Senti Bio Determines Recommended Phase 2 Dose (RP2D) in Phase 1 Study of SENTI-202 for the Treatment of Relapsed/Refractory Hematologic Malignancies, Including Acute Myeloid Leukemia

Continued progress positions Company to report topline data for Phase 1 clinical trial of SENTI-202 before year-end

SOUTH SAN FRANCISCO, Calif., Aug. 05, 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 it has confirmed the recommended Phase 2 dose (RP2D) in its Phase 1 study of SENTI-202, the Company's potential first-in-class Logic Gated off-the-shelf chimeric antigen receptor natural killer (CAR-NK) investigational cell therapy, in development for the treatment of relapsed/refractory hematologic malignancies including acute myeloid leukemia (AML).

The Phase 1 clinical trial of SENTI-202 is enrolling adult patients with relapsed or refractory ("R/R) CD33 and/or FLT3 expressing hematologic malignancies, including AML, at multiple sites in the United States and Australia. The RP2D has been determined as Schedule I, Dose Level 2 (i.e. 1.5 x 10^9 CAR+ NK cells/dose) administered on Days 0,7 and 14 of 28 Day Cycles following lymphodepleting chemotherapy and the trial is actively enrolling additional R/R AML patients into an expansion cohort at the RP2D. The Company expects to report clinical data, including efficacy and durability, from the expansion cohort before year-end.

"Establishing the RP2D is a pivotal milestone in our clinical development program. This achievement reflects the strength of our preliminary data and positions us to advance into the next phase of development with confidence. We remain focused on the successful execution of the Phase 1 trial and, importantly, advance a potential new treatment option for patients with AML, who remain in urgent need of better therapeutic options," commented Timothy Lu, MD, PhD, Co-Founder and CEO of Senti Biosciences.

As previously announced, SENTI-202 was well-tolerated with no dose limiting toxicities and a maximum tolerated dose was not reached. 2 of 3 patients in the preliminary RP2D cohort achieved a composite Complete Remission (cCR), i.e. CR or CR with partial hematologic recovery or CRh; 5 of the 7 best overall response evaluable patients achieved an ORR (cCR + morphologic leukemia-free state) outcome and 4 of the 7 achieved cCR (3 CR with full hematologic recovery, and 1 CRh). All 4 of 4 cCR patients were MRD- (Measurable Residual Disease Negative) as assessed by local standard of care. Median duration of cCR is not reached with longest durability of 8+ months as reported previously.

SENTI-202 was previously granted Orphan Drug Designation by the U.S. Food and Drug Administration (FDA). For more information about the Phase 1 trial, visit clinicaltrials.gov and reference identifier NCT06325748.

About SENTI-202

SENTI-202 is a First-in-Class Off-the-Shelf Logic Gated Selective CD33 OR FLT3 NOT EMCN 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 (providing a "kill" signal), which is an activating CAR that recognizes CD33 and/or FLT3. By targeting either or both of these antigens, SENTI-202 is designed to effectively kill both leukemic blasts and leukemia stem cells, which constitute a difficult-to-eradicate reservoir of AML disease. Second, SENTI-202 contains a NOT GATE (providing a "protect" signal), which is an inhibitory CAR that is designed to recognize healthy cells and protect those healthy cells from being killed, even if they were to express CD33 and/or FLT3, thus potentially widening the therapeutic window. Third, SENTI-202 contains calibrated-release IL-15 (providing an "enhance" signal), 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 manufacture SENTI-202 are sourced from selected healthy adult donors. 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 off-the-shelf treatment for AML/MDS patients.

Senti Bio has published SENTI-202 preclinical data demonstrating the potential of Logic Gated CAR-NK cell therapy for the treatment of AML.

About AML

AML is a cancer of the blood and bone marrow and is the most common type of acute leukemia in adults. It is estimated there were 20,800 new cases of AML in the United States in 2024. The five-year survival rate for these patients is approximately 30%. 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 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.

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