Senti Bio Receives FDA Regenerative Medicine Advanced Therapy (RMAT) Designation for SENTI-202 in the Treatment of Adults with Relapsed or Refractory Acute Myeloid Leukemia

- RMAT designation indicates that SENTI-202 has the potential to address unmet medical needs for patients with Relapsed/Refractory (R/R) Acute Myeloid Leukemia (AML) based on preliminary clinical evidence, and offers benefits of FDA working closely with Senti Bio to provide guidance and advice on generating the data needed to support approval of the product in an efficient manner
- Second FDA designation for SENTI-202 this year, after Orphan Drug Designation, is supported by clinical data showing deep and durable complete remission rates combined with a well-tolerated safety profile
- Data released at the American Society of Hematology (ASH) Annual Meeting on December 8, 2025 showed 50% Overall Response Rate (ORR) and 42% Complete Remission (CR)/CRh at the Recommended Phase 2 Dose (RP2D), with 7.6 months median duration of composite Complete Remission across all patients

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, today announced that the U.S. Food and Drug Administration (FDA) has granted Regenerative Medicine Advanced Therapy (RMAT) designation to SENTI-202, the Company's potential first-in-class Logic Gated off-the-shelf chimeric antigen receptor natural killer (CAR-NK) investigational cell therapy, that is currently in development for the treatment of relapsed/refractory hematologic malignancies, including AML.

"This significant FDA designation validates both the tremendous need for better treatments for R/R AML and the promise of SENTI-202 to transform the therapeutic landscape for this notoriously aggressive cancer," Timothy Lu, MD, PhD, Co-Founder and CEO of Senti Biosciences. "We are incredibly pleased with the exciting clinical progress we recently shared at the ASH conference on SENTI-202."

SENTI-202 is Senti Bio's lead asset. The FDA granted the RMAT designation based on data from the Company's ongoing Phase 1 clinical trial of SENTI-202 in adult patients with relapsed or refractory (R/R) CD33 and/or FLT3 expressing hematologic malignancies, including AML. Updated clinical data demonstrating SENTI-202's efficacy, safety, and durability in treating R/R AML were presented orally on December 8 at the ASH Annual Meeting 2025. Pharmacodynamic data in ongoing clinical studies underscore a clinical proof-of-mechanism for 'OR/NOT' Logic Gate, showing selective killing of leukemic blasts and leukemic stem cells while sparing healthy hematopoietic stem and progenitor cells. RMAT marks SENTI-202's second FDA recognition this year, following receipt of Orphan Drug Designation, which was granted in June 2025.

"Leveraging our Logic Gate technology, SENTI-202 has continued to demonstrate its ability to aggressively kill cancer cells while protecting normal cells for hard-to-treat cancers such as AML, a central challenge in oncology," said Kanya Rajangam, M.D., Ph.D., Chief Medical Officer of Senti Biosciences. "We view the FDA's decision to grant RMAT and Orphan Drug designations to SENTI-202 as major milestones for the AML patient community and we look forward to working with regulators to develop this potentially first-in-class treatment as quickly as possible and to accelerate a paradigm shift in how we treat other difficult cancers."

At the ASH Annual Meeting, Senti delivered two presentations, including one oral and one poster, on its SENTI-202 clinical program. The Company presented updated clinical data from the patients included in the published abstracts, as well as additional patients' clinical data from a more recent data-cut. The Company's ASH oral and poster presentations can be found on its website through the following links: Oral Presentation, Poster. Senti will also host a webcast on Tuesday, December 9, 2025 at 8:00 a.m. EST to discuss the results.

The FDA established the RMAT designation to expedite the development and review of regenerative medicine therapies for serious or life-threatening diseases where early clinical evidence indicates the potential to address an unmet medical need. The designation provides benefits similar to the FDA's Breakthrough Therapy and the Fast Track programs, including enhanced and frequent interactions with the Agency throughout development, and eligibility for expedited review mechanisms such as rolling and priority review.

For more information about the ongoing Phase 1 trial, visit clinicaltrials.gov and reference identifier NCT06325748.

About SENTI-202

SENTI-202 is the first Logic Gated off-the-shelf CAR-NK cell therapy product 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/or 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, and cryopreserved to be 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.

Earlier this year, the U.S. Food and Drug Administration (FDA) granted Orphan Drug Designation to SENTI-202 for the treatment of relapsed/refractory hematologic malignancies including AML.

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. Preclinical work supports the Senti Gene Circuits' ability 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 the impact the RMAT designation will have on the future development of SENTI-202; Senti Bio's growth, strategy, progress and timing of its clinical trials for SENTI-202; the timing of availability of data from the ongoing Phase 1 clinical trial of SENTI-202; the ability of any product candidate to perform in humans in a manner consistent with nonclinical, preclinical or previous clinical study data; expectations regarding the anticipated dosing of patients and availability of data from clinical trials, and the timing thereof. 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 trial start up, clinical studies, patient enrollment, and GMP manufacturing startup activities, (vii) Senti Bio's dependence on third parties in connection with clinical trial startup, 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.

Investor Contact:
JTC Team, LLC
Jenene Thomas
(908) 824-0775
SNTI@jtcir.com

Press Contact:
Shira Derasmo
Cuttlefish Communications
(917) 280-2497
shira@cuttlefishpr.com