



Senti Bio Announces Updated SENTI-202 Clinical Data from Ongoing Phase 1 Trial in Relapsed or Refractory Acute Myeloid Leukemia Patients, Demonstrating Deep, MRD Negative, Durable Complete Remissions and a Favorable Safety Profile

- ASH 2025 oral presentation on SENTI-202 in 20 Relapsed/Refractory Acute Myeloid Leukemia (R/R AML) patients (18 response evaluable) shows high efficacy: 50% ORR and 42% CR/CRh (100% of CRs and 83% of all responses were MRD negative) at RP2D, 7.6 months median duration of composite Complete Remission across all patients, and a favorable safety profile
- Pharmacodynamic data from these patients validate SENTI-202's novel OR/NOT Logic Gate mechanism of action for selectively killing AML blasts and leukemic stem cells (LSCs) while sparing healthy hematopoietic stem and progenitor cells (HSPCs) and reinforce the potential of Senti's Logic Gates in a new generation of precise and effective cell therapies for hematologic and solid cancers
- These data, combined with FDA RMAT designation for SENTI-202 that was also announced today, supports the potential for rapid advancement of SENTI-202 into a pivotal study for R/R AML and potential expansion into other indications
- Virtual investor call and webcast to be held on [December 9 at 8:00 a.m. EST](#)

SOUTH SAN FRANCISCO, Calif., Dec. 09, 2025 (GLOBE NEWSWIRE) -- [Senti Biosciences, Inc.](#) (Nasdaq: SNTI) ("Senti Bio"), a clinical-stage biotechnology company developing next-generation cell and gene therapies using its proprietary Gene Circuit platform, announced new data from its ongoing multinational, multicenter clinical trial of SENTI-202, a first-in-class CD33/FLT3 targeting Logic Gated CAR NK cell therapy being studied in patients with relapsed or refractory Acute Myeloid Leukemia (R/R AML). Data from 20 patients (18 with evaluable responses) were presented at the American Society of Hematology (ASH) Annual Meeting in Orlando. The Company will host a [conference call and webcast](#) today, December 9th, at 8:00 AM ET to discuss the results (details below).

[Highlights of the latest findings](#) in the open-label study of the safety, efficacy, and pharmacodynamics of SENTI-202, when administered after Fludarabine (Flu)/Ara-C (cytarabine) lymphodepletion (LD), in R/R AML patients are summarized below.

- Deep and durable responses observed to-date build on a growing body of evidence of the potential efficacy and safety of SENTI-202.
 - 50% (6/12) of patients at the Recommended Phase 2 Dose (RP2D) and 50% (9/18) of all trial patients achieved an Overall Response Rate (ORR) outcome
 - 42% (5/12) of patients at the RP2D and 39% (7/18) of all patients overall achieved a Complete Remission (CR) or CR with Partial Hematologic Recovery (CRh)
 - 100% of all CRs and ~80%+ of all responses were MRD negative
 - With limited follow-up in the RP2D cohort, the Kaplan-Meier estimate of median duration of composite Complete Remissions across all patients is 7.6 months (6.1, NE)
 - Longest durability of response greater than 1 year and continuing as of data cut-off date
- Correlative data from patients validate the Logic Gate mechanism of action enabling selective killing of AML blasts and AML LSCs with sparing of healthy HSPCs in patients' bone marrow.
 - Potent AML blast killing in responders, even in a patient with 90% bone marrow AML blasts at baseline
 - >10-fold killing of AML LSCs in ORR responders
 - Responders with any level of HSPCs at baseline achieved CR/CRh, and exhibited preservation or increase of HSPCs after SENTI-202 treatment
- SENTI-202 continues to be well-tolerated, with no Dose-Limiting Toxicities, no SENTI-202-related serious adverse events, or adverse events resulting in discontinuation.
 - Most frequent Grade 3+ Adverse Events (AEs) were predominantly hematologic, unrelated to SENTI-202, and consistent with events observed in R/R AML patients receiving lymphodepletion
 - Most frequent SENTI-202-related Adverse Events of Interest (AEI) were Grade 1/2 pyrexia, likely representing delayed infusion related reactions that resolved rapidly with standard of care treatment
 - This safety profile supports the potential for outpatient delivery of SENTI-202
- SENTI-202 was detected in the peripheral blood of all patients, with pharmacokinetics that were consistent with other allogeneic NK cell therapies: expansion in the peripheral blood for the first 2 weeks followed by natural clearance.
- SENTI-202's clinical responses show that the product has conferred meaningful clinical benefits to a heavily pretreated R/R AML population.
 - The majority of patients (65%) had disease with adverse risk genetics by ELN 2022 criteria at diagnosis and entered the trial after previously having received a median of 2 lines of therapy within median of less than a year from diagnosis
 - All patients were previously exposed to chemotherapy, including Ara-C (cytarabine), and most had also received

anthracycline, venetoclax, and/or hypomethylating agents

- Patients with actionable mutations received prior targeted therapies, including FLT3 and IDH inhibitors
- Patients entered the trial with a median of 35% baseline bone marrow blasts, and 65% of patients overall had thrombocytopenia/neutropenia at study entry
- Responses were observed in patients with multiple poor prognostic indicators, such as adverse risk genetics, and being primary refractory, refractory to their most recent regimen, or refractory to Flu and/or Ara-C containing regimens

"SENTI-202 continues to demonstrate deep, durable responses and a favorable safety profile in patients with relapsed or refractory AML, where standard therapies often offer patients a survival rate of just a few months," said **Dr. Nosha Farhadfar, Hematologist & Adult Bone Marrow Transplant Specialist at the Sarah Cannon Transplant & Cellular Therapy Program at Methodist Hospital, which conducts research through Sarah Cannon Research Institute (SCRI)**. "I'm looking forward to continuing to participate in this clinical evaluation to further investigate SENTI-202's efficacy and safety in patients with R/R AML, with the ambitious and exciting goal of selectively targeting AML blasts and LSCs while protecting healthy HSPCs."

