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): February 6, 2019

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 8.01. Other Events

On February 6, 2019, the Company issued a press release announcing top-line results from its 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. A copy of the press release ("the Press Release") is attached as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits.

99.1 Press Release, dated February 6, 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: February 6, 2019

MACROGENICS, INC.

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

MacroGenics Announces Positive Results from Pivotal Phase 3 SOPHIA Study of Margetuximab

- Margetuximab improved progression-free survival (PFS) compared to HERCEPTIN® (trastuzumab), when used in combination with chemotherapy in patients with HER2+ metastatic breast cancer
- BLA submission targeted for second half of 2019
- Company to host conference call today at 8:30 a.m. (ET)

ROCKVILLE, MD, February 6, 2019 – 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 positive results from SOPHIA, the Company's Phase 3 clinical study of margetuximab in HER2-positive metastatic breast cancer patients. Margetuximab is an investigational immune-enhancing monoclonal antibody derived from the Company's proprietary Fc Optimization technology platform. The SOPHIA clinical trial met the primary endpoint of prolongation of progression-free survival (PFS) in patients treated with the combination of margetuximab plus chemotherapy compared to trastuzumab plus chemotherapy. Patients in the margetuximab arm experienced a 24% risk reduction in PFS compared to patients in the trastuzumab arm (HR=0.76, p=0.033). Notably, approximately 85% of patients in the study were carriers of the CD16A (FcγRIIIa) 158F allele, which has been previously associated with diminished clinical response to HERCEPTIN and other antibodies. In this pre-specified subpopulation, patients in the margetuximab arm experienced a 32% risk reduction in PFS compared to patients in the trastuzumab arm (HR=0.68, p=0.005). Results of the SOPHIA study are being prepared for submission for publication and presentation later this year at a major scientific conference. Follow-up for determination of the impact of therapy on the sequential primary endpoint of overall survival (OS) is ongoing, as pre-specified in the study protocol and recommended by the trial's independent Data Safety Monitoring Committee. MacroGenics anticipates submitting a Biologics License Application (BLA) to the U.S. Food and Drug Administration in the second half of 2019.

The SOPHIA study enrolled 536 patients at approximately 200 trial sites across North America, Europe and Asia. Patients were treated with either margetuximab or trastuzumab in combination with one of four chemotherapy agents (capecitabine, eribulin, gemcitabine or vinorelbine). All study patients had previously received trastuzumab and pertuzumab, and approximately 90% had previously received ado-trastuzumab emtansine. The combination of margetuximab and chemotherapy demonstrated acceptable safety and tolerability, comparable overall to that of trastuzumab and chemotherapy.

"There are currently no approved agents for the treatment of patients with metastatic HER2+ breast cancer who have previously received trastuzumab, pertuzumab and ado-trastuzumab emtansine. If margetuximab is approved, based on SOPHIA data, I believe that this agent could become a valuable treatment option for these patients," said Hope S. Rugo, M.D., Director, Breast Oncology and Clinical Trials Education, University of California San Francisco Comprehensive Cancer Center.

"We are pleased with the SOPHIA clinical results and are especially grateful to the patients, their caregivers, trial investigators and site personnel who participated in the study. I would also like to thank the entire MacroGenics team and our business partners who worked diligently to bring margetuximab to the clinic and execute the SOPHIA study," said Scott Koenig, M.D., Ph.D., MacroGenics' President and CEO. "Our Fc-engineered, immune-enhanced molecule has demonstrated a superior outcome in a head-to-head study against HERCEPTIN. We look forward to additional opportunities to develop margetuximab in other HER2-positive breast and gastric cancer populations."

Conference Call Information

MacroGenics will host a conference call today at 8:30 am (ET) to discuss the results of the SOPHIA clinical study. To participate in the conference call, please dial (877) 303-6253 (domestic) or (973) 409-9610 (international) five minutes prior to the start of the call and provide the Conference ID: 7965575.

The recorded, listen-only webcast of the conference call can be accessed under "Events & Presentations" in the Investor Relations section of the Company's website at http://ir.macrogenics.com/events.cfm. A replay of the webcast will be available shortly after the conclusion of the call and archived on the Company's website for 30 days following the call.

About Margetuximab

Margetuximab is an investigational monoclonal antibody that targets the human epidermal growth factor receptor 2, or HER2 oncoprotein. HER2 is expressed by tumor cells in breast, gastroesophageal and other solid tumors. Margetuximab was designed to provide HER2 blockade and has been engineered with an Fc domain to enhance the engagement of the immune system. In addition to studying margetuximab in breast cancer, MacroGenics is developing the antibody in combination with anti-PD-1 therapy to engage both innate and adaptive immunity for the treatment of patients with gastroesophageal cancer.

About MacroGenics' Fc Optimization Technology

MacroGenics' Fc Optimization platform is designed to modulate an antibody's interaction with immune effector cells. The Fc region of certain antibodies binds activating and inhibitory receptors, referred to as FcγRs, on immune cells found within the innate immune system. Such interactions affect killing of cancer cells through antibody dependent cellular cytotoxicity (ADCC), among other Fc-dependent functions.

Activating FcγRs occur in two variants, or alleles, with high (158V) or low (158F) affinity for the Fc domain of IgG1. A majority (approximately 85%) of the population carries the 158F allele, either in the homozygous or heterozygous form with 158V. Patients that carry the 158F allele have been reported to show diminished clinical responses to certain therapeutic antibodies, including HERCEPTIN.

MacroGenics' optimized Fc region binds with increased affinity to the activating FcγRs, including the 158F low-affinity allele, and, unique to MacroGenics' technology, with reduced affinity to the inhibitory FcγR, resulting in improved effector functions, such as ADCC. To date, MacroGenics has successfully incorporated its proprietary Fc Optimization technology in margetuximab, as well as enoblituzumab, an anti-B7-H3 monoclonal antibody currently in development in combination with anti-PD-1 therapy for cancer treatment.

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 and the MacroGenics logo 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 risk of delays or failure in reaching an agreement with the FDA regarding the release of a clinical hold, 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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