

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 30, 2024

MACROGENICS, INC.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction of Incorporation)

001-36112
(Commission
File Number)

06-1591613
(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

or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 8.01 Other Events

On July 30, 2024, the Company issued a press release regarding its Phase 2 TAMARACK clinical trial of vobramitamab duocarmazine in metastatic castration-resistant prostate cancer (the "Press Release"). The full text of the Press Release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

| Exhibit Number | Description of Exhibit |
|-----------------------|--|
| 99.1 | Press Release dated July 30, 2024 |
| 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 30, 2024

MACROGENICS, INC.

By: /s/ Jeffrey Peters

Jeffrey Peters

Senior Vice President and General Counsel



MacroGenics Provides Vobramitamab Duocarmazine Update

- *Abstract of clinical data accepted for poster presentation at ESMO Congress 2024 in September*
- *ESMO poster to include protocol-defined TAMARACK Phase 2 mCRPC study data, including pre-defined landmark primary endpoint of 6-month rPFS rate and updated safety*
- *Treatment recently discontinued for TAMARACK mCRPC study participants who remained eligible for further dosing following review of totality of data, including efficacy, and emerging adverse events associated with prolonged exposure and considering potential risk/benefit to participants; most had received at least 8 cycles of vobra duo*
- *Given embargoed TAMARACK data presentation at ESMO, Company plans to host an investor update call following ESMO presentation in September*

ROCKVILLE, MD., July 30, 2024 (GLOBE NEWSWIRE) — MacroGenics, Inc. (NASDAQ: MGNX), a biopharmaceutical company focused on discovering, developing, manufacturing and commercializing innovative antibody-based therapeutics for the treatment of cancer, today announced a poster (display) presentation of clinical data from the TAMARACK Phase 2 study of vobramitamab duocarmazine (vobra duo) at the upcoming European Society for Medical Oncology (ESMO) Congress 2024 taking place in Barcelona, Spain on September 13-17, 2024.

The abstract submitted to ESMO was based on an April 12 data cut off, and the poster will report additional data from a July 9 data cut-off, including safety, efficacy and landmark 6-month radiographic progression-free survival (rPFS) data. The poster is titled:

1654P; TAMARACK: Randomized Phase 2 trial of the B7-H3 targeting antibody drug conjugate (ADC) vobramitamab duocarmazine (vobra duo) in metastatic castration-resistant prostate cancer (mCRPC)

“We are pleased to have the opportunity to present updated safety and efficacy data from our TAMARACK trial at the upcoming ESMO Congress in September,” said Scott Koenig, M.D., Ph.D., President and CEO of MacroGenics. “We believe that these data will give us valuable insights to inform potential next steps for the vobra duo program in mCRPC, and we look forward to providing additional perspective to the investment community following our ESMO presentation.”

In accordance with ESMO’s embargo policy, the poster will be published under “Events & Presentations” in the Investor Relations section of MacroGenics’ website at <http://ir.macrogenics.com/events.cfm> on or around September 15, 2024. Given the embargoed TAMARACK data, the Company’s management has entered a quiet period and will not be hosting a conference call to discuss its financial results or corporate progress for the quarter ended June 30, 2024. The Company expects to issue a release detailing its financial results and corporate progress on or around August 6, 2024, and plans to host an investor conference call following the ESMO presentation to discuss the TAMARACK data and potential next steps for the vobra duo program.

TAMARACK Study Update

MacroGenics completed enrollment of the TAMARACK study in the fourth quarter of 2023, and plans to present at ESMO the study’s landmark primary endpoint of 6-month rPFS rate, which represents the proportion of study participants who remain alive and progression-free at 6 months.

In late July 2024, after a review of accumulated study data, MacroGenics agreed with the study’s Independent Data Monitoring Committee’s (IDMC) recommendation that study treatment should be discontinued for the remaining mCRPC study participants who potentially could have received additional doses. Most of these remaining study participants had already received 8-12 cycles of vobra duo. Participants continue to be monitored for adverse events, disease progression and survival.

“Patient safety is our top priority, and having reached the study’s primary endpoint, we decided to discontinue additional dosing for the remaining TAMARACK participants who had not yet completed treatment. We expect to have the data necessary to determine next steps for the vobra duo program later this year and will provide further updates on an investor call following our ESMO presentation,” continued Dr. Koenig. “We are committed to fully assessing the potential of vobra duo in mCRPC through rigorous evaluation of the data, including the mature median rPFS and OS. We look forward to completing follow-up for the TAMARACK trial before year-end and presenting final data at a future conference.”

The Company expects to have the mature efficacy findings, including median rPFS, later in the second half of 2024 and plans to present the data at a subsequent medical conference. The data to be presented at ESMO will be used to inform how future potential studies could be designed.

About Vobra Duo and the TAMARACK Study

Vobra duo is an antibody-drug conjugate (ADC) that targets B7-H3, an antigen with broad expression across multiple solid tumors and a member of the B7 family of molecules involved in immune regulation. The TAMARACK Phase 2 study of vobra duo is being conducted in participants with metastatic castration-resistant prostate cancer (mCRPC) who were previously treated with one prior androgen receptor axis-targeted therapy (ARAT). Participants may have received up to one prior taxane-containing regimen, but no other chemotherapy agents. The TAMARACK study is designed to evaluate vobra duo at two different doses: 2.0 mg/kg or 2.7 mg/kg every four weeks (q4W).

About MacroGenics, Inc.

MacroGenics (the Company) is a biopharmaceutical company focused on discovering, developing, manufacturing 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, MARGENZA 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, manufacturing services revenue, 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, as well as future global net sales of TZIELD and the Company's ability to achieve the milestone payments set forth under the terms of the agreement with DRI (or its successors or assigns with respect to such agreement), 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 TZIELD, vobramitamab duocarmazine, lorigerlimab, ZYNYZ, MARGENZA or any other product candidate's revenue, expenses and costs may not be as expected, risks relating to TZIELD, vobramitamab duocarmazine, lorigerlimab, ZYNYZ, MARGENZA or any other product candidate's market acceptance, competition, reimbursement and regulatory actions; future data updates, especially with respect to vobramitamab duocarmazine; our ability to provide manufacturing services to our customers; the uncertainties inherent in the initiation and enrollment of future clinical trials; the availability of financing to fund the internal 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; expectations of future milestone payments; 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, 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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