



SQZ Biotechnologies Presents Celiac Disease Tolerizing Antigen Carrier Preclinical Data at 2022 Federation of Clinical Immunology Societies (FOCIS) Annual Meeting

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SQZ® TACs Result in the In Vitro Presentation of Antigen Associated with Celiac Disease, Supporting T Cell Tolerizing Approach

Cell Squeeze® Process Leads to TACs with Consistently High Amounts of Antigen Cargo

Findings Build on Published Type 1 Diabetes TAC Data and Further Support Planned TAC IND Submission for Celiac Disease in First Half of 2023

WATERTOWN, Mass.--(BUSINESS WIRE)-- **SQZ Biotechnologies Company** (NYSE: SQZ), focused on unlocking the full potential of cell therapies for multiple therapeutic areas, today presented Tolerizing Antigen Carrier (TACs) nonclinical results at the 2022 Federation of Clinical Immunology Sciences (FOCIS) annual meeting. The new celiac disease research found that in an in vitro assay, SQZ® TACs with deamidated gliadin, a protein associated with celiac disease, resulted in dendritic cell presentation of tolerizing antigens to T cells. In addition, the early data showed that the company's Cell Squeeze® process could produce TACs with consistently high levels of antigen. The findings build upon additional research showing SQZ® TACs engineered to induce protection against type 1 diabetes could combat active autoimmune responses and prevent hyperglycemia.

"We've now shown in different preclinical models of autoimmune disease that SQZ® TACs have the ability to utilize the immune system's natural processes to tolerize T cells, demonstrating the flexible capabilities of this platform," said Howard Bernstein, M.D., Ph.D., Chief Scientific Officer at SQZ Biotechnologies. "We are excited to continue progressing this promising research as we move closer to our anticipated TAC IND submission for celiac disease in the first half of 2023."

SQZ® TACs act as Trojan horses, utilizing the body's natural cell clearance processes to allow for the presentation of antigen cargo that can support the tolerization of specific T cells involved in autoimmune diseases. Earlier this year in *Frontiers of Immunology*, the company published comprehensive preclinical research showing that SQZ® TACs

loaded with type 1 diabetes (T1D) autoantigens could induce multiple key mechanisms of antigen-specific tolerance in various model systems, including deletion of autoreactive T cells, anergy, and expansion of regulatory T cells (Tregs) capable of bystander suppression. In an in vivo model of T1D, the TAC treatment was able to combat active autoimmune responses and prevent hyperglycemia.

These research findings are part of the body of work that will support the company's anticipated TAC IND submission for celiac disease, the first autoimmune disease indication for the SQZ® TAC platform.

Major Findings from Autoimmune Disease Models:

- Gliadin Epitope T Cell Presentation: An in vitro assay found that TACs with deamidated gliadin cargo were taken up by dendritic cells, processed, and presented gliadin epitopes via MHC class II signaling to T cells
- Production of TAC Batches: The Cell Squeeze® process resulted in the manufacture of TACs with consistently high amounts of deamidated gliadin

Poster Presentation Details

Title: SQZ® TAC Cell Therapy Platform Induces Antigen Specific T-regs and Prevents Onset of Type 1 Diabetes in Adoptive Transfer Models

Abstract Number: Tu109

Poster Session: Tuesday, June 21, 2022, 6:15 PM – 7:45 PM PT

About Celiac Disease

Celiac disease is a chronic autoimmune disorder that occurs in genetically predisposed people.ⁱⁱⁱ The disease is triggered by eating foods containing gluten, which is found in wheat, barley, and rye. Disease symptoms can include abdominal pain, diarrhea, nausea, vomiting, and other common signs. When gluten is ingested, the body mounts an immune response that attacks and damages the villi that line the small intestine, which can impact nutrient absorption.ⁱⁱⁱ Many people who have celiac disease have not been diagnosed,^{iv} however population-based studies indicate that the disease affects about 2 million people in the United States and approximately 1% of the population worldwide, with regional differences.^{vi} There is currently no approved drug treatment and patients are advised to maintain a gluten-free diet, which involves strict, lifelong avoidance of exposure to gluten proteins. Long-term complications of celiac disease may include malnutrition, accelerated osteoporosis, nervous system problems and issues related to reproduction. Rare complications can include cancer of the small intestine, cirrhosis, and non-Hodgkin lymphoma.

