Happy Birthday Freeman

Will and Misti, parents of a little boy, turn their tragedy into a legacy of love. Learn more about their story on page 5.

The Beilman’s do it again!

Amy and Lewis never cease to amaze us. The Palm Coast, FL Chapter Facilitators have been a part of SPOHNC’s family for over a decade. Read about how they raised more than $20,000 for SPOHNC!

Next Generation Cell Therapies Fighting HPV Positive Head and Neck Cancers

Ricardo F. Zwirtes, MD, VP of Clinical Development at SQZ Biotechnologies

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Kudos to The Carleton Group at NY Institute of Technology, and Professor Louie Aragon and Kameline Pavez, for the PRO BONO redesign of News from SPOHNC. The Carleton Group has been a major part of New York Tech for more than 20 years. They are the second-oldest student-run ad agency in the United States, giving students in the field of advertising a true hands-on agency experience that will be useful in the pursuit of a future career.

SPOHNC is dedicated to raising awareness and meeting the needs of oral and head and neck cancer patients through its resources and publications.

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Next Generation Cell Therapies Fighting HPV Positive Head and Neck Cancers

Ricardo Zwirtes, M.D.
Vice President of Clinical Development
SQZ Biotechnologies

As we continue to search for more effective treatments for head and neck cancers, cell therapy is an exciting field within immunotherapy that offers significant promise.

Though there is broad potential for using cell therapy across different types of cancers, we have only scratched the surface. The major challenges to the cell therapy approach include altering cells without impairing their health and manufacturing the modified cells in large quantities.

Because of these constraints, there are few approved cell therapy options currently available to patients (CAR T-cell therapy being a recent example). These treatments often have their own challenges, including long hospital stays, harsh preconditioning, and costly and time-intensive manufacturing. Additionally, while cell therapies have proven successful in treating blood cancers like leukemia and lymphoma, they have been less successful in tackling solid tumors.

Beyond CAR T-cell therapies and checkpoint inhibitors, therapeutic cancer vaccines offer another promising method of improving the immune system's response to cancer. Cancer vaccines have been pursued for many decades because of their potential to drive a powerful, tumor-specific immune response. They are intended to prime the patient’s T cells to generate an anti-tumor response and/or boost pre-existing anti-tumor immunity.

However, prior cancer vaccine attempts have failed to elicit a meaningful response from a special type of cell in our immune system that is responsible for the tumor killing – the CD8+ T cells, or killer T cells. This is underscored by the fact that to date, only one therapeutic cancer vaccine has been approved for use in prostate cancer.

Even still, cell therapies may be our best hope against solid tumors and have the potential to overcome the challenges of CAR T-cell therapy and prior cancer vaccines. If successful, a safe and effective therapeutic vaccine could be transformative for diseases like head and neck cancers.

THERAPEUTIC VACCINE POTENTIAL FOR HPV+ CANCERS

Human papillomavirus (HPV) is one of the leading causes of cancers of the head and neck. According to the Centers for Disease Control, HPV infection plays a significant role in the formation of about 70 percent of oropharyngeal cancers.

The current standard of care, however, still involves treating all head and neck cancers basically the same way, regardless of whether the cancer was caused by HPV, smoking or other factors. While tremendous strides have been made in cancer care, particularly with the introduction of new immunotherapies and checkpoint inhibitors, only a small proportion of head and neck cancer patients benefit from this type of therapy.

There is increasing hope for head and neck cancer patients with HPV positive tumors. Next generation therapeutic vaccines that are designed to teach a patient’s own immune system to recognize the HPV viral proteins in the tumor are actively in clinical development.

SQZ Biotechnologies is developing treatments that may enable cell-based vaccines to effectively recruit killer T cells and aim their attack on HPV positive solid tumors.
PUTTING A PATIENT’S IMMUNE SYSTEM TO WORK TO ATTACK DISEASE

Our technology works by using a patient’s own cells to manufacture a personalized cell therapy.

