

## Potential Side Effects of Immunotherapy in Head and Neck Cancer

Dan Zandberg, MD

### Introduction

Currently, two immunotherapy medications, Nivolumab (Opdivo) and Pembrolizumab (Keytruda) are approved in the USA for recurrent and/or metastatic squamous cell carcinoma of head and neck (HNSCC) after a patient received and failed “platinum” based chemotherapy. Both Nivolumab and Pembrolizumab belong to a class of immunotherapy medications called checkpoint inhibitors, specifically they are anti-PD-1 monoclonal antibodies. With the success and subsequent wide spread use of these drugs the identification and proper management of side effects has become even more important. This article will discuss potential side effects with anti-PD-1 monoclonal antibodies Nivolumab and Pembrolizumab. This discussion will not encompass all side effects ever reported with these medications but rather will focus on those that are more common and those that your treating physician will be evaluating you for.



### Background

As mentioned in the introduction, Nivolumab and Pembrolizumab are anti-PD-1 monoclonal antibodies, which means that they block Programmed Death 1 (PD-1), which is a molecule expressed on immune cells. Thinking about the immune system like a car, there are two ways to make a car go faster. One is to push on the gas pedal and the other is to take your foot off the break. The immune

system has many breaks and many gas pedals that help it determine precisely when to attack and when to stop attacking. PD-1 is akin to a “break” of the immune system, and cancers, including head and neck cancer, can step on this break. Cancers do this primarily via expressing another molecule called PD-L1, which sends a signal through PD-1 on an immune cell to tell that immune cell to stop attacking the cancer. Nivolumab and Pembrolizumab and other drugs with the same target block this break so it cannot be “stepped on” by the cancer to slow down the immune system.

Every drug has potential side effects. These anti-PD-1 monoclonal antibodies have general side effects as well as other side effects that are specific to how these drugs work on the immune system. These later side effects are called immune related adverse events. Because these drugs take the foot off the break of the immune system to allow it to go faster and try and attack the cancer, the immune system can also potentially attack and cause inflammation of normal tissue and organs in the body. When this happens the side effects are described as immune related adverse events.

### General Side Effects

General side effects that may commonly be experienced include fatigue, nausea, and decreased appetite. Every patient is an individual, and so there can be variability in these side effects. Some patients experience little if any change in appetite or energy, while others may experience significant fatigue and low appetite. However, most patients experience some element of fatigue and mild decreased appetite. Nausea can occur, however it is typically significantly less than with traditional chemotherapy medications, like Cisplatin, that are commonly used in head and neck cancer. Additionally, like other cancer medications, a patient may have an allergic reaction to the drug when it is infused.

### Immune Related Adverse Events

Immune related adverse events can affect any part of the body. The more common areas that may be affected include the glands, the lungs, the liver, the skin, and the colon. They can occur at any time during your treatment. If a patient develops an immune related adverse event, the severity will determine the treatment. General treatment for mild immune related adverse events includes stopping treatment until the side effects resolve. For moderate or severe adverse events, treatment is stopped and immunosuppressive medications are started to suppress the immune system and stop it from attacking the normal tissue/organs in your body. Steroids are the first type of immunosuppressive medication that is started, and if the steroids start working, it is recommended that they continue for at least a month. In most cases, immune related adverse events can be managed effectively with immunosuppressive medications, and after the immune related adverse event resolves and the steroids

IMMUNOTHERAPY SIDE EFFECTS continued on page 2

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are finished, the immunotherapy may be restarted depending on the initial severity of the side effect that occurred.

However, these adverse events can become very serious and life threatening if treatment for them does not occur early. Therefore, it is important for your physician to always consider whether your symptoms are immune related and for you to always report how you are feeling, so that your physician can make an assessment. As will be described below, some of the symptoms of immune related adverse events are non-specific and like side effects that you may have experienced in the past with other treatments. Some of them, like diarrhea for example, you may have managed prior by yourself at home without a call to the physician. Therefore, a patient undergoing this treatment must stay vigilant in letting their physician know if you have developed any new symptoms. There is not one sole diagnostic test that can determine if you have an immune related adverse event. The diagnosis is often based on ruling out other non-immune related causes to the symptoms. Just as you stay vigilant in terms of reporting your symptoms, your treating physician will remain on alert to consider whether a symptom that has developed is an immune related adverse event.

**Organs That May be Affected by Immune Related Adverse Events**

*The Endocrine System (Glands)*

The glands in the body, including the thyroid gland, the adrenal glands, and the pituitary gland, make substances called hormones that help regulate how the body works. While if the glands are inflamed and not working properly you may feel symptoms, your treating physician will need to draw blood work to confirm if the endocrine system is being affected.

