Magenta Therapeutics Reports Second Quarter Financial Results and Recent Program Highlights

August 4, 2022

– MGTA-117 Phase 1/2 clinical trial progress continues and remains consistent with earlier observations of target binding, target cell reductions, rapid drug clearance and a favorable tolerability profile; interim clinical data disclosure anticipated in Q4 2022 –

– IND-enabling preclinical studies ongoing for CD45 antibody-drug conjugate; in-life portion of dose-ranging toxicology study complete; program update and development timeline expectations anticipated in Q4 2022 –

– Clinical trial active and enrolling for MGTA-145 stem cell mobilization in sickle cell disease clinical trial; initial data anticipated in Q4 2022 –

– Approximately $139.4 million in cash, cash equivalents and marketable securities at the end of Q2 2022 and maintains guidance that cash reserves are expected to fund operating plan into Q2 2024 –

CAMBRIDGE, Mass., Aug. 04, 2022 (GLOBE NEWSWIRE) -- Magenta Therapeutics (Nasdaq: MGTA), a clinical-stage biotechnology company developing novel medicines designed to bring the curative power of stem cell transplant to more patients, today reported financial results for the second quarter ending June 30, 2022, and recent program highlights.

"We continue to execute across the portfolio while maintaining our prioritized spending and program investment. We look forward to collecting additional data from multiple cohorts in our MGTA-117 Phase 1/2 dose escalation clinical trial and plan to disclose interim results in Q4 2022," said Jason Gardner, President and Chief Executive Officer of Magenta Therapeutics. "As our CD45 antibody drug conjugate program continues to progress with concept-validating preclinical data, we expect to be able to provide an overview of the program's clinical development plan and its anticipated timelines later this year as well. Finally, we are excited about initiating the MGTA-145 stem cell mobilization clinical trial in sickle cell disease at leading research hospitals to understand MGTA-145's potential for better mobilization that could result in better outcomes for patients with this debilitating disease."

Program Highlights:

MGTA-117 Phase 1/2 Clinical Trial Progression and Data Disclosure Expectations

MGTA-117 is Magenta's most advanced targeted conditioning product candidate. The program is in a Phase 1/2 clinical trial in patients with relapsed/refractory acute myeloid leukemia, or AML, and myelodysplastic syndromes, or MDS. MGTA-117 is an anti-CD117 antibody conjugated to an amanitin payload, and it is designed to target CD117, also known as c-Kit, which is highly expressed on hematopoietic stem cells and leukemic cells.

- The MGTA-117 clinical trial continues to make progress with additional clinical trial site activations, patient identification, patient screening and enrollment.
- Magenta expects clinical data from additional dose-escalation cohorts will support its earlier reported clinical observations from Cohort 1, which indicated evidence of MGTA-117's potential to bind CD117+ cells, reduce CD117+ erythroid progenitor cells in the bone marrow, reduce leukemic blasts in the bone marrow, rapidly clear the body and maintain a favorable tolerability profile.
- Magenta expects to report interim clinical data from multiple dose-escalation cohorts from the clinical trial in Q4 2022.
- Magenta anticipates using the interim clinical data from this trial to engage with regulatory authorities to plan for the transition of the trial into transplant-eligible AML patients. Although the timing and scope of the discussion with regulators will be determined by the available clinical data, Magenta anticipates engagement with regulators in Q4 2022.
- Magenta also expects the interim clinical data to inform next steps towards development of MGTA-117 as a conditioning agent for autologous gene therapy, including existing clinical collaboration partnerships in hemoglobinopathies and lysosomal storage disorders, with Beam Therapeutics and AVROBIO, Inc. respectively.
- Magenta will participate in both the BTIG 2022 Virtual Biotechnology Conference on Monday, August 8th, 2022 and the Gene Modulation Panel Discussion at the 2022 Wedbush PacGrow Healthcare Conference, to be held virtually, on Tuesday, August 9th, 2022 at 9:45 a.m. ET. A live webcast of the Gene Modulation Panel can be accessed via the Magenta Therapeutics website at https://investor.magentatx.com/events-and-presentations.