Following a standard blood collection procedure, we isolate target cell types and engineer the cell therapy by physically squeezing the blood cells at high speeds through a microfluidic chip. As they move through the chip, the cells’ membranes are temporarily opened, which enables specific cargo, like mRNA or HPV-specific antigens, to be inserted into the cells before the membrane reseals.

The cell therapy is then given to the patient through a syringe push, and the engineered cells are intended to direct the patient’s immune system to target HPV-driven tumors (see graphic).

This cell engineering approach has been used to create three different cell therapy candidates for testing in clinical trials:

- In the first approach, a patient’s white blood cells are squeezed with HPV-specific antigens to create a therapeutic vaccine that we call SQZ® APCs, or antigen presenting cells. Antigen presenting cells (APCs) are responsible for activating CD8+ T cells – the immune cells that track down and kill cancer cells. After the APCs are given to the patient, they work to directly prime CD8+ T cells so that they begin attacking the patient’s cancer.

- In the second approach, an enhanced APC (SQZ® eAPC) is designed to leverage the advantages and functionalities of five different mRNAs squeezed into white blood cells. mRNA, or messenger RNA, carries instructions that direct our cells to make proteins that can treat or prevent disease. The mRNAs squeezed into the eAPCs code for HPV antigens as well as stimulators of killer T cells. The eAPCs are meant to increase killer CD8+ T cells’ response, which may result in more effective attacks against the cancer cells. FDA clearance to open a clinical trial evaluating this approach was recently granted.

- While the first two approaches use a patient’s white blood cells, the third method engineers red blood cells. After blood collection, the red blood cells are squeezed with disease-specific antigens and immune activators, creating what we call Activating Antigen Carriers, or SQZ® AACs. Once delivered back to the patient, the AACs act as a “trojan horse” by carrying and delivering the target antigen to very specialized cells (antigen presenting cells) in the patient’s lymphoid organs to direct the killer T cells to attack the tumor cells.

All of these approaches potentially offer advantages for patients.

First, these cell therapy candidates can be manufactured in about a week, which is significantly faster than most cell therapy approaches. In addition, these cell therapy candidates are designed to be administered without preconditioning. Further, treatment would not require a planned hospitalization.

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In December 2021, promising data were presented that showed the SQZ® APC clinical trial candidate had induced a radiographic, symptomatic and an immune response as monotherapy in a post-checkpoint inhibitor treated HPV positive solid tumor patient (1 out of 5 evaluable patients in that cohort). This data was presented as an oral presentation at the European Society for Medical Oncology Im-muno-Oncology (ESMO-IO) Congress, an annual global meeting highlighting the latest scientific advancements in immuno-oncology.

In this case study, the patient had been diagnosed with oropharyngeal cancer almost four years prior. Before joining our clinical trial, the patient had received six prior lines of therapy, including a checkpoint inhibitor therapy nine months prior, to no effect. The patient was unable to eat, drink or breathe normally due to the substantial lesion on the throat.

The patient response in the SQZ® APC trial is what drives us each day. Our hope is that we can eventually offer HPV positive head and neck cancer patients a personalized therapeutic vaccine that is fast to manufacture, safe, and effective.

Our three clinical trials are actively enrolling patients with HPV positive cancers, including head and neck cancers. The trials are open to patients aged 18 and older with recurrent, locally advanced or metastatic HPV 16+ solid tumors that have progressed while on the standard of care treatment options.

With no pre-conditioning required for SQZ's therapeutic candidate, the patient's treatment journey consisted of a single session to collect white blood cells; after about a week the patient's engineered cells were delivered back into the body.

After receiving the investigational therapy, a significant increase in the patient's T cells infiltrating the tumor was observed, which was associated with an improvement in the patient's ability to eat. There were no treatment-related adverse effects. This has substantially improved the patient's quality of life, according to the treating doctor.

