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): September 16, 2021

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** (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 (§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 September 16, 2021, MacroGenics, Inc. (the "Company") issued a press release announcing clinical results from Cohort A Part 1 of the Phase 2/3 MAHOGANY study of margetuximab in combination with retifanlimab in gastroesophageal adenocarcinoma (the "MAHOGANY Study Press Release").

In addition, on September 16, 2021, the Company also issued a press release announcing preliminary clinical results from the Phase 1 cohort expansion of the ongoing MGC018 study (the "MGC018 Study Press Release").

Copies of the MAHOGANY Study Press Release and MGC018 Study Press Release are attached as Exhibits 99.1 and 99.2 to this Current Report on Form 8-K and are incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits.

Exhibit Number	Description of Exhibit
99.1	MAHOGANY Study Press Release, dated September 16, 2021
99.2	MGC018 Study Press Release, dated September 16, 2021
104	Cover Page Interactive Data (embedded within the Inline XBRL document)

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: September 16, 2021

MACROGENICS, INC.

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

MacroGenics Announces Clinical Results from Cohort A Part 1 of Phase 2/3 MAHOGANY Study of Margetuximab in Combination with Retifanlimab in Gastroesophageal Adenocarcinoma at ESMO 2021

- 21 of 40 patients (53%) achieved confirmed responses by independent review, exceeding prespecified futility boundary for trial; enrollment proceeding to Part 2 of Cohort A
- 78% of patients had tumor shrinkage at first scan
- Median duration of response was 10.3 months as of data cutoff
- Margetuximab plus retifanlimab was well tolerated with Grade 3 treatment-related adverse events (TRAEs) in 19% of patients; no Grade 4 TRAEs or treatment-related deaths
- Findings suggest this chemotherapy-free combination, if validated and approved, may be a potential option for first-line HER2+ patients

ROCKVILLE, MD, Sept. 16, 2021 (GLOBE NEWSWIRE) – MacroGenics, Inc. (NASDAQ: MGNX), a biopharmaceutical company focused on developing and commercializing innovative monoclonal antibody-based therapeutics for the treatment of cancer, today announced results from Cohort A Part 1 of the Phase 2/3 MAHOGANY clinical trial of margetuximab. MARGENZA® (margetuximab-cmkb) is approved in HER2+ metastatic breast cancer and is being investigated as a potential first-line treatment for patients with HER2+ gastric cancer (GC) or gastroesophageal junction (GEJ) cancer in combination with a checkpoint inhibitor, with or without chemotherapy. The dataset is available in a poster titled **"Margetuximab With Retifanlimab in HER2+, PD-L1+ First-Line Unresectable/Metastatic Gastroesophageal Adenocarcinoma (GEA): MAHOGANY Cohort A"** (Poster #1379P) at the 2021 European Society for Medical Oncology (ESMO) Virtual Conference taking place September 16-21, 2021.

The efficacy data and safety cutoff dates were July 19, 2021 and August 3, 2021, respectively. In Cohort A Parts 1 and 2, the efficacy and safety of combining margetuximab and retifanlimab (investigational anti-PD-1 monoclonal antibody licensed to Incyte by MacroGenics) is planned to be evaluated in approximately 100 patients whose tumors are HER2+ at the 3+ level by immunohistochemical (IHC) staining, PD-L1+ (combined positive score ≥1%) and non-microsatellite instability-high (non-MSI-H). A pre-specified interim analysis assessing efficacy and safety was conducted on the first 40 non-MSI-H patients enrolled in Part 1. These data support advancement to Part 2 with plans to enroll approximately 60 additional response-evaluable non-MSI-H patients.

A total of 43 HER2 3+ and PD-L1+ patients were enrolled in Cohort A Part 1 and received margetuximab 15 mg/kg plus retifanlimab 375 mg/kg administered intravenously every three weeks. Twenty-five patients (58%) had gastric cancer and 18 patients (42%) had gastroesophageal junction cancer; 36 patients (84%) had metastatic disease at study entry.

