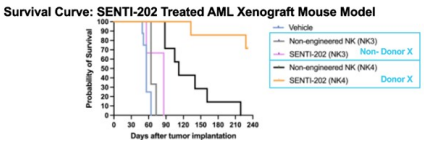
Senti Biosciences Holdings Announces Positive FDA RMAT Meeting on Registrational Clinical and CMC Strategy for SENTI-202 in Relapsed/Refractory AML, Along with Important Efficacy and Durability Updates on the SENTI-202 Clinical Program

Following a Type B meeting with FDA, Senti Bio plans to proceed with a single-arm multi-center registrational trial for SENTI-202, building off the strong Phase 1 clinical results demonstrating deep and durable MRD-negative complete remissions

To further optimize SENTI-202 efficacy, the selection criteria for donors for all future manufacturing will include the "Donor X" phenotype

Phase 1 clinical trial patients receiving SENTI-202 from Donor X-derived NK cells achieved a 50% composite CR (cCR) rate

Survival Curve:



SENTI-202 Treated AML Xenograft Mouse Model

SOUTH SAN FRANCISCO, Calif., May 14, 2026 (GLOBE NEWSWIRE) -- Senti Biosciences Holdings, Inc. (Nasdaq: SNTI) ("Senti Bio" or the "Company"), a clinical-stage biotechnology company developing next-generation cell and gene therapies using its proprietary Gene Circuit platform, today announced the successful completion of a Type B Initial Comprehensive Multidisciplinary Regenerative Medicine Advanced Therapy (RMAT) meeting with the U.S. Food and Drug Administration (FDA) regarding SENTI-202, the Company's first-in-class Logic Gated off-the-shelf CAR-NK cell therapy for relapsed/refractory acute myeloid leukemia (R/R AML) and updated Phase 1 clinical data.

Following the RMAT meeting, the Company has finalized its pivotal clinical and chemistry, manufacturing and controls (CMC) strategy for SENTI-202. The Company plans to implement a single-arm, multi-center pivotal trial intended to support potential SENTI-202 registration in patients with R/R AML. This study is expected to evaluate SENTI-202 administered following lymphodepletion (LD) chemotherapy in a patient population consistent with the Phase 1 trial population.

In addition to the positive RMAT meeting, after conducting exploratory efficacy covariate analysis of the Phase 1 trial results, Senti has identified a specific Donor X attribute that correlates with efficacy of SENTI-202, with 50% (7/14) of the patients achieving a cCR when they received any SENTI-202 doses manufactured from Donor X-characteristic-derived NK cells in Cycle 1 versus 12.5% (1/8) achieving a cCR when they received SENTI-202 manufactured from non-Donor X NK cells (see Table below). As a result of this discovery, all future SENTI-202 manufacturing, including for pivotal study use, will use Donor X material. The Donor X attribute is found in ~50% of adult donors, and published literature supports increased NK cell cytotoxicity in donors with this phenotype. The Donor X NK phenotype is independent of HLA or KIR matching, thus supporting SENTI-202's allogeneic off-the-shelf usage. Retrospective analysis of preclinical MV4-11 NSG mouse model data confirmed increased activity and survival with Donor X product (see Figure below).

Senti Bio also announced that SENTI-202 continues to exhibit durable MRD-negative responses in the full 22 patient Phase 1 trial, which compares favorably with current FDA approved therapies for R/R AML. At RP2D, across all patients receiving a mix of Donor X and non-Donor X material, an ORR of 44% and cCR of 37.5% was observed with 100% of CRs being MRD negative. The complete remissions continue to be durable, with all the CR/CRh responders who were in remission as of the data-cut supporting the oral presentation at the 2025 ASH annual meeting continuing to maintain remission with an additional 7 months of follow up, the longest duration being 21+ months.

"This positive FDA RMAT meeting marks a transformational moment for Senti Bio and significantly advances our path toward potential registration of SENTI-202," said Tim Lu, M.D., Ph.D., Chief Executive Officer and Co-Founder of Senti Bio. "This news, combined with the compelling clinical responses observed to date that led to refinements in our donor selection strategy, positions us to advance SENTI-202 toward a potential registrational study in relapsed/refractory AML. We believe this milestone further validates both our Gene Circuit platform and the differentiated therapeutic potential of Logic Gated cell therapies."