The SQZ® APC trial is now advancing into combination approaches with checkpoint inhibitors. This combination may work synergistically and potentially enhance killer T cells' ability to attack tumors.

The three trials are running at cancer centers around the country, and we will be happy to assist potential patients to gain access to these studies. For more information on our open clinical trials, visit sqzbiotech.com/head-neck-trial.

We are also always available to speak with patients and their treating physicians, and we want to thank the staff at SPOHNC for being a terrific partner in generating awareness for the potential of cell therapies in the treatment of head and neck cancers.

Editors Note: Ricardo F. Zwirtes, MD, is the VP of Clinical Development at SQZ Biotechnologies where he oversees the clinical trials for patients with cancers caused by HPV. He is an infectious disease physician by training with over a decade of experience in drug development across several therapeutic areas.

“"We all need hope and to know there are others like us. It may not be an easy path all the time but we can certainly do it. Just knowing we're not alone is a huge help.”

~ Pat L.

Contact SPOHNC today at 1-800-377-0928 or at info@spohnc.org

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One Family’s Inspiring Tube Feeding Journey

Freeman Ellis Staley was born April 2015.

He spent 3 and a half months in the Arkansas Children’s NICU, home for 5 weeks, and then 5 long months in the PICU before Freeman sadly lost his battle with pulmonary hypertension at 10 months old. His parents, Will and Misti spent every day by his side cheering him on. It has now been 6 years since Will and Misti lost Freeman, but they are happy to continue Freeman’s legacy of love through the FreeArm Tube Feeding Assistant, making gravity feeds, pump feeds and IV infusions easier for families and hospital staff around the world.

Freeman had a feeding tube his entire life. While in the hospital, nurses were unable to stand and hold the gravity feeding syringe, they had other patients to look after, so they would always rig it. Tape the syringe to Freeman’s swing or the side of his crib, or rubber band it to the oxygen meter on the wall, or hang it over his tall canopy crib with a ribbon. Rigging the syringe in all of these different places, never fed Freeman at the same rate, the syringe was always too high or too low making his feed go in too fast or too slow and the ribbon over Freeman’s crib was always in the way. Freeman would spit up, aspirate, and turn blue. Doctors would have to rush over to bag him, having to fight with the ribbon to reach him quickly. This was always so scary!

While Freeman was home, Misti and Will needed help with his gravity syringe feeds during the day and his pump feeds at night. It was overwhelming to sit on the couch and try to hold Freeman, hold the gravity syringe, put in meds and perform therapies, like holding his paci in, so that he could suck as his tummy filled, they had to do all of these things at the same time. They needed an extra hand, so they created one- The FreeArm!

The FreeArm clamps to many surfaces, flat surfaces such as dining tables and side tables, and rounded bars, like the bars on a wheelchair or hospital bed, giving every “Tubie” of any age a helping hand at the hospital, home and on-the-go. The arm bends up easily for travel and can bend to the exact height above the person’s abdomen where gravity feeds are tolerated best, providing a consistent way to tube feed in all situations.

The FreeArm Muscle holds a gravity syringe and a lightweight pump and feedbag up to 1,200ml, freeing your hands for gravity feeds and allowing you to ditch the iv pole around the house and while traveling. The FreeArm is helpful for babies and adults, especially adult #freearmfans undergoing head and neck cancer and ALS. The FreeArm Muscle comes in 4 fun colors! Pink, white, blue and green. It’s frustrating to not have any control over a medically complex life, so being able to choose your favorite color FreeArm spreads a little happiness!

The FreeArm Muscle is billable for insurance coverage and can be requested from several DMES and hospitals. If your DME or hospital does not currently supply the FreeArm Muscle, please request that they begin supplying. The more requests, the more clinicians learn about this helpful product. The FreeArm Muscle is also available for purchase directly from www.freearmcare.com. Use discount code SPOHNC20 to save 20% off a FreeArm Muscle, in addition to the already reduced at-home patient pricing.

