



2seventy bio to Present New Preclinical and Clinical Data from Broad Portfolio of Investigational Cell Therapies at the ASGCT 26th Annual Meeting

May 2, 2023 8:37 PM EDT

Late-breaking oral presentation will show early findings from Phase I PLAT-08 study of SC-DARIC33, an investigational, potentially first-in-class CD33-targeting CAR T in pediatric and young adults with relapsed/refractory acute myeloid leukemia (AML)

Updates on the Company's portfolio include investigational therapies in AML, non-Hodgkin lymphoma (NHL) and solid tumors

CAMBRIDGE, Mass.--(BUSINESS WIRE)--May 2, 2023-- [2seventy bio, Inc.](https://www.2seventybio.com) (Nasdaq: TSVT), a leading immuno-oncology cell therapy company, today announced the presentation of five abstracts, including one late-breaking oral presentation, at this year's American Society of Gene & Cell Therapy (ASGCT) Annual Meeting, taking place in Los Angeles, California from May 16-20, 2023.

The late-breaking abstract featuring early findings from the ongoing Phase 1 PLAT-08 trial in collaboration with Seattle Children's Therapeutics, evaluating SC-DARIC33 in pediatric and young patients with relapsed/refractory AML, will be presented on Friday, May 19. SC-DARIC33 is an investigational CD33-targeted chimeric antigen receptor (CAR) T cell therapy that utilizes 2seventy bio's proprietary Dimerizing Agent Regulated Immunoreceptor Complex (DARIC) T cell platform, a regulatable CAR T cell technology. A second oral presentation will feature preclinical data on enhanced anti-AML potency of DARIC33 by coupling it with iSynPro-IL-15, an encoded IL-15 expression module driven by an antigen-regulated synthetic promoter that will be presented on Thursday, May 18.

"At 2seventy bio, we are focused on utilizing our advanced scientific toolkit to develop innovative cell therapies with the goal of achieving tumor control and elimination across hematologic cancers and solid tumors," said Philip Gregory, D.Phil., chief scientific officer, 2seventy bio. "Our data at ASGCT demonstrate continued progress in deepening our next-generation cell therapy product engine and pipeline, particularly early findings for DARIC33 that continue to reinforce its potential as a new T cell therapy approach in AML, CBLB gene edited CAR T cell therapy advancements with bbT369, and our potency enhanced MAGE-A4 TCR program in solid tumors. We are also revealing, for the first time, our novel receptor architecture called RESET, which is designed to blend both the sensitivity of TCRs with the ease of tumor antigen targeting through CARs, all within a drug-regulated CAR T platform."

Key data presentations include:

Details of 2seventy bio Presentations at ASGCT Annual Meeting

Late-breaking Oral Presentation [#3092]: First in human studies show activation of SC-DARIC33, a rapamycin-regulated anti-CD33 CAR T cell therapy, in patients with AML

Presenting Author: Jacob Appelbaum, M.D., Ph.D., Hematologist, Fred Hutch Cancer Center & Acting Instructor, Hematology, Univ. of Washington

Date/Time: Friday, May 19, 2023, 11:30 – 11:45am PT

Oral Presentation [#148]: Enhanced anti-AML potency of DARIC33 by iSynPro-IL-15*: an IL-15 expression module driven by a tightly regulated synthetic promoter activated by antigen receptor signaling

Presenting Author: Jacob Appelbaum, M.D., Ph.D., Hematologist, Fred Hutch Cancer Center & Acting Instructor, Hematology, Univ. of Washington

Date/Time: Thursday, May 18, 2023, 2:30 – 2:45pm PT

Poster Presentation [#585]: bbT369, a clinical-stage dual-targeted and CBLB gene edited autologous CAR T product for non-Hodgkin Lymphoma, shows edit driven enhanced activity in preclinical in vitro and in vivo models

Presenting Author: Michael Certo, 2seventy bio

Date/Time: Wednesday, May 17, 2023, 12:00 – 2:00pm PT

Poster Presentation [#612]: Novel TGFb switch receptor drives robust MAGE-A4 TCR anti-tumor activity with a favorable safety profile

Presenting Author: Esteban Carrizosa, 2seventy bio

Date/Time: Wednesday, May 17, 2023, 12:00 – 2:00pm PT

Poster Presentation [#608]: RESET: a novel TCR coupled antigen receptor displaying superior targeting sensitivity and pharmacologically controlled anti-tumor activity

Presenting Author: Jardin Leleux, 2seventy bio

Date/Time: Wednesday, May 17, 2023, 12:00 – 2:00pm PT

About SC-DARIC33

2seventy bio is collaborating with Seattle Children's Therapeutics to rapidly accelerate development of potential new therapies for patients with acute myeloid leukemia (AML). This research collaboration is investigating potential solutions to two challenges in treating AML: disease heterogeneity and toxicity due to shared expression of targets between tumor and normal tissue.