MAHOGANY Cohort A Interim Analysis

Anti-tumor activity was observed in patients treated with margetuximab plus retifanlimab in MAHOGANY Cohort A after the first scan. Tumor shrinkage was observed in 32 of 41 patients (78%) with at least one post-baseline target lesion measurement. Twenty-one of 40 response-evaluable patients achieved an objective response (53%, 95% confidence interval (CI): 36%-69%), including four confirmed complete responses and 17 confirmed partial responses. The number of confirmed responders by independent assessment exceeded the prespecified futility boundary for the trial, and enrollment is proceeding to Cohort A Part 2.

Disease control was achieved in 29 of 40 patients (73%, CI: 56%-85%) and the median duration of response was 10.3 months (range: 2.1 – 14.5 months, CI: 4.6 months – not evaluable (NE)). Median progression-free survival (PFS) was 6.4 months by independent assessment (CI: 6.0 months – NE); median overall survival (OS) was not yet reached. At both 12 and 18 months, OS was 85% (CI: 63%-95%).

Antitumor activity was comparable to historical data from the experimental arm of the Trastuzumab for Gastric Cancer (ToGA) study (trastuzumab + chemotherapy; n=294; objective response rate (ORR) of 47%; median duration of response (DOR) of 6.9 months)[1] and initial data from the control arm (placebo + trastuzumab + chemotherapy) of the KEYNOTE-811 study (ORR of 52%; median DOR of 9.5 months).[2]

The safety analysis of all 43 patients treated with margetuximab plus retifanlimab suggests the combination was well tolerated in the study population. The most common TRAEs were fatigue (21% Grade 1-2, 0% Grade ≥3), infusion-related reaction (19% Grade 1-2, 0% Grade ≥3), rash (19% Grade 1-2, 0% Grade ≥3), diarrhea (16% Grade 1-2, 2% Grade 3), and pruritus (16% Grade 1-2, 0% Grade ≥3). A total of nine Grade 3 TRAEs were reported in eight patients (19%); no Grade 4 TRAEs were observed. Eight serious TRAEs were reported in seven patients. Infusion-related reactions considered as adverse events (AEs) of special interest occurred in six patients.

Treatment-emergent AEs of Grade 3 occurred in 18 of 43 patients (42%) of patients. Three of 43 patients (7%) discontinued therapy due to immune-related AEs: renal dysfunction (Grade 3), hepatitis (Grade 3), and diabetic ketoacidosis (Grade 1); no AEs led to death.

Safety data from MAHOGANY compare favorably to the experimental arm of ToGA in which overall Grade 3-4 AEs were 68% and the treatment-related mortality was 3%.[1] Initial results from KEYNOTE-811 data presented at the 2021 ASCO Annual Meeting indicated that AEs of Grade 3-5 occurred in 57.1% of patients in the experimental arm (pembrolizumab + trastuzumab + chemotherapy) and in 57.4% of patients in the control arm, AEs leading to death occurred in 3.2% vs 4.6%, and AEs leading to discontinuation of any study drug occurred in 24.4% vs 25.9% of patients, respectively. Despite limitations of cross-study comparisons, regimens containing chemotherapy may have clinically relevant safety differences compared to the chemotherapy-free regimen in MAHOGANY Cohort A.

“We are excited to share our results from the interim analysis of Part 1 of the MAHOGANY Cohort A study at ESMO,” said Scott Koenig, M.D., Ph.D., President and CEO of MacroGenics. “This study is designed to support potential registration of margetuximab in combination with other agents for patients with gastric or gastroesophageal junction cancer as part of our strategy to advance margetuximab in HER2+ cancer. The findings suggest the combination of margetuximab and retifanlimab may potentially provide a chemotherapy-free option as a first-line treatment for patients whose tumors are positive for both HER2 and PD-L1. We are pleased these data support the protocol’s prespecified advancement into Part 2 of MAHOGANY Cohort A. We plan to discuss these results and future development of the combination in an upcoming scheduled meeting with the FDA.”

ESMO Presentation
MacroGenics’ Cohort A Part 1 MAHOGANY Study poster presentation is available for on-demand viewing on the ESMO website and on the “Events & Presentations” page on MacroGenics’ website at http://ir.macrogenics.com/events.cfm.