FDA previously granted RMAT designation to SENTI-202. This program is intended to facilitate the expedited development and review of regenerative medicine therapies addressing serious or life-threatening diseases.

"The FDA feedback provides important clarity around our registrational development strategy and further supports our conviction in the SENTI-202 program," said Kanya Rajangam, M.D., Ph.D., Chief Medical Officer of Senti Bio. "The excellent clinical activity observed thus far, including MRD-negative durable complete remissions alongside a favorable safety profile, gives us confidence as we transition toward later-stage development. We are focused on rapidly implementing the pivotal study while also exploring potential expansion opportunities in newly diagnosed AML and pediatric AML. Since the filing of our IND, Senti has focused on donor selection to minimize variability. We are in a strong position as we prepare for our clinical trials with the identification of a donor phenotype that correlates with increased activity and continues to support SENTI-202's allogeneic manufacturing."

Relapsed/refractory AML remains an aggressive hematologic malignancy with limited therapeutic options and poor long-term survival outcomes. Senti Bio believes SENTI-202's differentiated mechanism, off-the-shelf availability, and encouraging early clinical profile position the program as a potentially important next-generation treatment option for AML patients.

Table: Phase 1 SENTI-202-101 Trial R/R AML Patient Efficacy Data Based on Donor Phenotype

All Patients (N=22)	**Any Donor X in Cycle 1**	**No Donor X in Cycle 1**
ORR (Overall Response Rate)	**8/14 (57%)**	2/8 (25%)
cCR	**7/14 (50%)**	1/8 (12.5%)

	Vehicle	Non-engineered NK (NK3)	SENTI-202 (NK3)	Non-engineered NK (NK4)	SENTI-202 (NK4)
Median Survival (d)	56.0	64.0	86.0	112.0	Not Reached
Figure: Retrospective analysis of preclinical MV4-11 NSG mouse model data confirms increased activity and survival with SENTI-202 made from Donor X product. Donor X characteristic was confirmed post-hoc.					

About SENTI-202
SENTI-202 is a first-in-class Logic Gated off-the-shelf CAR-NK cell therapy designed to selectively target and eliminate CD33 and/or FLT3 expressing hematologic malignancies, including AML and myelodysplastic syndrome (MDS), while sparing healthy bone marrow cells. SENTI-202 incorporates multiple engineered Gene Circuits, including OR GATE and NOT GATE logic systems and calibrated-release IL-15, to improve tumor specificity, persistence, and therapeutic activity.

SENTI-202 has received Regenerative Medicine Advanced Therapy (RMAT) designation and Orphan Drug Designation (ODD) from the U.S. Food and Drug Administration.

About the Phase 1 Study
The multinational, multicenter dose-finding study of SENTI-202 (NCT06325748) comprised an initial dose finding using a modified "3+3" study design to determine the maximum tolerated dose (MTD) and/or recommended phase two dose (RP2D) of SENTI-202 when administered after lymphodepleting chemotherapy (Part 1) followed by disease-specific expansion cohorts at the RP2D (Part 2).

The primary objectives were to evaluate safety, determine the MTD and RP2D, and assess efficacy in expansion cohorts using ELN 2022 consensus criteria for AML, with key secondary objectives including measurable residual disease assessment, pharmacokinetics, and pharmacodynamics using CyTOF on serial bone marrow samples. For more information visit clinicaltrials.gov.

About Senti Bio
Senti Bio is a clinical stage biotechnology company developing a new generation of cell and gene therapies for patients living with incurable diseases. To achieve this, Senti Bio is leveraging its synthetic biology platform to engineer Gene Circuits into new medicines with enhanced precision and control. These Gene Circuits are designed to precisely kill cancer cells, to spare healthy cells, to increase specificity to target tissues, and/or to be controllable even after administration. The Company's wholly-owned pipeline comprises cell therapies engineered with Gene Circuits to target challenging liquid and solid tumor indications. Senti Bio's Gene Circuits have been shown preclinically to work in both NK and T cells. Senti Bio has also preclinically demonstrated the potential breadth of Gene Circuits in other modalities and diseases outside of oncology, and continues to advance these capabilities through partnerships.