Through extreme tragedy, comes hope and help for all. The FreeArm is sold worldwide with users in every US state and over 24 countries. FreeArm instructions are currently available in English, French, Italian and German. The FreeArm Muscle is offering a helping hand to people around the world. The FreeArm would not be here today without sweet, little Freeman Ellis Staley.
The Beilman’s

For Oral, Head and Neck Cancer Awareness month, SPOHNC chose a very special couple as our April Champions of Hope. The story begins like this…

In 2011, Sandy Walker connected with SPOHNC. She called to find out what kind of support services we could offer to her friends, Amy and Lewis Beilman. Lewis had just been diagnosed, and Amy needed help. She was not prepared for the caregiver role she was about to take on. Lewis had been diagnosed with tonsil cancer, and treatment began.

After being matched with a survivor volunteer for Lewis, and a caregiver match for Amy, the Beilman’s began their cancer journey, and their relationship with SPOHNC. From support, to friendship and beyond, this amazing couple has given back to so many in so many ways, and they remain steadfast in their support of those who travel the head and neck cancer journey.

After more than a year of scans, tests, appointment, treatments and follow up appointments, Lewis was finished with treatment and on the road to recovery. Amy and Lewis had already decided that once the worst part was over, they were going to give back – and that is an understatement!

In 2012, Amy and Lewis started a SPOHNC Chapter support group, so that others who were traveling the journey could support each other along the way. The bonds and friendships that were born out of the group have only deepened over time, and the group grew and grew. It was apparent to all that this was a very special couple.

The Beilman’s were instructors for an exercise class in their Grand Haven community, and in 2013, they decided that they could, and would, turn this class into a fundraiser, for none other than SPOHNC. And so, the ball started rolling…

Each year, the Beilman’s worked harder and harder, all while continuing to support patients and caregivers through their SPOHNC Chapter, and while living life to the fullest. They even managed to take a trip up north, by car, to visit family. While the family visit is an entirely different story (which no one would ever believe!) the Beilman’s and their beloved dog, Hero, decide to “stop in to SPOHNC” for a visit on their way. Meanwhile - the little village in Locust Valley where SPOHNC’s main office is, was hardly along the way to their final destination, but they came to see us anyway!

We had a little continental breakfast celebration in the office, and we had gifts for Hero, and a Welcome sign on the door. The truth is, we don’t get many visitors at SPOHNC, so this was a pretty big deal! It was like having family visit, and we were instantly hooked on this couple and their beautiful dog. So special!
The first Move to Music fundraiser was held and was a terrific success. There were bagels, raffles, and the exercise class. Lewis even made a special inspirational music mix cd to raise the energy and get the gang moving! The event drew a crowd, and the excitement over the planning for the following year began almost instantly. Each year, the friends and survivors who attended looked forward to participating, volunteering, and helping any way they could. It became an annual happening in Grand Haven, and even the staff on site participated. The Beilman’s have a way with getting people on board!

Even though Covid put a damper on the support group, and the annual event, the Beilman’s never gave up hope. The event resumed this year, and the Beilman’s broke their own previous record for fundraising, supporting SPOHNC’s programs and services with a grand total of more than $21,000. Wow!!!

We count our blessings every day for two amazing human beings who understand and know the value of support. The Beilman’s are true “Champions of Hope” and are always there for others who need guidance and compassion.

Amy and Lewis, your caring hearts and positivity have been such a bright light to everyone around you. It is people like you that make life beautiful!

Thank you for helping us to continue SPOHNC’s mission, and our Founder, Nancy Leupold’s legacy. She would be so proud of and thrilled with the tremendous support you have given to SPOHNC for the patients and families we reach out to. Our hearts are full of gratitude. Three cheers for our April Champions of Hope...Amy and Lewis Beilman!

**In Memoriam**

SPOHNC is deeply saddened to learn of the unexpected passing of Hero. The national office received word at press time. We know how special Hero was to Amy and Lewis. Our hearts are broken and our prayers are with them at this very difficult time. May God bless Hero as he crosses the Rainbow Bridge.

