



SQZ Biotechnologies Announces FDA Clearance of IND Application to Allow for Clinical Trial with SQZ Activating Antigen Carriers (SQZ AACs) in Patients with HPV+ Tumors

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SQZ AACs generated from red blood cells are designed to leverage a patient's professional antigen-presenters to drive T cells to attack tumors

WATERTOWN, Mass.--(BUSINESS WIRE)-- SQZ Biotechnologies (NYSE: SQZ), a cell therapy company developing novel treatments for multiple therapeutic areas, today announced that the company's Investigational New Drug (IND) application for SQZTM Activating Antigen Carriers (SQZ AACs) in HPV+ tumors was cleared by the U.S. Food and Drug Administration (FDA). The clinical trial will investigate SQZ-AAC-HPV, a cell therapy candidate generated from red blood cells (RBCs) engineered with tumor-specific antigen to treat HPV+ tumors. This trial, SQZ-AAC-HPV-101, marks the first clinical program from the company's wholly-owned SQZ AAC platform.

SQZ AACs are a novel cellular immunotherapy candidate designed to transport tumor-specific antigen and TLR agonists to the patient's endogenous, professional, antigen presenting cells in vivo. These antigen presenting cells are capable of potent T cell activation that could potentially drive an anti-tumor effect. In preclinical studies, SQZ AACs in mouse models have demonstrated robust immune responses, CD8 T cell infiltration, and correlated tumor reduction.

"Advancing our SQZ AAC program into the clinic is a significant milestone for our team," said Armon Sharei, PhD, founder and chief executive officer of SQZ Biotechnologies. "This program further illustrates the broad cell engineering capabilities of our core technology and the diversity of our pipeline. SQZ AACs potentially open another dimension of biology where SQZ cell therapy candidates could drive patient impact."

The Phase 1 multi-center trial will enroll multiple cohorts to assess SQZ-AAC-HPV as both monotherapy and in combination with other immunoncology therapies. HLA-A*02+ patients with recurrent, locally advanced or metastatic HPV16+ head & neck, cervical, anal, penile, vulval and vaginal cancers are all eligible for the study.

"We are dedicated to leveraging our unique capabilities and novel cell therapy candidates to try to improve patients'

lives by offering them potential outcomes that they need and deserve. SQZ AACs are our next approach for a potential differentiated cell therapy targeting solid tumors that could represent an exciting evolution in the cancer patient experience,” said Oliver Rosen, MD, chief medical officer.

About SQZ-AAC-HPV

SQZ AACs are generated by squeezing red blood cells (RBCs) with an antigen and activating adjuvant. The process is tuned to make the engineered RBCs appear aged. Once administered to patients, SQZ AACs aim to be rapidly taken up by professional antigen presenting cells through a natural process to destroy aged RBCs in the body known as eryptosis. To take advantage of this process, SQZAACs are designed to act as a “Trojan horse” to deliver significant quantities of antigen and activation factors to the professional, endogenous antigen presenting cells in the lymphoid organs and drive subsequent activation of T cells specific to HPV+-tumors. SQZ-AAC-HPV is the first product candidate from the SQZ AAC platform.

About SQZ Biotechnologies

SQZ Biotechnologies is a clinical-stage biotechnology company developing transformative cell therapies for patients with cancer, infectious diseases, and other serious conditions. Using its proprietary technology, SQZ Biotechnologies offers the unique ability to deliver multiple materials into many patient cell types to engineer what we believe can be an unprecedented range of potential therapeutics for a variety of diseases. SQZ Biotechnologies has the potential to create well-tolerated cell therapies that can provide therapeutic benefit for patients and to 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 goal is to use the SQZ approach to establish a new paradigm for cell therapies. Our first therapeutic applications aim to leverage the potential to generate target-specific immune responses, both in activation for the treatment of solid tumors and 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 may contain 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 statements relating to upcoming events and presentations, our product candidates, preclinical and clinical activities, regulatory requirements, clinical efficacy and therapeutic impact. These forward-looking statements are based on management's current expectations. The words “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “estimate,” “believe,” “predict,” “potential” or “continue” or the negative of these terms or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this press release.

These and other important factors discussed under the caption "Risk Factors" in our Form 10Q filed with the U.S. Securities and Exchange Commission (SEC) on December 10, 2020 and our other filings with the SEC 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. New risk factors and uncertainties may emerge from time to time, and it is not possible to predict all risk factors and uncertainties. While we may elect to update forward-looking statements in the future, except as required by law, we disclaim any obligation to do so, even if subsequent events cause our views to change. Although we believe the expectations reflected in such forward-looking statements are reasonable, we can give no assurance that such expectations will prove to be correct.

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.

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