Forward-Looking Statements
This press release and document contain certain statements that are not historical facts and are considered forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These forward-looking statements generally are identified by the words "believe," "could," "predict," "continue," "ongoing," "project," "expect," "anticipate," "estimate," "intend," "strategy," "future," "opportunity," "plan," "may," "should," "will," "would," "will be," "will continue," "will likely result," "forecast," "seek," "target" and similar expressions that predict or indicate future events or trends or that are not statements of historical matters. Forward-looking statements are predictions, projections, and other statements about future events that are based on current expectations of Senti Bio's management and assumptions, whether or not identified in this document, and, as a result, are subject to risks and uncertainties. Forward-looking statements include, but are not limited to, expectations regarding Senti Bio's future results. These forward-looking statements are provided for illustrative purposes only and are not intended to serve as and must not be relied on by any investor as, a guarantee, an assurance, a prediction, or a definitive statement of fact or probability. Actual events and circumstances are difficult or impossible to predict and will differ from assumptions. Many actual events and circumstances are beyond the control of Senti Bio. Many factors could cause actual future results to differ materially from the forward-looking statements in this document, including but not limited to: (i) changes in domestic and foreign business, market, financial, political and legal conditions, (ii) changes in the competitive and highly regulated industries in which Senti Bio operates, variations in operating performance across competitors, changes in laws and regulations affecting Senti Bio's business, (iii) the ability to implement business plans, forecasts and other expectations, (iv) the risk of downturns and a changing regulatory landscape in Senti Bio's highly competitive industry, (v) risks relating to the uncertainty of any projected financial information with respect to Senti Bio, (vi) risks related to uncertainty in the timing or results of Senti Bio's , clinical studies, patient enrollment, and GMP manufacturing startup activities, (vii) Senti Bio's dependence on third parties in connection with clinical studies, and GMP manufacturing activities, (viii) risks related to delays and other impacts from macroeconomic and geopolitical events, increasing rates of inflation and rising interest rates on business operations, (ix) risks related to the timing and utilization of the grant from CIRM, and (x) the success of any future research and development efforts by Senti Bio. The foregoing list of factors is not exhaustive. You should carefully consider the foregoing factors and the other risks and uncertainties described in the "Risk Factors" section of Senti Bio's most recent annual report filed with the U.S. Securities and Exchange Commission ("SEC"), and other documents filed by Senti Bio from time to time with the SEC. These filings identify and address other important risks and uncertainties that could cause actual events and results to differ materially from those contained in the forward-looking statements in this document. There may be additional risks that Senti Bio does not presently know, or that Senti Bio currently believes are immaterial that could also cause actual results to differ from those contained in the forward-looking statements in this document. Forward-looking statements speak only as of the date they are made. Senti Bio anticipates that subsequent events and developments may cause Senti Bio's assessments to change. Except as required by law, Senti Bio assumes no obligation to update publicly any forward-looking statements, whether as a result of new information, future events, or otherwise.

Availability of Other Information About Senti Biosciences Holdings, Inc.
For more information, please visit the Senti Bio website at www.sentibio.com or follow Senti Bio on X (@SentiBio) and LinkedIn (Senti Biosciences). Investors and others should note that we communicate with our investors and the public using our company website (www.sentibio.com), including, but not limited to, company disclosures, investor presentations and FAQs, Securities and Exchange Commission filings, press releases, public conference call transcripts and webcast transcripts, as well as on X and LinkedIn. The information that we post on our website or on X or LinkedIn could be deemed to be material information. As a result, we encourage investors, the media and others interested to review the information that we post there on a regular basis. The contents of our website or social media shall not be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended.

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A photo accompanying this announcement is available at https://www.globenewswire.com/NewsRoom/AttachmentNg/aae7bc52-613b-4390-92fc-

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