Do you have a topic of interest that you’d like to see covered in a future feature article in “News from SPOHNC”

Email us to today at info@spohnc.org. We want to hear from you!
SPOHNC is honored to welcome Patrick Byrne, MD, of the Cleveland Clinic, to our Medical Advisory Board.

Dr. Byrne joins a group of highly esteemed healthcare professionals from across the United States who serve on this Board. Dr. Byrne has been a good friend to SPOHNC and has authored a feature article for “News from SPOHNC” in the past.

Dr. Byrne earned his M.D. from the University of California San Diego School of Medicine. He completed a surgical internship at the University of California in San Francisco and a residency in otolaryngology/head and neck surgery at the University of California San Diego. He was a research fellow at the San Diego Cancer Center at the University of California followed by a fellowship in facial plastic and reconstructive surgery at the University of Minnesota. Additionally, Dr. Byrne completed a fellowship in Health Care Management at the Advisory Board Company. In 2015, he earned a Masters degree in Business Administration from the Wharton School of The University of Pennsylvania.

Dr. Byrne was previously at The Johns Hopkins Hospital, where he served as director of the Division of Facial Plastic and Reconstructive Surgery in the Department of Otolaryngology/Head and Neck Surgery. He also was professor of Otolaryngology/Head and Neck Surgery, Dermatology and Biomedical Engineering at the Johns Hopkins University School of Medicine, director of the Johns Hopkins Facial Plastic and Reconstructive Surgery Fellowship program, and a co-director of the Johns Hopkins Face Transplant Team.

A holder of U.S. patents, Dr. Byrne developed a specialized mechanism that assists surgeons working with cartilage, safeguarding this tissue by preventing its entry into the cutting apparatus. He has worked in conjunction with basic science researchers to develop a novel regenerative biomaterial, funded by the Department of Defense, which recently completed a Phase II FDA trial. He also invented a Class I medical device to aid in nasal breathing that recently completed a first of its kind human clinical trial.

Dr. Byrne is very involved in international and humanitarian work. He served as a Johns Hopkins International Medical Director for over 10 years, assisting with the achievement of Joint Commission International accreditation for medical centers in Central America and Asia. Dr. Byrne has traveled overseas his entire career, leading teams performing volunteer surgery and providing medical relief to those in need in developing countries around the world. He led a sustained effort with nonprofit organizations to develop a comprehensive multidisciplinary free program dedicated to the treatment of cleft lip, cleft palate and other facial deformities for children in Nicaragua and other developing countries.

SPOHNC is honored and grateful that Dr. Byrne has accepted this position on our MAB. We appreciate his dedication to those who we both serve. Welcome, Dr. Byrne. We look forward to working with you.

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Support for People with Oral and Head and Neck Cancer, Inc. is grateful for the generosity of its contributors. Thanks to their support, SPOHNC is able to maintain and extend its programs of education and support to cancer survivors, their families and friends. With sincere appreciation to all.

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- by Nancy E. Leupold & James J. Sciubba, DMD, PhD

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Augusto Cunha, Janice Daly,
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Gabrielle Duval by Ari Kaplan
Everyone fighting cancer by Loretta Crawford
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Jonathan Freilich by Cherise Tasker
Gabriel Garcia by Edna Angeli

Honorariums

Joseph Prete by Marie Prete
Ted Reuter by Laurie Braatem-Reuter
George & Carole Saire by Mr. & Mrs. Brindle
Steven Sheppard by Steven Sheppard
Dawn Sherwood by Geoffrey Sherwood
Dr. Anurag Singh by Boris Kuvshinoff
SPOHNC’s Executive Director, Mary Ann Caputo by Dr. Eugene & Mrs. Barbara Myers, Lawrence & Gina DiGiovanna, Steven Stern
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Janet Williams by Susan O’Connor
Cassandra E. Woods by Lewis Knight
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