



SQZ Biotechnologies Announces Lead Cell Therapy Candidate Induced Radiographic, Symptomatic and Immune Response as Monotherapy in Post-Checkpoint HPV+ Solid Tumor Patient

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Patient's Clinical, Radiographic and Histologic Results Support Potential Impact of SQZ Investigational Therapeutic

- Patient Demonstrated Symptomatic Improvement
- Radiographic Response Observed in Target Lesion
- Tumor Conversion from Desert to Inflamed Phenotype with 8-Fold Increase in CD8 T Cell Tumor Infiltration and 50-Fold Increase in Tumor PD-L1 Expression
- Interim Results from Ongoing Phase 1/2 Trial Showed Favorable Safety Data and Investigational Therapy was Generally Well Tolerated

Company to Host Conference Call Today at 8:00 a.m. ET

WATERTOWN, Mass.--(BUSINESS WIRE)-- SQZ Biotechnologies Company (NYSE: SQZ), a cell therapy company developing novel treatments for multiple therapeutic areas, today presented interim results from the highest-dose cohort of its ongoing Phase 1/2 clinical trial of lead Antigen Presenting Cell (APC) therapy candidate targeting Human Papillomavirus positive (HPV16+) solid tumors at the European Society for Medical Oncology Immunology (ESMO-IO) Congress. Of the five patients in this cohort evaluable for efficacy, one checkpoint refractory head-and-neck cancer patient showed a radiographic response and symptomatic improvement. The target lesion demonstrated a complete response at both radiographic assessments. At the most recent assessment, the major oropharyngeal lesion demonstrated continued improvement upon physical examination; however, a new dermal lesion was detected. The investigational therapy was well-tolerated, and no dose-limiting toxicities were observed as of October 8, 2021.

"The combined radiographic response and symptomatic improvement observed in this patient and the strong correlation with histological data demonstrated the investigational therapy's intended cellular vaccine mechanism at work," said study first author and presenter Jong Chul Park, MD, Medical Oncologist and Investigator, Massachusetts General Hospital Cancer Center. "This heavily treated patient with significant tumor burden in the

neck had marked increases in CD8 T cell tumor infiltration which correlated with clinical improvement, including the ability to swallow more easily. SQZ-PBMC-HPV showed favorable safety data and was generally well tolerated in this patient and across all patients in the highest-dose cohort.”

“While our clinical study is ongoing, we believe that this is a ‘Kitty-Hawk moment’ for the SQZ APC cell therapy platform,” said Armon Sharei, Ph.D., Chief Executive Officer and Founder of SQZ Biotechnologies. “Our goal has been to develop a new generation of cell therapies - one that could potentially enable significant and broad patient impact by unlocking historically challenging biology while remaining practical and accessible. We believe this patient’s journey is consistent with the trial’s practical and rapid approach. We manufactured a cell therapy in under a day, administered it with mild treatment-related adverse events, and generated clinical benefit by marshalling the power of endogenous killer T cells. We are very excited for the advancement of this program into combination therapy and the broader future potential of SQZ cell therapy candidates.”

Responder Patient Characteristics & Treatment Journey

The patient in the highest-dose cohort who achieved a complete response in the target lesion (patient 17) was a 52-year-old male diagnosed over three-and-a-half years prior to first dose with a locally advanced squamous cell carcinoma of the tonsil, a part of the oropharynx. He initially had chemo-radiation treatment but developed recurrence in the throat and the chest almost two years prior. At trial entry, patient 17 had received six prior lines of therapy, including two combination approaches with the checkpoint inhibitor pembrolizumab.

Patient 17 did not require pre-conditioning. Following a single leukapheresis session, his investigational therapy was manufactured in 18 hours and produced 7 doses.

Clinical Results

- Patient 17 had marked improvement of the target lesion on physical examination and reported that his ability to swallow had substantially improved
- Patient 17 experienced two low grade treatment related adverse events, i.e., grade 1 flushing and grade 1 fatigue
- As of October 20, 2021, he received all seven doses of SQZ-PBMC-HPV and the investigational therapy was well tolerated

Radiographic Response

- Patient 17’s main lesion was a large, diffuse, non-measurable oropharyngeal lesion
- The target tumor lesion selected for response assessment was a mediastinal lymph node measuring 17.1mm in diameter, which decreased at second assessment below 10.0mm resulting in a complete response of the target lesion according to RECIST 1.1
- At the second on treatment tumor assessment, despite continuing improvement of the target lesion and

patient symptoms, a new dermal lesion was found in the previously irradiated region

Histologic Assays

- At day 28 on treatment, patient 17's matched tumor biopsy samples from the main oropharyngeal lesion showed an 8-fold increase in CD8 T cell tumor infiltration and a conversion of the tumor phenotype from desert to inflamed
- PD-L1 expression, an additional marker of tumor inflammation, increased from 2 percent at baseline to 100 percent in the matched tumor biopsies
- An RNA in situ hybridization (ISH) assay used for the detection of E6 and E7 expression demonstrated a dramatic reduction in the number of cells with high E6 and E7 antigen expression. E6 and E7 are the two antigens targeted by the SQZ APC cell therapy candidates

Highest Dose Monotherapy Cohort Interim Safety and Manufacturing Findings as of October 8, 2021

- There were no observed treatment-related serious or severe (grade 3 or greater) adverse events in the highest-dose cohort
- The investigational therapy was generally well-tolerated, and no dose-limiting toxicities were observed
- All patient batches were produced in less than 24 hours and yielded multiple cryopreserved doses

Clinical Trial Progress

- The combination stage of SQZ-PBMC-HPV-101 trial with checkpoint inhibitors (CPI) is now enrolling. The company believes the increase in PD-L1 expression observed in the patient 17 data suggests potential synergy with a CPI combinatory approach
- The highest-dose monotherapy stage of the trial continues enrollment to further evaluate the investigational candidate in single agent settings

Today's ESMO-IO presentation can be found on the **Events & Presentations** section of the company's website.

Conference Call

The company will host a conference call and webcast today at 8:00 a.m. ET to discuss the ESMO-IO presentation. Participants can join via webcast [link](#) or by dialing 1-877-805-7920 (domestic) or 1-629-228-0702 (international) five minutes prior to the start of the call. An archived webcast will be accessible for 90 days after the event.

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 stages 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.

About Human Papillomavirus Positive Cancers

Human papillomavirus (HPV) is one of the most common viruses worldwide and certain strains persist for many years 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 Company is a clinical-stage biotechnology company focused on unlocking the full potential of cell therapies for patients around the world and has active programs in Oncology, Autoimmune and Infectious Diseases, as well as additional exploratory initiatives to support future pipeline growth. The company's proprietary Cell Squeeze® technology offers the unique ability to deliver multiple biological materials into many cell types to engineer what we believe can be a broad range of potential therapeutics. With demonstrated production timelines under 24 hours and the opportunity to eliminate preconditioning and lengthy hospital stays, our approach could significantly broaden the therapeutic range and accessibility of 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 infectious diseases, and in immune tolerance for the treatment of autoimmune diseases. 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, our platform development, our product candidates, clinical activities, progress and outcomes, development plans, manufacturing, clinical safety and efficacy results, therapeutic impact, market opportunities 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 strategic collaborators; 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, as updated by our Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2021 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 we undertake 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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