



FOR IMMEDIATE RELEASE

MacroGenics Enters into Agreement with TerSera Therapeutics for the Sale of MARGENZA®

ROCKVILLE, MD and DEERFIELD, IL — October 22, 2024 — MacroGenics, Inc. (NASDAQ: MGNX), a biopharmaceutical company focused on discovering, developing, manufacturing and commercializing innovative antibody-based therapeutics for the treatment of cancer, and TerSera Therapeutics LLC, a privately-held biopharmaceutical company with a focus in oncology and non-opioid pain management, announced today that they have entered into an agreement in which TerSera will acquire global rights to MARGENZA® (margetuximab-cmkb).

MARGENZA was approved by the U.S. Food and Drug Administration (FDA) in December 2020 in combination with chemotherapy for the treatment of adult patients with metastatic HER2-positive breast cancer who have received two or more prior anti-HER2 regimens, at least one of which was for metastatic disease. The approval was based on results from the pivotal Phase 3 head-to-head clinical trial (SOPHIA) evaluating the safety and efficacy of MARGENZA vs. Herceptin® (trastuzumab), both combined with chemotherapy.

Pursuant to the terms of the agreement, TerSera will pay MacroGenics \$40 million at closing. MacroGenics may receive additional sales milestone payments of up to an aggregate of \$35 million. The transaction is expected to close in the fourth quarter of 2024, subject to customary closing conditions.

“This transaction will enable us to focus our efforts on advancing our pipeline of novel and differentiated oncology product candidates,” said Scott Koenig, M.D., Ph.D., President and Chief Executive Officer of MacroGenics. “We believe TerSera’s established and complementary U.S. commercial infrastructure has the potential to broaden patient access to MARGENZA.”

“MARGENZA is an important treatment option for patients with metastatic HER2+ breast cancer,” said Edward Donovan, Chief Executive Officer of TerSera. “We are very excited to add MARGENZA to our existing oncology portfolio, deepening our commitment to the treatment of patients with breast cancer.”

IMPORTANT SAFETY INFORMATION

BOXED WARNING: LEFT VENTRICULAR DYSFUNCTION AND EMBRYO-FETAL TOXICITY

- **Left Ventricular Dysfunction:** MARGENZA may lead to reductions in left ventricular ejection fraction (LVEF). Evaluate cardiac function prior to and during treatment. Discontinue MARGENZA treatment for a confirmed clinically significant decrease in left ventricular function.
- **Embryo-Fetal Toxicity:** Exposure to MARGENZA during pregnancy can cause embryo-fetal harm. Advise patients of the risk and need for effective contraception.

WARNINGS & PRECAUTIONS:

Left Ventricular Dysfunction

- Left ventricular cardiac dysfunction can occur with MARGENZA.
- In SOPHIA, left ventricular dysfunction occurred in 1.9% of patients treated with MARGENZA.



- MARGENZA has not been studied in patients with a pretreatment LVEF value of <50%, a prior history of myocardial infarction or unstable angina within 6 months, or congestive heart failure NYHA class II-IV.
- Withhold MARGENZA for $\geq 16\%$ absolute decrease in LVEF from pretreatment values or LVEF below institutional limits of normal (or 50% if no limits available) and $\geq 10\%$ absolute decrease in LVEF from pretreatment values.
- Permanently discontinue MARGENZA if LVEF decline persists greater than 8 weeks, or dosing is interrupted more than 3 times due to LVEF decline.
- Evaluate cardiac function within 4 weeks prior to and every 3 months during and upon completion of treatment. Conduct thorough cardiac assessment, including history, physical examination, and determination of LVEF by echocardiogram or MUGA scan.
- Monitor cardiac function every 4 weeks if MARGENZA is withheld for significant left ventricular cardiac dysfunction.

Embryo-Fetal Toxicity

- Based on findings in animals and mechanism of action, MARGENZA can cause fetal harm when administered to a pregnant woman. Post-marketing studies of other HER2 directed antibodies during pregnancy resulted in cases of oligohydramnios and oligohydramnios sequence manifesting as pulmonary hypoplasia, skeletal abnormalities, and neonatal death.
- Verify pregnancy status of women of reproductive potential prior to initiation of MARGENZA.
- Advise pregnant women and women of reproductive potential that exposure to MARGENZA during pregnancy or within 4 months prior to conception can result in fetal harm.
- Advise women of reproductive potential to use effective contraception during treatment and for 4 months following the last dose of MARGENZA.