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[1] Bang YJ, et al., Lancet. 2010; 376 (9742): 687-697.
[2] Janjigian YY, et al., J Clin Oncol. 2021; 39 (suppl 15): 4013.

The MAHOGANY Study Design

MAHOGANY (NCT04082364) is a Phase 2/3 clinical trial in two cohorts designed to evaluate margetuximab in combination with a checkpoint inhibitor, with or without chemotherapy, as a potential first-line treatment for patients with advanced or metastatic HER2+ GEJ/GC.

Cohort A is designed as a single arm study to test margetuximab plus retifanlimab (previously known as MGA012 and INCMGA00012), an investigational anti-PD-1 monoclonal antibody, in patients with HER2+ and PD-L1+ tumors. The primary outcome measure for efficacy is ORR per Response Evaluation Criteria in Solid Tumors (RECIST 1.1).

Cohort B is designed as a randomized trial to test margetuximab plus a checkpoint inhibitor in combination with chemotherapy compared to standard of care therapy of trastuzumab with chemotherapy in patients with HER2+ tumors irrespective of PD-L1 expression. Patients randomized to one of two experimental arms containing a checkpoint inhibitor will receive either retifanlimab or tebotelimab (previously known as MGD013), an investigational DART® molecule targeting PD-1 and LAG-3. The primary outcome measure for efficacy is OS.

The Phase 2/3 clinical trial is being conducted at clinical sites globally, in collaboration with Zai Lab, the company's regional partner in Greater China. For additional information about the MAHOGANY study, please visit https://clinicaltrials.gov/ct2/show/NCT04082364.

About Gastric and Gastroesophageal Junction Cancer

Cancer of the stomach (gastric cancer, GC), or the gastroesophageal junction (GEJ) where the esophagus joins the stomach, is collectively known as gastroesophageal adenocarcinoma and is the fifth most common tumor type worldwide. Both GC and GEJ cancer are often diagnosed at an advanced stage and therefore have very poor prognosis, with a 5-year survival of 5-20%. Chemotherapy is the standard of care for first-line therapy and may be combined with trastuzumab for the approximately 20% of patients whose tumors are HER2+.

About Margetuximab

MARGENZA® (margetuximab-cmkb) is approved in HER2+ metastatic breast cancer and is being investigated as a potential first-line treatment for patients with HER2+ GC or GEJ cancer in combination with a checkpoint inhibitor, with or without chemotherapy. Margetuximab is an Fc-engineered monoclonal antibody that targets the HER2 oncoprotein. HER2 is expressed by tumor cells in breast, gastroesophageal and other solid tumors. Through MacroGenics' Fc Optimization technology, margetuximab has been engineered to enhance the engagement of the immune system.

Margetuximab is also being evaluated in combination with tebotelimab (PD-1 × LAG-3 bispecific DART® molecule) in various HER2+ tumors (NCT03219268). MacroGenics is partnered with Zai Lab for the development and commercialization of margetuximab in Greater China. For more information, please visit www.clinicaltrials.gov.

About Retifanlimab

Retifanlimab is an investigational, humanized, proprietary anti-PD-1 monoclonal antibody being developed for use as monotherapy as well as in combination with other potential cancer therapeutics.

Retifanlimab was licensed to Incyte Corporation in 2017 under an exclusive global collaboration and license agreement. MacroGenics retains the right to develop its pipeline molecules with retifanlimab. Incyte is pursuing development of retifanlimab monotherapy in four potentially registration-directed trials for patients with MSI-high endometrial cancer, Merkel cell carcinoma, anal cancer and non-small cell lung cancer. Incyte and MacroGenics are each conducting multiple studies of retifanlimab in combination with other agents.

About Tebotelimab

Tebotelimab is an investigational, first-in-class bispecific DART molecule designed to provide co-blockade of PD-1 and LAG-3 for the potential treatment of a range of solid tumors and hematological malignancies.

About MacroGenics, Inc.

