy in relapsed/refractory HER2-positive metastatic breast cancer patients. This registration study has sequential primary endpoints, which include PFS and overall survival. For additional information on the ongoing SOPHIA trial, visit www.clinicaltrials.gov.

About Margetuximab

Margetuximab is an Fc-optimized monoclonal antibody that targets the human epidermal growth factor receptor 2, or HER2, oncoprotein. HER2 is expressed by tumor cells in breast, gastric, and other forms of solid tumor cancers, making it a key marker for biologic therapy. In addition to being studied in metastatic breast cancer, margetuximab is also being studied in combination with an anti-PD-1 agent in a Phase 1b/2 clinical trial in gastric cancer, for which data was recently presented at the recent ASCO Gastrointestinal Symposium.

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, as well as autoimmune disorders and infectious diseases. The company generates its pipeline of product candidates primarily from its proprietary suite of next-generation antibody-based technology platforms. 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.

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