Infusion-Related Reactions (IRRs)

- MARGENZA can cause IRRs. Symptoms may include fever, chills, arthralgia, cough, dizziness, fatigue, nausea, vomiting, headache, diaphoresis, tachycardia, hypotension, pruritus, rash, urticaria, and dyspnea.
- In SOPHIA, IRRs were reported by 13% of patients on MARGENZA plus chemotherapy. Most of the IRRs occur during Cycle 1. Grade 3 IRRs were reported in 1.5% of MARGENZA-treated patients.
- Monitor patients during and after MARGENZA infusion. Have medications and emergency equipment to treat IRRs available for immediate use.
- In patients experiencing mild or moderate IRRs, decrease rate of infusion and consider premedications, including antihistamines, corticosteroids, and antipyretics. Monitor patients until symptoms completely resolve.
- Interrupt MARGENZA infusion in patients experiencing dyspnea or clinically significant hypotension and intervene with supportive medical therapy as needed. Permanently discontinue MARGENZA in all patients with severe or life-threatening IRRs.

MOST COMMON ADVERSE REACTIONS:

The most common adverse drug reactions (>10%) with MARGENZA in combination with chemotherapy are fatigue/asthenia (57%), nausea (33%), diarrhea (25%), vomiting (21%), constipation (19%), headache (19%), pyrexia (19%), alopecia (18%), abdominal pain (17%), peripheral neuropathy (16%),



arthralgia/myalgia (14%), cough (14%), decreased appetite (14%), dyspnea (13%), infusion-related reactions (13%), palmar-plantar erythrodysesthesia (13%), and extremity pain (11%).

You may report side effects to the FDA at (800) FDA-1088 or www.fda.gov/medwatch or to MacroGenics at (844)-MED-MGNX (844-633-6469).

INDICATION

MARGENZA is a HER2/neu receptor antagonist indicated, in combination with chemotherapy, for the treatment of adult patients with metastatic HER2-positive breast cancer who have received two or more prior anti-HER2 regimens, at least one of which was for metastatic disease.

Please see full [Prescribing Information](#), including [Boxed Warning](#).

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 targeting HER2 have greatly improved outcomes; however, a significant number of patients progress to later lines of therapy. Effective treatments for metastatic HER2-positive breast cancer continue to remain an unmet need.

About MARGENZA

MARGENZA (margetuximab-cmkb) is an Fc-engineered, monoclonal antibody that targets the HER2 oncoprotein. HER2 is expressed by tumor cells in breast, gastroesophageal and other solid tumors. Similar to trastuzumab, margetuximab-cmkb inhibits tumor cell proliferation, reduces shedding of the HER2 extracellular domain and mediates antibody-dependent cellular cytotoxicity (ADCC). However, through MacroGenics' Fc Optimization technology, margetuximab-cmkb has been engineered to enhance the engagement of the immune system. In vitro, the modified Fc region of margetuximab-cmkb increases binding to the activating Fc receptor FCGR3A (CD16A) and decreases binding to inhibitor Fc receptor FCGR2B (CD32B). These changes lead to greater in vitro ADCC and NK cell activation. The clinical significance of in vitro data is unknown.

About MacroGenics, Inc.

MacroGenics 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.

About TerSera Therapeutics

TerSera Therapeutics is a biopharmaceutical company with a focus in oncology and non-opioid pain management. Founded in 2016, TerSera is building new cornerstones of care through its portfolio of unique therapeutics, amplifying their ability to deliver meaningful outcomes for patients. TerSera has been recognized as a 2024 Healthcare Top Workplace. For additional information, please visit tersera.com and follow us on [LinkedIn](#).



MacroGenics' 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 and regulatory plans for the Company's therapeutic candidates, expected timing of the release of final safety and efficacy data, including mature median rPFS 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 timing and results of mature median radiographic progression-free survival, other efficacy and safety data 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; costs of litigation and the failure to successfully defend lawsuits and other claims against us; 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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