MacroGenics is a biopharmaceutical company focused on developing and commercializing 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 MARGENZA 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, including enrollment in clinical trials, commercial prospects of or product revenues from MARGENZA, milestone or opt-in payments from the Company's collaborators, the Company's anticipated milestones and other statements containing the words "subject to", "believe", "anticipate", "plan", "expect", "intend", "estimate", "potential, " "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: risks that MARGENZA revenue, expenses and costs may not be as expected, risks relating to MARGENZA's market acceptance, competition, reimbursement and regulatory actions, 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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MacroGenics Announces Preliminary Clinical Results from Phase 1 Cohort Expansion of the Ongoing MGC018 Study Presented at ESMO 2021 Virtual Annual Congress

- Metastatic castration-resistant prostate cancer (mCRPC): 21 of 39 patients (54%) achieved ≥ 50% prostate-specific antigen (PSA) reduction; 10 of 16 (63%) RECIST-evaluable patients had anti-tumor activity; 4 of 16 (25%) achieved partial responses (two confirmed and two unconfirmed)
- Non-small cell lung cancer (NSCLC): 13 of 16 (81%) evaluable patients had anti-tumor activity; 4 of 16 (25%) achieved unconfirmed partial responses
- Manageable safety profile overall, with low rate (7%) of discontinuation due to treatment-related adverse events (TRAEs)

ROCKVILLE, MD, Sept 16, 2021 (GLOBE NEWSWIRE)—MacroGenics, Inc. (NASDAQ: MGNX), a biopharmaceutical company focused on developing and commercializing innovative monoclonal antibody-based therapeutics for the treatment of cancer, today announced preliminary safety and anti-tumor activity data from dose expansion cohorts of the Company's ongoing Phase 1 clinical trial of MGC018. This investigational antibody-drug conjugate (ADC) was designed to deliver a DNA-alkylating duocarmycin payload to both dividing and non-dividing cells in a B7-H3-dependent manner. The dataset is being presented in a poster titled **"MGC018, an Anti-B7-H3 Antibody-Drug Conjugate (ADC), in Patients with Advanced Solid Tumors: Preliminary Results of Phase 1 Cohort Expansion"** (Poster #620P) at the 2021 European Society for Medical Oncology (ESMO) Virtual Conference taking place September 16-21, 2021.

Cohort Expansion Results Update

As of the August 16, 2021 data cut-off, a total of 86 patients with advanced solid tumors were enrolled in the cohort expansion of MGC018 at the recommended Phase 2 dose (RP2D) of 3.0 mg/kg, administered intravenously every three weeks. The enrollment includes 40 patients with mCRPC, 21 patients with NSCLC, 16 patients with triple negative breast cancer (TNBC) and nine patients with melanoma. In addition, enrollment of patients with squamous cell carcinoma of the head and neck (SCCHN) was recently initiated. The safety analysis both in the poster and below includes all enrolled patients, whereas the efficacy analysis was limited to mCRPC and NSCLC patients, as enrollment continues in the other tumor cohorts.

In the cohort expansion, tumor response by investigator per Response Evaluation Criteria in Solid Tumors (RECIST v1.1) was evaluated every nine weeks for all patients and PSA was assessed every three weeks in mCRPC.

Preliminary Anti-tumor Results for mCRPC Cohort Expansion

As of the August 16, 2021 data cut-off, all 40 patients in the mCRPC cohort expansion had been enrolled. Patients had previously received a median of three prior therapies for advanced disease, with all 40 patients having received both chemotherapy and next-generation hormonal therapy. The median B7-H3 H-score for all mCRPC patients was 223.

A total of 39 mCRPC patients were evaluable for PSA response. Reductions in PSA levels of ≥ 50% were observed in 21 of 39 patients (54%). Twenty-four of the 39 patients (62%) remained on treatment as of the data cut-off.

Of the 40 patients in the mCRPC cohort, 16 of the 23 patients with measurable disease were evaluable for tumor response by RECIST as of the data cut-off. Ten of these 16 patients (63%) had reductions in their target lesion sums from baseline. Four patients (25%) demonstrated a partial response (PR), consisting of two confirmed and two unconfirmed PRs. Treatment was ongoing in six of 16 patients with evaluable tumor response as of the data cut-off.

