SQZ Biotechnologies Receives FDA Fast Track Designation for its eAPC Therapeutic Candidate for Treatment of HPV16+ Tumors and Presents Clinical Data for Multiple Programs at the European Society for Medical Oncology Immuno-Oncology Congress

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- Designation Represents Potential to Bring Important New Therapy to Patients Earlier
- Stable Disease Observed in Two Out of Four Evaluable Patients in eAPC Phase 1/2 Trial Including a Pronounced Pharmacodynamic Response in a Patient with Prolonged Stable Disease
- Interim Results from Ongoing SQZ® eAPC Phase 1/2 Trial Showed Favorable Safety Data and Investigational Therapy was Generally Well Tolerated
- Median Drug Viability of Greater than 90 Percent for Both SQZ® eAPC and SQZ® APC Clinical Trials

WATERTOWN, Mass.--(BUSINESS WIRE)-- SQZ Biotechnologies Company (NYSE: SQZ) today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track Designation for the company’s Enhanced Antigen Presenting Cell (eAPC) candidate for the treatment of HPV16+ advanced or metastatic solid tumors. Fast Track Designation is designed to accelerate the development and review of treatments for serious and life-threatening diseases where no treatment currently exists or where the treatment in discovery may be better than what is currently available.

The SQZ® eAPC platform is the company’s second-generation cell therapy platform which simultaneously delivers five different mRNAs—each encoding for a different protein which plays a part in stimulating key T cell activation signals required to generate an immune response against tumors—to four different cell types.

The company also presented clinical data from its ongoing Antigen Presenting Cells (APC) and eAPC clinical trials at the European Society for Medical Oncology Immuno-Oncology (ESMO-IO) Congress. Data also demonstrated that its APC and eAPC therapeutic candidates were well-tolerated among patients treated in its trials. Manufacturing of the cell product took less than 24 hours, and the median viability of all lots, in both clinical trials, was greater than 90 percent.

In the SQZ® eAPC clinical trial, scans showed stable disease as the best overall response for two out of four...
evaluable patients in low dose Cohort 1. A positive ELISPOT response for the E7 antigen was observed in one of these patients and correlated with prolonged stable disease. This patient remains on treatment.

“Receiving FDA Fast Track Designation underscores the significant potential of our SQZ® eAPC candidate, which is designed to generate an even more powerful immune response than our APC candidate,” said Marshelle Smith Warren, M.D., Chief Medical Officer at SQZ Biotechnologies. “The initial safety and tolerability data presented at ESMO-IO today supports our recent portfolio prioritization decision to focus on our eAPC program. In addition to the clean safety profile, we were pleased to observe stable disease in two of the four evaluable patients in the eAPC trial. The team is working diligently to add more eAPC sites to our study to achieve our goal of a highest-dose monotherapy data readout by the middle of 2023.”

Major Findings from Clinical Research:

Poster #183P: COMMANDER-001: Initial safety data from a phase I/II dose escalation/expansion study of SQZ-eAPC-HPV, a cell-based mRNA therapeutic cancer vaccine for HPV16+ solid tumors

- All patients in Cohort 1 completed the 28-day dose limiting toxicity (DLT) period without experiencing a DLT. No related serious adverse events were reported
- Of the four patients enrolled in Cohort 1, two patients (50%) experienced a best overall response of stable disease, including one patient who had a pronounced pharmacodynamic response with prolonged stable disease
- Cell collection to product release took approximately 1 week. One year’s worth of SQZ-eAPC-HPV, the maximum amount of drug able to be administered on study, was able to be manufactured for all patients in Cohort 1
- Median viability of all lots was 94%

Poster #191P: Preliminary biomarker and safety results of SQZ-PBMC-HPV at recommended phase II dose (RP2D) in monotherapy and combination with checkpoint inhibitors in HLA A*02+ patients with recurrent, locally advanced, or metastatic HPV16+ solid tumors

- Data suggests SQZ-PBMC-HPV is capable of stimulating an anti-tumor immune response in a subset of patients. As observed in patient 17 (presented at ESMO-IO 2021), increased CD8 tumor infiltration in conjunction with a reduction of E6 (and E7) expressing cells in the presence of elevated MHCI expression is consistent with a biomarker signature of antigen-specific killing
- SQZ-PBMC-HPV is considered safe and well-tolerated at RP2D both in monotherapy and in combination with checkpoint inhibitors. The safety profile consisted of mostly low grade (grades 1 and 2) non-specific AEs, only one patient experienced serious adverse events (unrelated to SQZ-PBMC-HPV), and no dose-limiting toxicities observed
- All batches produced under cGMP yielding multiple cryopreserved doses in <24hrs with about 1 week
collection-to-release time. Product characterization confirmed antigen presentation and high viability in all patient batches.

