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): **October 22, 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)

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 (§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 8.01 **Other Events**

.

On October 22, 2019, MacroGenics, Inc. issued a press release announcing topline results from the second pre-specified interim overall survival analysis for its Phase 3 SOPHIA study of margetuximab. 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 October 22, 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: October 22, 2019

MACROGENICS, INC.

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

Exhbit 99.1

MacroGenics Announces Second Interim Overall Survival Data from Phase 3 SOPHIA Study of Margetuximab in Patients with HER2-Positive Metastatic Breast Cancer

ROCKVILLE, MD, October 22, 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 topline results from the second pre-specified interim overall survival (OS) analysis for the Phase 3 SOPHIA study of margetuximab in patients with HER2-positive metastatic breast cancer who have previously been treated with anti-HER2-targeted therapies. Margetuximab is an investigational, immune-enhancing monoclonal antibody derived from the Company's proprietary Fc Optimization technology platform.

The second interim OS analysis was based on 270 events. In the intent-to-treat (ITT) population, the median OS of patients treated with margetuximab and chemotherapy was prolonged by 1.8 months compared to that of patients who received trastuzumab and chemotherapy (21.6 months versus 19.8 months; hazard ratio [HR]=0.885; 95% CI: 0.693-1.130; p=0.326). A pre-specified exploratory objective was to evaluate the effect of CD16A allelic variation on margetuximab activity. Among the approximately 85% of patients carrying a CD16A 158F allele, the median OS was prolonged by 4.3 months in the margetuximab arm compared to the trastuzumab arm (23.7 months versus 19.4 months; HR=0.793; 95% CI: 0.607-1.035; p=0.087). Among the approximately 15% of patients who were homozygous for the CD16A 158V allele, the trastuzumab arm performed better than the margetuximab arm. The final pre-specified OS analysis is planned after 385 events have accrued, which is projected to occur in 2020. The first sequential primary endpoint of progression-free survival (PFS) in the ITT population was achieved, with statistical significance as previously reported.

Margetuximab plus chemotherapy had a generally comparable safety profile overall to that of trastuzumab plus chemotherapy, consistent with data previously reported from the study. Grade 3 or greater adverse events occurred in 145 (55%) patients on the margetuximab arm compared to 140 (53%) patients on the trastuzumab arm. Serious adverse events occurred in 45 (17%) patients on the margetuximab arm compared to 50 (19%) patients on the trastuzumab arm. Infusion-related reactions were more common with margetuximab treatment than with trastuzumab (13% versus 3%) and were mostly Grade 1 or 2 and associated with the first dose.

Detailed results from the second interim OS analysis from the SOPHIA study are scheduled to be presented during an oral session at the upcoming San Antonio Breast Cancer Symposium (SABCS) in December. MacroGenics expects to submit a Biologics License Application (BLA) to the FDA before the end of 2019.

About the SOPHIA Study

The SOPHIA study (NCT02492711) is a randomized, open-label Phase 3 clinical trial evaluating margetuximab plus chemotherapy compared to trastuzumab plus chemotherapy in patients with HER2-positive metastatic breast cancer. To be eligible for the study, patients must have received at least two prior lines of anti-HER2-directed therapy in the metastatic setting, or in the case of having received (neo)adjuvant pertuzumab, at least one prior line of anti-HER2-directed therapy in the metastatic setting; and who have received at least one and no more than three prior lines of therapy overall in the metastatic setting. All study patients had previously received trastuzumab and pertuzumab, and approximately 90% had previously received ado-trastuzumab emtansine, or T-DM1.

The study enrolled 536 patients who were randomized 1:1 to receive either margetuximab (n=266) given intravenously at 15 mg/kg every three weeks or trastuzumab (n=270) given intravenously at 6 mg/kg (or

8 mg/kg for loading dose) every three weeks in combination with one of four chemotherapy agents (capecitabine, eribulin, gemcitabine or vinorelbine) given at the standard dose. Patients were stratified by the number of metastatic sites (≤2 or >2), number of lines of prior therapy for metastatic disease (≤2 or >2) and choice of chemotherapy. Intent-to-treat analysis occurred after 265 PFS events.

Primary endpoints are sequentially-assessed PFS, determined by centrally-blinded radiological review, and OS. Key secondary endpoints are PFS by investigator assessment and objective response rate (ORR). PFS and ORR were assessed according to Response Evaluation Criteria in Solid Tumors version 1.1 (RECIST 1.1).

About HER2-positive Breast Cancer

Human epidermal growth factor receptor 2 (HER2) is a protein found on the surface of some cancer cells that promotes growth and is associated with aggressive disease and poor prognosis. Approximately 15-20% of breast cancer cases are HER2-positive. Monoclonal antibodies (mAbs) targeting HER2 have greatly improved outcomes of patients with HER2-positive breast cancer and are now standard of care in both early-and late-stage disease. However, metastatic breast cancer remains an unmet need that eventually advances to the point where no currently approved HER2-targeting therapy continues to control the disease. Ongoing HER2 blockade is recommended for relapsed or refractory patients, but there is no approved therapy in the third line and beyond setting, or established standard of care after progression with trastuzumab, pertuzumab and ado-trastuzumab emtansine.

About Margetuximab

Margetuximab is an investigational monoclonal antibody that targets the HER2 oncoprotein. HER2 is expressed by tumor cells in breast, gastroesophageal and other solid tumors. Margetuximab was designed to provide HER2 blockade and has similar HER2 binding and antiproliferative effects as trastuzumab. In addition, margetuximab has been engineered with MacroGenics' Fc Optimization technology to enhance the engagement of the immune system. Margetuximab is also being evaluated in combination with anti-PD-1 therapy for the treatment of patients with HER2-positive gastroesophageal cancer and the registration-directed Phase 2/3 MAHOGANY trial (NCT04082364) has recently opened to patient enrollment.

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.

The activating CD16A FcγR occurs 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 form or as heterozygous with 158V. Patients that carry the 158F allele have been reported to show diminished clinical responses to certain therapeutic antibodies, including trastuzumab.

MacroGenics' optimized Fc region binds with increased affinity to CD16A, including the 158F low-affinity allele, and, unique to MacroGenics' technology, with reduced affinity to CD32B, the inhibitory FcγR. MacroGenics' optimized Fc mediates improved effector functions, such as ADCC. To date, MacroGenics has 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 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:

Jim Karrels, Senior Vice President, CFO
Anna Krassowska, Ph.D., Vice President, Investor Relations & Corporate Communications
1-301-251-5172, info@macrogenics.com