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 8, 2022

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 July 8, 2022, MacroGenics, Inc. issued a press release in which it announced closure of the CP-MGA271-06 study evaluating enoblituzumab plus checkpoint inhibition in head and neck cancer. A copy of the press release is attached to this Current Report on Form 8-K as Exhibit 99.1 and is incorporated by reference into this Item 8.01.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits.

Exhibit Number	Description of Exhibit
99.1	Press Release, dated July 8, 2022.
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: July 8, 2022

MACROGENICS, INC.

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

MacroGenics Announces Closure of CP-MGA271-06 Study Evaluating Enoblituzumab plus Checkpoint Inhibition in Head and Neck Cancer

ROCKVILLE, MD, July 08, 2022 (GLOBE NEWSWIRE) -- MacroGenics, Inc. (NASDAQ: MGNX), a biopharmaceutical company focused on developing and commercializing innovative antibody-based therapeutics for the treatment of cancer, today announced that effective as of July 7, 2022, the Company closed the Phase 2 study (CP-MGA271-06) evaluating the investigational regimen of enoblituzumab (Fc-optimized B7-H3-directed monoclonal antibody) in combination with either retifanlimab (anti-PD-1 monoclonal antibody) or tebotelimab (PD-1 × LAG-3 bispecific DART® molecule) in the first-line treatment of patients with recurrent or metastatic squamous cell carcinoma of the head and neck (SCCHN).

The decision to discontinue the study was based on an internal review of safety data, which included the occurrence of seven fatalities potentially associated with hemorrhagic events in both arms of the study (of 62 total patients treated). Six of the seven fatal events observed in the CP-MGA271-06 study were assessed by investigators as secondary to disease progression and/or unrelated to the study treatment, and one event was assessed as possibly related. Fatal tumor-related hemorrhages and airway obstruction are known risks in patients with SCCHN. The incidence of fatal events observed in the study that were potentially hemorrhagic in origin was higher than what has been reported for this patient population in the medical literature (i.e., 1 - 3.6% as per Argiris, et al., J Clin Oncol. 2019 Dec 1, 37(34):3266) and in the context of a risk : benefit analysis, prompted the Company's decision to close the study. Accordingly, the Company informed investigators and the U.S. Food and Drug Administration (FDA) of the study closure and instructed investigators that no additional patients in the study were to be enrolled or receive further treatments as of July 7, 2022.

MacroGenics continues to investigate and monitor these events, and an analysis of the data is ongoing. There were no hemorrhagic events or coagulopathies observed in nonclinical toxicology studies of enoblituzumab, and the incidence of any fatal hemorrhage reported in earlier studies of enoblituzumab evaluated in over 340 patients across a broad range of tumor types was less than 1%.

"Our top concern in conducting clinical trials is the safety of study participants," said Scott Koenig, M.D., Ph.D., President and CEO of MacroGenics. "We were surprised by the emergence of these events in first-line SCCHN patients, as we had not observed any such events in an earlier, smaller study in patients with later-line SCCHN disease who were treated with enoblituzumab in combination with an anti-PD-1 antibody. Similar safety events have not been reported in patients treated with MGC018, our B7-H3-

targeted ADC molecule, and the decision to close the CP-MGA271-06 study does not impact our ongoing MGC018 study activities. We'd like to thank all patients, their families and caregivers who participated in the CP-MGA271-06 study."

About Enoblituzumab

Enoblituzumab is an investigational anti-B7-H3 monoclonal antibody that incorporates an immunoglobulin G1 fragment crystallizable (Fc) domain designed to enhance Fcγ receptor-mediated antibody-dependent cellular cytotoxicity. B7-H3, a protein in the B7 family of immune regulator proteins, is widely expressed by a number of different tumor types and may play a key role in regulating the immune response to various types of cancer.

About Retifanlimab

Retifanlimab is an investigational 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 a global collaboration and license agreement. MacroGenics retains the right to develop the molecule in combination with product candidates from its pipeline.

About Tebotelimab

Tebotelimab is an investigational, bispecific DART molecule designed to block PD-1 and lymphocyte-activation gene 3 (LAG-3) checkpoint molecules to sustain or restore the function of exhausted T cells.

About MacroGenics, Inc.

MacroGenics (the Company) 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 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 MacroGenics ("Company"), including statements about the Company's strategy, future operations, clinical development of the Company's therapeutic candidates, including initiation and enrollment in clinical trials, expected timing of results from clinical trials, discussions with regulatory agencies, commercial prospects of or

product revenues from MARGENZA and the Company’s product candidates, if approved, 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”, “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 MGC018, MARGENZA or any other product candidate’s revenue, expenses and costs may not be as expected, risks relating to MGC018, MARGENZA or any other product candidate’s market acceptance, competition, reimbursement and regulatory actions, the uncertainties inherent in the initiation and enrollment of future clinical trials, the availability of financing to fund the development of our product candidates, expectations of expanding ongoing clinical trials, availability and timing of data from ongoing clinical trials, expectations for the timing and steps required in the regulatory review process, expectations for regulatory approvals, the impact of competitive products, our ability to enter into agreements with strategic partners and other matters that could affect the availability or commercial potential of the Company's product candidates, business, or economic or political disruptions due to catastrophes or other events, including natural disasters, terrorist attacks, civil unrest and actual or threatened armed conflict, or public health crises such as the novel coronavirus (referred to as COVID-19 pandemic), 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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