Preliminary Anti-tumor Results for NSCLC Cohort Expansion

As of the August 16, 2021 data cut-off, the NSCLC cohort expansion had been fully enrolled with 21 patients. Patients had previously received a median of two prior therapies for advanced disease, with 15 (71%) having previously received anti-PD-1/PD-L1 therapy. The median B7-H3 H-score for these patients was 139.

A total of 16 NSCLC patients were evaluable for tumor response by RECIST. Thirteen of 16 (81%) patients had reductions in their target lesion sums from baseline. Four of these 16 patients (25%) experienced unconfirmed partial responses. Another one of these 16 patients experienced a 30% reduction in target lesions; however, the patient's non-target lesions were not evaluated due to an obstruction of the bronchus and overall response was not evaluable. Treatment was ongoing in seven of 16 patients as of the data cut-off.

Preliminary Safety Results

The safety analysis includes all 86 patients enrolled in the cohort expansion as of the August 16, 2021 data cut-off. The median number of doses received by mCRPC patients was 3.5 (range: 1-8); those with NSCLC received 3.0 (range: 1-7). Adverse events for the dose expansion cohorts of 3 mg/kg were generally consistent with those previously reported at ASCO 2021. TRAEs included hematologic and skin toxicities that have been clinically manageable to date. In the cohort expansion study overall, at least one TRAE of any grade was experienced by 78 of 86 patients (91%), with 43 of 86 patients (50%) experiencing a Grade ≥3 TRAE. There were two Grade 5 fatal events: one from an unknown cause and one due to SARS-CoV-2.

The most common TRAEs were fatigue (37% all grades; 1% Grade ≥3), neutropenia (34% all grades; 22% Grade ≥3), palmar plantar erythrodysesthesia syndrome (31% all grades; 4% Grade ≥3), pleural effusion (23% all grades; 1% Grade ≥3), nausea (22% all grades; 1% Grade ≥3), asthenia (20% all grades; 5% Grade ≥3) and thrombocytopenia (14% all grades; 7% Grade ≥3). The overall results have demonstrated a manageable safety profile with a low rate of treatment discontinuation due to TRAEs: only six of 86 (7%) patients had discontinued therapy in the cohort expansion as of the data cut-off date due to TRAEs.

"We are highly encouraged by the growing data from our ongoing Phase 1 study of MGC018," said Scott Koenig, M.D., Ph.D., President and CEO of MacroGenics. "Consistent with previously presented data, we observed PSA reductions of 50% or greater in 54% of patients with metastatic castration-resistant prostate cancer. And now, we are particularly pleased to see partial responses emerge – both confirmed and unconfirmed – in mCRPC and NSCLC patients, with encouraging anti-tumor activity observed in the majority of patients for both tumor types. Also, we are very pleased with the evolving safety profile of MGC018, which showed neutropenia as the only Grade 3 or higher TRAE that exceeded a rate of 10% in this trial. Finally, further optimization of patient management has resulted in a low rate of MGC018 discontinuation due to TRAEs as of the data cutoff. Enrollment is ongoing in the TNBC, SCCHN, and melanoma cohorts and we look forward to providing further updates on patients in these cohorts, as well as patients in the mCRPC and NSCLC cohorts, at subsequent scientific conferences."

ESMO Presentation

MacroGenics' MGC018 poster presentation is available for on-demand viewing on the ESMO website and on the "Events & Presentations" page on MacroGenics' website at http://ir.macrogenics.com/events.cfm.

About MGC018

MGC018 is an ADC comprised of an anti-B7-H3 humanized IgG1/kappa monoclonal antibody conjugated via a cleavable linker to the prodrug seco-DUocarmycin hydroxyBenzamide Azaindole (DUBA; licensed from Byondis, B.V.), with an average drug-to-antibody ratio (DAR) of ~2.7. DUBA is an alkylating agent that can damage DNA in both dividing and non-dividing cells, causing cell death. B7-H3 is a molecule highly expressed on many solid tumors and associated with a poor clinical outcome. MGC018 is being evaluated in a Phase 1 study (NCT03729596). MacroGenics retains worldwide rights to MGC018.

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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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