CD45-Antibody Drug Conjugate (ADC): Second Targeted Conditioning Program

CD45 is broadly expressed on hematopoietic cells and Magenta's CD45-ADC is designed to selectively target and deplete both stem cells and lymphocytes, and is intended to enable patients with blood cancers and autoimmune diseases to avoid the use of chemotherapy prior to stem cell transplant.

- Magenta has recently completed the in-life portion of a dose-ranging toxicology study and will use the resulting data to inform dosing for its planned GLP toxicology study. Other IND-enabling activities and plans are ongoing. Magenta expects to provide a further update on the CD45 program in Q4 2022.

MGTA-145 Stem Cell Mobilization and Collection

Magenta is developing MGTA-145, in combination with plerixafor, to improve the process by which stem cells are stimulated out of the bone marrow and into the bloodstream, so they are available for collection for future re-infusion, known as stem cell mobilization, which is required for all transplants and ex vivo gene therapy applications.

- Magenta has initiated a Phase 2 clinical trial in sickle cell disease (SCD) at multiple clinical trial sites. The clinical trial operates in collaboration with bluebird bio to evaluate the utility of MGTA-145, in combination with plerixafor, for the mobilization and collection of stem cells in patients with SCD where mobilization and collection are difficult and there is a clear unmet medical need. Magenta expects initial data from this trial in Q4 2022.

Financial Results:
Cash Position: Cash, cash equivalents and marketable securities as of June 30, 2022, were $139.4 million, compared to $176.9 million as of December 31, 2021. Magenta anticipates that its cash, cash equivalents and marketable securities will be sufficient to fund its current operational plan into Q2 2024.

Research and Development Expenses: Research and development expenses were $11.6 million in the second quarter of 2022, compared to $11.1 million in the second quarter of 2021. The increase was driven primarily by higher preclinical and manufacturing costs to support our IND enabling studies for CD45-ADC, offset by a decrease in costs related to our completed Phase 2 investigator-initiated clinical trial in multiple myeloma patients.

General and Administrative Expenses: General and administrative expenses were $6.5 million for both the second quarter of 2022 and the second quarter of 2021.

Net Loss: Net loss was $17.3 million for the second quarter of 2022, compared to net loss of $16.9 million for the second quarter of 2021.

About Magenta Therapeutics
Magenta Therapeutics is a clinical-stage biotechnology company developing medicines designed to bring the curative power of stem cell transplant to more patients with blood cancers, genetic diseases and autoimmune diseases. Magenta is combining leadership in stem cell biology and biotherapeutics development with clinical and regulatory expertise to revolutionize immune and blood reset to allow more patients to take advantage of the curative potential of stem cell transplant as well as potentially improve eligibility for future gene therapies.

Magenta is based in Cambridge, Mass. For more information, please visit www.magentatx.com.

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Forward-Looking Statements
This press release contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995, as amended. These statements include, without limitation, implied and express statements relating to: Magenta's future business expectations, plans and prospects; the potential of, and expectations for, Magenta's product candidate pipeline; the potential benefits and expected performance of Magenta's product candidates and programs; the development of product candidates and advancement of preclinical and clinical programs; expectations, plans and timing for preclinical activities, clinical trials and related results involving Magenta's product candidates; timing for the receipt and disclosure of preclinical and clinical trial data, clinical toxicology results, and other results involving Magenta's product candidates; timing for the disclosure of developmental timelines, developmental plans and program updates regarding Magenta's product candidates; timelines and expectations for patient dosing, dosing regimens and administration; the expectation that clinical data from additional dose-escalation cohorts will support Magenta's earlier reported clinical observations from Cohort 1 of the MGTA-117 Phase 1/2 clinical trial in patients with relapsed/refractory and MDS, which indicated evidence of MGTA-117's potential to bind CD117+ cells, reduce CD117+ erythroid progenitor cells in the bone marrow, reduce leukemic blasts in the bone marrow, rapidly clear the body and maintain a favorable tolerability profile; anticipation and timing regarding the use of interim clinical data from the MGTA-117 Phase 1/2 clinical trial to engage with regulatory authorities to plan for the transition of the trial into transplant-eligible AML patients; the expectation of using interim clinical data to inform next steps towards development of MGTA-117 as a conditioning agent for autologous gene therapy, including existing clinical collaboration partnerships in hemoglobinopathies and lysosomal storage disorders, with Beam Therapeutics and AVROBIO, Inc. respectively; the expectation of using resulting data from the CD45 in-life portion of a dose-ranging toxicology study to inform dosing for Magenta's planned GLP toxicology study for CD45; the belief that preliminary data from Cohort 1 of the MGTA-117 Phase 1/2 clinical trial provide an encouraging early signal in support of MGTA-117's planned transition to the transplant-eligible AML patient population; the anticipation that dose escalation will lead to further drug activity and enable identification of an appropriate dose for development in patients eligible for transplant; the anticipation that further data from the current clinical trial showing MGTA-117 at high receptor occupancy levels with well-tolerated cell depletion in the blood and/or bone marrow will be supportive of the planned transition to transplant-eligible patients; the anticipated benefits of Magenta's revised operating plan; and Magenta's current anticipation and guidance regarding the ability of its cash, cash equivalents and marketable securities to fund its current operating plan into Q2 2024.