About SQZ-eAPC-HPV

SQZ® Enhanced Antigen Presenting Cells (eAPC) are derived from peripheral blood mononuclear cells (PBMCs), which are primarily composed of monocytes, T cells, B cells, and NK cells, and engineered with various mRNA encoding for multiple target antigens and immuno-stimulatory signals, including CD86 and membrane-bound IL-2 and IL-12. The company has presented preclinical findings showing that SQZ® eAPCs have generated robust T cell responses in human in vitro and in vivo models. Additionally, it was demonstrated preclinically that HPV16-encoding mRNA delivery to PBMCs stimulated CD8+ T cells across a range of HLA haplotypes, supporting eAPC clinical development in broader HPV16+ patient populations.

COMMANDER-001 Trial Design

SQZ-eAPC-HPV is being evaluated in a Phase 1/2 clinical trial (COMMANDER-001) for the treatment of HPV16+ advanced or metastatic solid tumors. The clinical candidate, which targets E6 and E7 oncoproteins, is being studied as a monotherapy and in combination with pembrolizumab, an immune checkpoint inhibitor. The study consists of two parts. The first part is designed to assess safety and tolerability of multiple doses of SQZ-eAPC-HPV in treatment-experienced patients, following a dose-escalation scheme for monotherapy, and a dose de-escalation for the combination with pembrolizumab. The second part of the study will assess clinical response of SQZ-eAPC-HPV in combination with pembrolizumab in immune checkpoint inhibitor treatment-naive patient populations.

About SQZ-PBMC-HPV

SQZ-PBMC-HPV is the company’s Antigen Presenting Cell (APC) autologous cell therapy clinical candidate and is derived from peripheral blood mononuclear cells (PBMCs), primarily composed of monocytes, T cells, B cells, and NK cells, and engineered with tumor specific E6 and E7 peptide antigens. It received FDA fast track designation in April 2022. In December 2021, the company presented clinical data at the European Society for Medical Oncology Immuno-Oncology (ESMO-IO) congress that included a checkpoint refractory head-and-neck cancer patient who demonstrated a radiographic, symptomatic, and immune response in the monotherapy cohort of the Phase 1/2 clinical trial.

SQZ-PBMC-HPV-101 Trial Design

SQZ-PBMC-HPV is being evaluated in a Phase 1/2 clinical trial for the treatment of HPV16+ advanced or metastatic solid tumors. Patients must be positive for the human leukocyte antigen serotype HLA-A*02. The investigational candidate, which targets E6 and E7 oncoproteins, is being studied as a monotherapy and in combination with immuno-oncology agents. The study’s primary outcome measures in the monotherapy and combination phases of the trial include safety and tolerability. Antitumor activity is a secondary outcome measure in both the monotherapy and combination phases of the trial, and manufacturing feasibility is a secondary outcome measure in the monotherapy phase of the trial. The monotherapy phase of the study includes escalating dose cohorts with a
dose-limiting toxicity (DLT) window of 28 days and is designed to identify a recommended phase 2 dose. The planned combination phase of the study will include SQZ-PBMC-HPV and checkpoint inhibitors. DLT will be measured over 42 days. Patient enrollment is expected to be discontinued by the end of the year with a transition to the currently enrolling COMMANDER-001 trial featuring the second-generation SQZ® eAPC candidate for the treatment of HPV16+ advanced or metastatic solid tumors.

About Human Papillomavirus Positive Cancers
Human papillomavirus (HPV) is one of the most common viruses worldwide and certain strains persist for many years, often leading to cancer. According to the Centers for Disease Control (CDC), in the United States HPV+ tumors represent 3% of all cancers in women and 2% of all cancers in men, resulting in over 39,000 new cases of HPV+ tumors every year. HPV infection is larger outside of the U.S., and according to the International Journal of Cancer, HPV+ tumors account for 4.5% of all cancers worldwide resulting in approximately 630,000 new cases every year. According to the CDC, HPV infection plays a significant role in the formation of more than 90% of anal and cervical cancers, and most cases of vaginal (75%), oropharyngeal (70%), vulval (70%) and penile (60%) cancers.

About SQZ Biotechnologies
SQZ Biotechnologies is a clinical-stage biotechnology company focused on unlocking the full potential of cell therapies. 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. For more information, please visit www.sqzbiotech.com.

Forward Looking Statements
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, the timing and outcome of the company's clinical trials, clinical safety and efficacy of its therapeutic candidates, strategic prioritization, manufacturing capabilities, and Fast Track Designation. 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; our ability to continue as a going concern; our ability to successfully execute or achieve the benefits of our strategic prioritization and other cost saving measures; 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 Quarterly Report on Form 10-Q, 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.

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