"Existing cell therapies and biologic drugs have generally been limited to a subset of indications that have cancer-specific targets due to difficulty in killing cancer aggressively without triggering dangerous attacks on healthy tissues," said **Timothy Lu, MD, PhD, Co-Founder and CEO of Senti Biosciences**. "To overcome this longstanding key challenge, our Logic Gated cell therapies recognize and kill cancer cells based on multiple targets while simultaneously protecting healthy cells from toxicity. Since CD33 and/or FLT3 are expressed in most AML patients, we believe that SENTI-202 has a multi-billion dollar market potential. Moreover, our positive SENTI-202 data further validates the potential for Senti Bio's platform to transform the treatment of a broad set of cancers where other medicines have insufficient therapeutic windows."

Senti Biosciences also [announced today](#) that the FDA has granted SENTI-202 Regenerative Medicine Advanced Therapy (RMAT) designation, which validates its potential to address a serious unmet medical need. In June 2025, SENTI-202 also received [Orphan Drug Designation](#).

"The encouraging SENTI-202 data presented at ASH 2025 demonstrating deep, durable Complete Remissions and a favorable safety profile in a heavily pretreated patient population directly shapes Senti Bio's clinical development strategy," said **Kanya Rajangam, M.D., Ph.D. Chief Medical Officer at Senti Bio**. "This clinical evidence, together with the receipt of recent RMAT and Orphan Drug Designations from the FDA, allows us to rapidly advance SENTI-202 into pivotal studies and to explore its potential in broader patient populations that may include newly diagnosed AML, pediatric AML, and myelodysplastic syndromes (MDS)."

Conference Call and Webcast Details

As previously announced the Company will host a conference call and [webcast](#) to discuss the updated clinical results from SENTI-202 today, Tuesday, December 9, 2025 at 8:00 a.m. EST.

The call will be hosted by Timothy Lu, MD, PhD, Chief Executive Officer and Co-Founder, and Kanya Rajangam, MD, PhD, President, Head of R&D and Chief Medical Officer, of Senti Bio, who will be joined by Nosha Farhadfar, MD, Hematologist and Bone Marrow Transplant Physician, Sarah Cannon Transplant & Cellular Therapy Program at Methodist Hospital which conducts research through Sarah Cannon Research Institute (SCRI). Interested participants and investors may access the conference call by dialing (877) 524-8416 (domestic) or +1 (412) 902-1028 (international). The [webcast](#) will be accessible on the [Events](#) page under the [Investors](#) section of the Company's website (www.sentibio.com) and will be archived for 90 days following the live event.

About the Study

The multinational, multicenter dose-finding study of SENTI-202 (NCT06325748) is comprised of 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 are 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-202

SENTI-202 is the first Logic Gated off-the-shelf CAR-NK cell therapy product candidate designed to selectively target and eliminate CD33 and/or FLT3 expressing hematologic malignancies, such as AML and myelodysplastic syndrome (MDS), while sparing healthy bone marrow cells. SENTI-202 has three main components. First, SENTI-202 contains an OR GATE, which is an activating CAR that recognizes and kills CD33 and FLT3 expressing cells. By targeting either or both of these antigens, SENTI-202 is designed to effectively kill both leukemic blasts (that largely express CD33) and leukemic stem cells (that predominantly express FLT3), which constitute a difficult-to-eradicate reservoir of AML disease. Second, SENTI-202 contains a NOT GATE, which is an inhibitory CAR that is designed to recognize EMCN selectively expressed on healthy hematopoietic stem and progenitor cells and protect those healthy cells from being killed even if they express CD33 and/or FLT3, thus potentially widening the therapeutic window. Third, SENTI-202 contains calibrated-release IL-15, which is designed to significantly increase cell persistence, expansion and activity of both the CAR-NK cells and host immune cells. The NK cells used to construct SENTI-202 are sourced from selected healthy adult donors, manufactured, cryopreserved and available off-the-shelf for use as needed. Senti Bio is currently enrolling adult patients with R/R CD33 and/or FLT3 expressing heme malignancies in a Phase 1 clinical trial for SENTI-202, which can be a potential first-in-class allogeneic treatment for AML/MDS patients.

The U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation (ODD) and Regenerative Medicine Advanced Therapy (RMAT) designation to SENTI-202 for the treatment of relapsed/refractory hematologic malignancies including AML.

About AML

AML is a cancer of the blood and bone marrow and is one of the most common types of acute leukemia in adults. It is estimated there will be 22,010 new cases of AML in the United States in 2025. At diagnosis, the five-year survival rate for these patients is approximately 32.9%. Newly diagnosed AML is currently treated with chemotherapy, targeted therapies, and/or allogeneic or autologous stem cell transplant. For patients with R/R AML, there are few treatment options and median overall survival is typically approximately five months.

About Senti Bio

Senti Bio is a 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 is comprised of cell therapies engineered with Gene Circuits to target challenging liquid and solid tumor indications. Senti'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 periodic 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, 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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