Words such as "anticipate," "believe," "continue," "could," "designed," "endeavor," "estimate," "expect," "intend," "may," "might," "plan," "potential," "predict," "project," "seek," "should," "target," "preliminary," "will," "would" and similar expressions are intended to identify forward-looking statements. The express or implied forward-looking statements included in this press release are only predictions and are subject to a number of risks, uncertainties and assumptions, including, without limitation: volatility and uncertainty in the capital markets for biotechnology companies; uncertainties inherent in preclinical and clinical trials, and in the availability and timing of data from ongoing and planned clinical and preclinical trials; the ability to initiate, enroll, conduct or complete ongoing and planned preclinical and clinical trials; vulnerability and/or fragility of, and the presence of underlying disorders in, the patient population for the clinical trials of Magenta's product candidates, including the MGTA-117 Phase 1/2 clinical trial in patients with relapsed/refractory AML and MDS; the delay of any current or planned preclinical or clinical trials, or the delay in development of Magenta's product candidates; whether results from preclinical or earlier clinical trials will be predictive of the results of future trials; interactions with regulatory agencies such as the U.S. Food and Drug Administration; the expected timing of submissions for regulatory approval to conduct or continue trials or to market products; Magenta's ability to successfully demonstrate the safety and efficacy of its product candidates; whether Magenta's cash resources will be sufficient to fund Magenta's foreseeable and unforeseeable operating expenses and capital expenditure requirements; and risks, uncertainties and assumptions regarding the impact of the continuing COVID-19 pandemic on Magenta's business, operations, preclinical activities, clinical trials, strategy, goals and anticipated timelines. These and other risks are described in additional detail in Magenta's Quarterly Report on Form 10-Q for the quarter ended June 30, 2022, expected to be filed on or about August 4, 2022, and its other filings made with the Securities and Exchange Commission from time to time. Any forward-looking statements contained in this press release represent Magenta's views only as of today and should not be relied upon as representing its views as of any subsequent date. Magenta explicitly disclaims any obligation to update any forward-looking statements, except to the extent required by law.

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Magenta Therapeutics, Inc.

STATEMENTS OF OPERATIONS
(unaudited)
(In thousands, except share and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	**2021**	**2022**	**2021**
Operating expenses:				
Research and development	$ 11,603	$ 11,129	$ 28,150	$ 22,857
General and administrative	6,480	6,481	13,767	13,450
Total operating expenses	18,083	17,610	41,917	36,307
Loss from operations	(18,083)	(17,610)	(41,917)	(36,307)
Interest and other income, net	812	682	1,696	1,890
Net loss	$ (17,271)	$ (16,928)	$ (40,221)	$ (34,417)
Net loss per share, basic and diluted	$ (0.29)	$ (0.32)	$ (0.68)	$ (0.67)
Weighted average common shares outstanding, basic and diluted	58,815,543	53,705,289	58,807,395	51,150,391

BALANCE SHEET DATA
(unaudited)
(In thousands)

	June 30, 2022	December 31, 2021
Cash, cash equivalents and marketable securities	$ 139,425	$ 176,926
Working capital	130,786	169,830
Total assets	175,121	189,934
Stockholders' equity	135,678	172,672

Source: Magenta Therapeutics