2seventy bio Announces Clinical Study Pause of PLAT-08 Trial of SC-DARIC33 in Acute Myeloid Leukemia

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CAMBRIDGE, Mass.--(BUSINESS WIRE)--Jun. 14, 2023-- 2seventy bio, Inc. (Nasdaq: TSVT), a leading immuno-oncology cell therapy company, today announced that the Phase 1 trial of the PLAT-08 study of SC-DARIC33 in Acute Myeloid Leukemia (AML) has been paused by Seattle Children's, the Company's partner and the regulatory sponsor of the study. The pause was instituted as part of the clinical study protocol stopping rules in response to a recent Grade 5 (fatal) serious adverse event (SAE) and was followed by the required notification to the U.S. Food & Drug Administration (FDA). The root cause of this SAE and its potential relationship to the study drug is currently under investigation.

PLAT-08 is the Phase 1 study of SC-DARIC33 in relapsed/refractory pediatric AML, conducted by Seattle Children's, and couples 2seventy bio's DARIC T cell platform with Seattle Children's expertise in oncology cell therapies. This study is a first-in-human investigation of the DARIC T cell platform. The SAE occurred in the first patient treated at the second dose level in the Phase 1 trial.

"Importantly, I'd like to offer that our thoughts are with the family during this time. The safety of every patient who participates in our studies or is treated with our therapies is the utmost priority for us, and we are in communication with FDA while we assess the data surrounding this SAE, and the potential next steps for the study," said Steve Bernstein, M.D., chief medical officer, 2seventy bio.

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
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 the Grade 5 SAE in the PLAT-08 study, the root cause of this toxicity and its relationship to the study drug, and the implication of this SAE on our other clinical programs. 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. 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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