About Type 1 Diabetes

Nearly 1.6 million Americans are living with Type 1 Diabetes (T1D), including about 1.4 million adults and 200,000 children and adolescents (<20 years). Five million people in the U.S. are expected to have T1D by 2050. A separate CDC study of T1D cases in youth showed that 60 percent of diagnoses occur between the ages of 5 and 14. Worldwide incidence is 15 patients diagnosed per every 100,000 people. There is no cure for T1D, and it requires

chronic disease management through exogenous insulin therapy, insulin analogs and adjunctive treatments for glycemic control. The life expectancy for T1D patients is 10–15 years less than the healthy population due to hypoglycemia events and long-term risks of cardiovascular complications, neuropathy, kidney damage, and retinopathy. There remains significant unmet need for disease-modifying therapeutics that address the autoimmune-mediated attack of beta cells as a driving factor of disease pathogenesis.

About SQZ® TACs

SQZ® TACs are a red blood cell-derived engineered cell therapy candidate being developed as an antigen-specific immune tolerance platform. The platform is designed to leverage the natural process of RBC clearance by professional antigen presenting cells (APCs) in the lymphoid organs, where they engulf aged RBCs and present their components to CD4 and CD8 T cells. This physiological mechanism is tolerogenic by default, instructing the immune system to not mount an attack. SQZ® TACs are generated by engineering RBCs with disease-specific antigen using the Cell Squeeze® technology and are made to appear aged. SQZ® TACs are designed to be rapidly engulfed in vivo by the patient's professional APCs and to act as a "Trojan horse" to drive high quantities of antigen through the tolerogenic RBC clearance process, which may ultimately induce tolerization of the patient's T cell and antibody responses against the specific target.

About SQZ Biotechnologies

SQZ Biotechnologies is a clinical-stage biotechnology company focused on unlocking the full potential of cell therapies to benefit patients with cancer, autoimmune and infectious diseases. The company's proprietary Cell Squeeze® technology offers the unique ability to deliver multiple biological materials into many patient cell types to engineer what we believe can be a broad range of potential therapeutics. Our goal is to create well-tolerated cell therapies that can provide therapeutic benefit for patients and improve the patient experience over existing cell therapy approaches. With accelerated production timelines under 24 hours and the opportunity to eliminate preconditioning and lengthy hospital stays, our approach could change the way people think about cell therapies. The company's first therapeutic applications seek to generate target-specific immune responses, both in activation for the treatment of solid tumors and in immune tolerance for the treatment of unwanted immune reactions and autoimmune diseases. For more information, please visit www.sqzbiotech.com.

Forward Looking Statement

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained that do not relate to matters of historical fact should be considered forward-looking statements, including without limitation statements relating to events and presentations, platform and clinical development, product candidates, preclinical and clinical activities, progress and outcomes, development plans, clinical safety and efficacy results, therapeutic potential and disease prevalence. These forward-looking statements are based on management's current expectations. Actual results could differ from those projected in any forward-looking statements due to several risk factors. Such factors include, among others, risks and uncertainties related to our limited operating history; our significant losses incurred since inception and expectation to incur significant additional losses for the foreseeable future; the development of our initial product

candidates, upon which our business is highly dependent; the impact of the COVID-19 pandemic on our operations and clinical activities; our need for additional funding and our cash runway; the lengthy, expensive, and uncertain process of clinical drug development, including uncertain outcomes of clinical trials and potential delays in regulatory approval; our ability to maintain our relationships with our third party vendors; and protection of our proprietary technology, intellectual property portfolio and the confidentiality of our trade secrets. These and other important factors discussed under the caption "Risk Factors" in our Annual Report on Form 10-K and other filings with the U.S. Securities and Exchange Commission could cause actual results to differ materially from those indicated by the forward-looking statements. Any forward-looking statements represent management's estimates as of this date and SQZ undertakes no duty to update these forward-looking statements, whether as a result of new information, the occurrence of current events, or otherwise, unless required by law.

Certain information contained in this press release relates to or is based on studies, publications, surveys and other data obtained from third-party sources and our own internal estimates and research. While we believe these third-party sources to be reliable as of the date of this press release, we have not independently verified, and we make no representation as to the adequacy, fairness, accuracy, or completeness of any information obtained from third-party sources.

i Leonard MM, Sapone A, Catassi C, et al. **Celiac Disease and Nonceliac Gluten Sensitivity: A Review**. JAMA 2017;318:647-656

ii Celiac Disease Foundation **website** (as of Sept 13,2021)

iii Beyond Celiac **website** (as of Sept 13, 2021)

iv National Institute of Diabetes and Digestive and Kidney Diseases **website** (as of Sept 13, 2021)

v Lionetti E, Gatti S, Pulvirenti A, et al. **Celiac disease from a global perspective**. Best Pract Res Clin Gastroenterol 2015;29:365-79.

vi Leonard MM, Sapone A, Catassi C, et al. **Celiac Disease and Nonceliac Gluten Sensitivity: A Review**. JAMA 2017;318:647-656

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