

# Sana Biotechnology Announces Increased Focus on Hypoimmune-Related Pipeline with the Potential to Deliver Clinical Proof of Concept Data from Four Programs in 2023 and 2024 with a 2024 Operating Burn under \$200M

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Increasing focus on ex vivo cell therapy platform based on extensive preclinical and early translational clinical data suggesting ability of hypoimmune (HIP)-modified cells to evade immune detection

Human proof of concept data in multiple clinical settings – including oncology, autoimmune diseases, and type 1 diabetes – expected in 2023 and 2024

IND submitted to investigate SC291 in multiple B-cell-mediated autoimmune diseases with initial proof of concept data expected in 2024

Enrollment continues in SC291 Phase 1 ARDENT trial in patients with refractory B-cell malignancies with data expected in 2023 and 2024

CTA submitted for investigator sponsored trial exploring HIP-modified primary islet cells in patients with type 1 diabetes; on track for initial HIP proof of concept data in 2023 and 2024

IND submission for SC262 in patients with B-cell malignancies who have failed a CD19 therapy on track for this quarter with initial proof of concept data expected in 2024

Reducing near-term investment on fusogen in vivo delivery platform clinical and preclinical programs, including delaying SG299 IND (in vivo CD19 CAR T)

2024 operating cash burn expected below \$200 million following 29% headcount reduction and decreased expenses related to the fusogen platform

SEATTLE, Oct. 10, 2023 (GLOBE NEWSWIRE) -- Sana Biotechnology, Inc. (NASDAQ: SANA), a company focused on changing the possible for patients through engineered cells, today announced a portfolio update, including both increased focus on its *ex vivo* cell therapy product candidates and an IND submission for SC291 in autoimmune diseases. Sana is positioned to generate clinical proof of concept from multiple programs in 2023 and 2024, with a goal of better understanding its allogeneic HIP CAR T programs in blood cancers, allogeneic HIP CAR T program in autoimmune diseases, and HIP pancreatic islet cells in type 1 diabetes. The company will reduce near-term spend on its fusogen platform for *in vivo* gene delivery, which postpones the planned SG299 IND and decreases its expected forward operating burn.

"We have increased confidence in the potential of our HIP platform, and near-term, we are increasing focus on three therapeutic areas that utilize this platform and have the potential to address large unmet needs with curative intent – allogeneic CAR T cells in oncology, allogeneic CAR T cells in autoimmune diseases, and pancreatic islet cell transplantation in type 1 diabetes. We plan to present clinical data in these areas at various times across 2023 and 2024," said Steve Harr, President and CEO of Sana. "The SC291 IND submission for the treatment of autoimmune diseases positions us to move into the rapidly emerging opportunity of utilizing CAR T cells in these large and underserved populations, leveraging the investments we have made to date in the HIP platform, T cell therapeutics, and scaled manufacturing that can produce hundreds of patient doses per run. We need to ensure that we have a financeable cost structure with these emerging opportunities factored in, and this strategic re-positioning enables us to deliver significant clinical data across multiple drug candidates with the current balance sheet. These changes unfortunately mean that many talented and valued colleagues will depart the company, and we thank them for their contributions and commitment to our mission."

# **Select Program Review**

SC291 Oncology (HIP-modified CD19-directed allogeneic CAR T): Enrollment continues in Sana's ARDENT Phase 1 study for the treatment of B-cell lymphomas and leukemias with clinical data expected in 2023 and 2024.

SC291 Autoimmune (HIP-modified CD19-directed allogeneic CAR T): Sana submitted an IND for the treatment of multiple autoimmune diseases, with preliminary clinical data expected across multiple indications in 2024.

SC262 (HIP-modified CD22-directed allogeneic CAR T): Sana expects to submit an IND in 4Q 2023 for the treatment of B-cell lymphomas and leukemias in patients who have failed CD19-directed CAR T therapies, with preliminary clinical data expected in 2024.

