Senti Biosciences Completes Enrollment in Phase 1 Clinical Trial of SENTI-202 for the Treatment of Relapsed or Refractory Acute Myeloid Leukemia (R/R AML)

Robust SENTI-202 clinical data presented at ASH 2025 demonstrated deep, MRD-negative, durable complete remissions and a favorable safety profile

Company planning for rapid advancement of SENTI-202 into R/R AML pivotal study and evaluating indication expansion to include newly diagnosed AML and pediatric AML; Preparing for FDA discussions in the first half of 2026

SENTI-202 has received Regenerative Medicine Advanced Therapy (RMAT) designation, which may enable an expedited development and review process

SOUTH SAN FRANCISCO, Calif., Feb. 11, 2026 (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 the completion of enrollment in its Phase 1 clinical trial evaluating SENTI-202, a first-in-class CD33/FLT3-targeting Logic Gated CAR NK cell therapy, in patients with relapsed or refractory acute myeloid leukemia (R/R AML).

"The completion of enrollment in our Phase 1 trial represents a significant clinical milestone for our SENTI-202 program," said Kanya Rajangam, M.D., Ph.D. Chief Medical Officer at Senti Bio. "Importantly, the encouraging clinical data from this study provide a strong foundation as we actively design our pivotal program for SENTI-202 in AML, as well as potential indication expansion and later-stage clinical development. We look forward to having productive discussions and working closely with the FDA in the first half of this year to discuss the next phase of development for our RMAT-designated program."

Completion of enrollment follows the Company's recent presentation of positive clinical data from the study at the American Society of Hematology (ASH) Annual Meeting, where SENTI-202 demonstrated deep, MRD-negative, durable complete remissions and a favorable safety profile in a heavily pretreated R/R AML patient population.

With enrollment now complete, the Company plans to have discussions with the U.S. Food and Drug Administration in the first half of 2026 regarding the potential for a pivotal, registration program of SENTI-202 in R/R AML as well as the evaluation of additional indications including newly diagnosed AML and pediatric AML.

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Information about SENTI-202's Phase 1 clinical trial is publicly available and can be referenced on ClinicalTrials.gov under identifier NCT06325748.

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 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 comprises 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.

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.

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.

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