# Sana Biotechnology Presents Data at ISSCR 2021 Virtual Annual Meeting Showing Survival of Transplanted Hypoimmune Stem Cells Without Immunosuppression in Non-Human Primates

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*First demonstration of the survival of allogeneic iPSCs transplanted into an immunocompetent non-human primate model without the need for immune suppression*

*Transplanting allogeneic cells into a primate without immune suppression represents a key step toward widespread treatment of disease using engineered cells*

SEATTLE, June 26, 2021 (GLOBE NEWSWIRE) -- Sana Biotechnology, Inc. (NASDAQ: SANA), a company focused on creating and delivering engineered cells as medicines, today presented data showing survival of transplanted stem cells without immunosuppression in non-human primates (NHPs). The transplanted cells were induced pluripotent stem cells (iPSCs) with Sana's hypoimmune gene modifications that enable immune evasion. Data were presented by Sonja Schrepfer, M.D., Ph.D., Head of Hypoimmune Platform at Sana, during the plenary session on Cellular Therapy and Tissue Engineering at the International Society for Stem Cell Research 2021 Virtual Annual Meeting.

"These findings represent a major breakthrough in cell transplantation, as demonstration of immune evasion and durable cell survival in non-human primates with a healthy immune system has not been achieved before," said Steve Harr, Sana's President and Chief Executive Officer. "Since the debut of organ, tissue, and cellular transplantation, immune rejection of allogeneic transplants has been a significant challenge preventing widespread utilization of these therapies. Our team has now shown the potential of these gene-modified cells in multiple animal models, and the next step is to apply this technology in humans in several therapeutic contexts, with our first investigational new drug (IND) application as early as next year."

Transplanting cells or tissues from a donor to a different recipient currently requires intense immunosuppression to prevent rejection of the transplant. Sana's hypoimmune (HIP) platform's goal is to eliminate the need for immunosuppression by cloaking cells from immune recognition. The platform disrupts major histocompatibility (MHC) class I and MHC class II expression to hide cells from the adaptive immune system, which includes antibody and T cell responses. However, these changes make cells susceptible to innate immune cell killing, in particular by natural killer (NK) cells. Sana's HIP platform additionally provides for the overexpression of CD47, a molecule that protects HIP-modified cells from innate cell killing involving either NK cells or macrophages. HIP-modified pluripotent stem cells can serve as the starting material for manufacturing cell-based therapeutics, differentiating into specialized cell types. Sana's goal is to use these HIP-modified cells to replace damaged or missing cells in the body in a number of different diseases, including cancer, type I diabetes, cardiac disease, and others.

In this study, allogeneic iPSCs were transplanted intramuscularly into healthy NHPs without immunosuppression (n=8), split into two cohorts. The first cohort received unmodified allogeneic iPSCs, while the second cohort received HIP-modified allogeneic iPSCs. The unmodified cells disappeared rapidly in all NHPs, with significant T cell activation and antibody production. The HIP-modified iPSCs survived in all four monkeys for the duration of the study (up to four months at data lock), and there was no evidence of a systemic immune response, including no T cell activation, antibody production, or NK cell activity ($p<0.007$ comparing cell survival, $p<0.0001$ comparing T cell activation and antibody production).

Six weeks after the initial dose, the dosing was reversed, or crossed over, so that the NHPs received the opposite type of cells in another site in the body. Unmodified iPSCs again evoked a rapid systemic immune response in all NHPs, with activation of T cells and antibody production, and disappeared within days. Importantly, HIP-modified cells continued to survive in another site in the body, despite the immune response against unmodified cells. Separately, HIP-modified iPSCs were transplanted into the four NHPs that had previous T cell and antibody responses to unmodified cells. In these animals, there was no evidence of immune response and the HIP modified cells again survived through the end of the study ($p<0.006$ comparing cell survival, $p<0.0001$ comparing T cell activation and antibody production). These data, showing survival for HIP-modified iPSCs despite either an ongoing or pre-existing immune response, suggest the potential to use HIP-modified cells in patients with auto-immune disorders and to re-administer HIP-modified cells.

"We have previously shown that our hypoimmune platform can create cells that evade the adaptive and innate immune systems in mouse models, and we are thrilled to now show this immune evasion in a model that better simulates the complexity of the human immune environment," said Sonja Schrepfer, M.D., Ph.D. "The next step is to move this technology into human testing, where it has the potential to impact patients with a broad array of diseases."

Sana intends to submit the data behind its presentation for publication in a peer-reviewed journal.

**About Sana**

Sana Biotechnology, Inc. is focused on creating and delivering engineered cells as medicines for patients. We share a vision of repairing and controlling genes, replacing missing or damaged cells, and making our therapies broadly available to patients. We are more than 300 people working together to create an enduring company that changes how the world treats disease. Sana has operations in Seattle, Cambridge, and South San Francisco. For more information about Sana Biotechnology, please visit https://sana.com/.

**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; expectations for the presentation or publication of data, including in medical or scientific journals; the ability to make HIP-modified iPSCs that evade the innate and adaptive immune system or that persist without immunosuppression; and the ability to treat diseases using the hypoimmune platform technology. 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 the economic, market and social disruptions due to the ongoing COVID-19 public health crisis. 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 Annual Report on Form 10-K dated March 24, 2021 and Quarterly Report on Form 10-Q dated May 5, 2021. Except as required by law, the Company undertakes no obligation to update publicly any forward-looking statements for any reason.



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