SC-DARIC33 is an investigational, pharmacologically controlled CD33-targeted autologous T cell product that utilizes 2seventy bio's proprietary Dimerizing Agent Regulated Immunoreceptor Complex (DARIC) T cell platform, a regulatable CAR T cell technology. DARIC T cells are intended to be switched from "OFF" to "ON" in the presence of rapamycin, such that while in the "ON" state the T cell is poised to be activated upon encounter with its target antigen.

PLAT-08, the Phase 1 study of SC-DARIC33 in relapsed/refractory pediatric AML, led by Seattle Children's Therapeutics, couples 2seventy bio's DARIC T cell platform with Seattle Children's world-class bench-to-bedside expertise in oncology cell therapies. This study is a first-in-human investigation of the DARIC T cell platform and is open for enrollment at Seattle Children's. For more information visit: clinicaltrials.gov using identifier

[NCT05105152](#).

SC-DARIC33 is not approved for any indication in any geography.

About bbT369

bbT369 is an investigational dual-targeting CAR T cell therapy with a gene edit for patients with relapsed and/or refractory B-NHL.

bbT369 has three layers of innovation, purposely designed to address the potential mechanisms of anti-CD19 CAR T cell therapy failure: dual targeting (CD79a/CD20), split co-stimulation signaling technology, and a gene edit to remove the function of *CBLB*.

In December 2021, the FDA cleared the Investigational New Drug (IND) application for bbT369. The clinical development program for bbT369 includes the Phase 1/2 CRC-403 study (NCT05169489). Safety and potential efficacy of bbT369 in patients with specific subtypes of relapsed and/or refractory B-NHL will be assessed, including patients who relapsed after CD19 CAR T cell therapy as well as patients who are CAR-naïve.

bbT369 is not approved for any indication in any geography.

About the MAGE-A4 Program

MAGE-A4 is a member of the MAGE family of cancer-testis antigens expressed in a number of solid tumor types. Our program employs a highly potent TCR discovered in our MediGene collaboration that recognizes HLA-presented MAGE-A4 peptides and further enhances the potency of these re-directed T cells using our CTBR12 TGF-beta "flip" receptor technology -- which converts the immunosuppressive effects of TGF-beta into an activation signal for the T cells. Regeneron and 2seventy bio are co-developing the program under their collaboration entered into in 2018.

About 2seventy bio

Our name, 2seventy bio, reflects why we do what we do - TIME. Cancer rips time away, and our goal is to work at the maximum speed of translating human thought into action – 270 miles per hour – to give the people we serve more time. We are building the leading immuno-oncology cell therapy company, focused on discovering and developing new therapies that truly disrupt the cancer treatment landscape.

With a deep understanding of the human body's immune response to tumor cells and how to translate cell therapies into practice, we're applying this knowledge to deliver next generation cellular therapies that focus on a broad range of hematologic malignancies, including the first FDA-approved CAR T cell therapy for multiple myeloma, as well as solid tumors. Our research and development is focused on delivering therapies that are designed with the goal to "think" smarter and faster than the disease. Importantly, we remain focused on accomplishing these goals by staying genuine and authentic to our "why" and keeping our people and culture top of mind every day.

For more information, visit www.2seventybio.com.

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Cautionary Note Regarding Forward-Looking Statements of 2seventy bio

This release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These statements include, but are not limited to: statements about our plans, strategies, timelines and expectations with respect to statements about the efficacy and perceived therapeutic benefits of our product candidates and the potential indications, statements about the strategic plans for 2seventy bio; statements about the potential efficacy of any product candidate; and statements about our ability to execute our strategic priorities. Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release, including, without limitation; the risk that our plans with respect to the preclinical and clinical development and regulatory approval of our product candidates may not be successfully achieved on the planned timeline, or at all. For a discussion of other risks and uncertainties, and other important factors, any of which could cause our actual results to differ from those contained in the forward-looking statements, see the section entitled "Risk Factors" in our annual report on Form 10-K for the year ended December 31, 2022, as supplemented and/or modified by our most recent Quarterly Report on Form 10-Q and any other filings that we have made or will make with the Securities and Exchange Commission in the future. All information in this press release is as of the date of the release, and 2seventy bio undertakes no duty to update this information unless required by law.

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2seventy bio

Investors:

Jenn Snyder, 617-448-0281
jenn.snyder@2seventybio.com

Media:

Morgan Adams, 774-313-9852
morgan.adams@2seventybio.com

Source: 2seventy bio