



Senti Bio Granted U.S. FDA Orphan Drug Designation for Use of First-in-Class Off-the-Shelf Logic Gated Selective CD33 OR FLT3 NOT EMCN CAR NK Cell Therapy, SENTI-202 to Treat Acute Myeloid Leukemia

Ongoing progress in Phase 1 clinical trial of SENTI-202 for the treatment of Acute Myeloid Leukemia (AML)

20,800 newly diagnosed AML patients in the U.S. every year¹ with 60% of patients experiencing relapse or death within 12 months²

Management releases Virtual Investor "What This Means" segment; [Access here](#)

SOUTH SAN FRANCISCO, Calif., June 18, 2025 (GLOBE NEWSWIRE) -- Senti Biosciences, Inc. (Nasdaq: SENTI) ("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 that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation to SENTI-202 for the treatment of relapsed/refractory hematologic malignancies including AML. Additionally, the Company released a Virtual Investor "What This Means" segment to discuss the Orphan Drug Designation for SENTI-202, now available [here](#).

Timothy Lu, MD, PhD, Co-Founder and CEO of Senti Biosciences commented, "SENTI-202 continues to demonstrate encouraging promise as a potential treatment option for relapsed/refractory AML, an indication with significant unmet need and a dismal median survival rate of 5.3 months³. Receiving Orphan Drug Designation for SENTI-202 provides further validation to our novel approach to overcoming AML heterogeneity and protecting healthy cells, and underscores the need for new and effective treatment options. Building upon our recently reported positive preliminary results, this important milestone bolsters our commitment to advancing the development of this important program forward."

SENTI-202 is the Company's first-in-class off-the-shelf Logic Gated 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 is currently being evaluated in a Phase 1 clinical trial ([NCT06325748](#)).

The FDA Office of Orphan Products Development grants Orphan Drug Designation to products that show the potential to treat rare diseases or conditions, which primarily are those that affect fewer than 200,000 people in the U.S. Orphan Drug Designation qualifies a company for a number of benefits intended to provide incentives to develop drugs for rare diseases or conditions, including tax credits, exemptions from certain FDA fees for clinical trials and the potential for seven years of market exclusivity following drug approval.

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 the referenced Virtual Investor "What This Means" segment 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 progress; future results from its clinical trials for SENTI-202; and the ability of any product candidate to perform in humans in a manner consistent with nonclinical, preclinical or previous clinical study data. 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 ongoing and 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 press release or the referenced Virtual Investor "What This Means" segment. 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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¹ SEER 2024

² Tenold Frontiers in Oncology 2021

³ Brandwein AJBR 2020