HIP-modified primary islet cells for the treatment of type 1 diabetes: A CTA has been submitted for an investigator sponsored trial exploring the potential of HIP modifications to allogeneic primary islet cells to enable immune evasion and overcome transplant rejection in type 1 diabetes; proof of concept data expected in 2023 and 2024.

SG299 (in vivo CAR T with CD8-targeted fusogen delivery of a CD19-directed CAR): Sana will continue its focused research on this innovative platform but not submit an IND at this time as previously planned.

### 2024 Operating Burn Guidance

Sana expects 2024 operating cash burn to be below \$200 million, allowing the current cash position to extend further into 2025. The strategic re-positioning will reduce headcount by 29% while allowing the company to invest in clinical capabilities across multiple indications in oncology, autoimmune diseases, type 1 diabetes, and central nervous system disorders. Sana will leverage its existing allogeneic manufacturing expertise and

continue development of its GMP manufacturing facility in Bothell, Washington.

#### **About Sana Biotechnology**

Sana Biotechnology, Inc. is focused on creating and delivering engineered cells as medicines for patients. We share a vision of controlling genes, replacing missing or damaged cells, and making our therapies broadly available to patients. We are a passionate group of people working together to create an enduring company that changes how the world treats disease. Sana has operations in Seattle, Cambridge, South San Francisco, and Rochester. For more information about Sana Biotechnology, please visit <a href="https://sana.com/">https://sana.com/</a>.

## **Cautionary Note Regarding Forward-Looking Statements**

This press release contains forward-looking statements about Sana Biotechnology, Inc. (the "Company," "we," "us," or "our") within the meaning of the federal securities laws, including those related to the Company's vision, progress, and business plans; expectations for its development programs, product candidates and technology platforms, including its pre-clinical, clinical and regulatory development plans and timing expectations, including with respect to the expected timing of IND submissions for the Company's product candidates; the Company's expectations regarding the timing, substance, and impact of the data from its clinical trials as well as the investigator sponsored trial exploring HIP-modified primarily islet cells in patients with type 1 diabetes; the potential ability of HIP-modified cells to evade immune detection and overcome allogeneic rejection; the Company's expected 2024 operating cash burn; the potential impact of the Company's reduction in its near-term spend on the fusogen program, including on the timing of an IND submission for the SG299 program and the Company's forward operating burn; the Company's expectations with respect to the potential therapeutic benefits and impact of its development programs and platforms, including in various indications; the potential of SC291 to treat autoimmune diseases; the potential impact of the portfolio update on the Company's clinical and manufacturing capabilities; and the Company's future plans with respect to its SG299 program. All statements other than statements of historical facts contained in this press release, including, among others, statements regarding the Company's strategy, expectations, cash runway and future financial condition, future operations, and prospects, are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "aim," "anticipate," "assume," "believe." "contemplate." "continue." "could," "design," "due," "estimate," "expect," "goal," "intend," "may," "objective," "plan," "positioned," "potential," "predict," "seek," "should," "target," "will," "would" and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology. The Company has based these forward-looking statements largely on its current expectations, estimates, forecasts and projections about future events and financial trends that it believes may affect its financial condition, results of operations, business strategy and financial needs. In light of the significant uncertainties in these forward-looking statements, you should not rely upon forward-looking statements as predictions of future events. These statements are subject to risks and uncertainties that could cause the actual results to vary materially, including, among others, the risks inherent in drug development such as those associated with the initiation, cost, timing, progress and results of the Company's current and future research and development programs, preclinical and clinical trials, as well as economic, market and social disruptions. For a detailed discussion of the risk factors that could affect the Company's actual results, please refer to the risk factors identified in the Company's SEC reports, including but not limited to its Quarterly Report on Form 10-Q dated August 3, 2023. Except as required by law, the Company undertakes no obligation to update publicly any forward-looking statements for any reason.

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