The thyroid gland makes thyroid hormone which has a number of functions including metabolism. Treatment with these immunotherapy medications may make the thyroid work too much (hyperthyroid) or not enough (hypothyroid). If the thyroid is working too much there will be higher than normal levels of thyroid hormone in the body which may cause you to feel hyper, feel hot, have heart palpitations, have frequent bowel movements, or lose weight, among other symptoms. If the thyroid is not working enough, then there will be too little thyroid hormone and you may feel fatigued, constipated, feel cold, or gain weight. The thyroid gland is the most common gland to be potentially affected, with hypothyroid being more common than hyperthyroid. If the thyroid gland is not working enough, your physician will give you thyroid hormone in the form of a pill.

The pituitary gland, which is located at the base of the brain, is called the “master gland” because it sends out hormones that control other glands. If the pituitary gland becomes inflamed as a side effect, this is called hypophysitis. If this develops, you may feel headache and fatigue and other glands in the body will not work as well because there is no signal coming from the pituitary gland. If hypophysitis occurs, in addition to starting immunosuppressive medication, your physician will also refer you to an endocrinologist for management and replacement of hormones that are needed.

Finally, the adrenal glands make numerous different substances

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for the body including steroids. While it is rare for the adrenal glands to become affected by these drugs, if they do, the glands typically are underactive, which can lead to fatigue, electrolyte imbalances, dizziness, and nausea. During treatment, your physician should check thyroid hormone levels in the blood regularly and will check for other glands as needed if there is suspicion based on symptoms.

### ***The Lungs***

The lungs are another organ system that can be affected by the immune system. This can lead to inflammation of the lungs called pneumonitis. Symptoms of pneumonitis include trouble breathing, cough, pain with deep breaths and fever. While pneumonitis is rare, occurring in around only 2% of patients, it can become severe, and so it is important to let your physician know right away if you are having any new respiratory symptoms. The physician will then based on your symptoms initiate a work up which in most cases includes doing imaging to visualize what is going on in the lungs and depending on the findings may include have you see a lung specialist (pulmonologist).

### ***The Gastrointestinal System***

The intestine includes the small intestine as well as the large intestine. Both the small and large intestine can become inflamed by the immune system. If this inflammation occurs a patient may experience diarrhea and abdominal pain. Diarrhea is something that you may have experienced from other chemotherapy medications you received prior and while in the past you may have just taken anti-diarrheal medications at home, it is very important to report these symptoms to your physician right away. Your treating physician will rule out any other infectious cause and may have you undergo imaging to evaluate what the small intestine and large intestine look like. Potentially an endoscopy (camera study) may be done to work up the symptoms.

### ***The Liver***

The liver can become inflamed which is called hepatitis. If the liver becomes very inflamed you may turn yellow which is called jaundice and additionally feel weak, nauseous, have pain underneath your rib cage on the right side and have itchy skin

and light-colored stools. Most of the time hepatitis is picked up on labs called liver function tests which are drawn routinely by your physician. Similar, to diarrhea the treating physician will want to rule out other causes, including medication or viruses, that can also cause abnormalities in your liver function tests.

### ***The Skin***

The skin is the most common organ to be affected by an immune related adverse event. This is most commonly in the form of a rash. The rash is typically red and involves the trunk and the arms/legs. Your physician will usually start with creams to apply directly to the skin if it appears. You may also experience some itching. Vitiligo, where the skin loses pigmentation and may become whiter, can also occur.

### ***Other Organ Systems***

Very rarely the heart, kidney, muscles, or nerves can become inflamed as a side effect of anti-PD-1 monoclonal antibodies.

### ***Pseudoprogession***

Rarely when being treated with anti-PD-1 monoclonal antibodies the tumor can enlarge before then responding to the drug and shrinking. This phenomenon termed pseudoprogession is felt to be from inflammation of the tumor itself from the immune system attacking it, which leads to enlargement before subsequent shrinkage. In the head and neck because tumors are close to the airway and areas that may cause pain with enlargement, a patient may experience some worsening of breathing or pain. These symptoms must be reported to your physician right way and that physician will decide as to whether the symptoms are felt to be from the cancer growing and not responding to the anti-PD-1 monoclonal antibody, or if he/she feels this may be pseudoprogession. Often times an imaging study is needed to evaluate the tumor to help make this determination. However, currently there are no specific tests or imaging studies that can be done to say for certain whether enlargement is failure of the cancer to respond to the drug or pseudoprogession. Therefore, your physician will weigh many factors, including how you are feeling overall, in determining whether to stop the drug because it is not working or to continue for a short time period longer to

re-evaluate whether this is pseudoprogession or not.

### ***Conclusion***

Checkpoint inhibitors targeting PD-1, like Nivolumab and Pembrolizumab, are now approved across many tumor types in addition to HNSCC, and have changed how we treat patients. The success of these drugs as single agents has led to a lot of exciting research and clinical trials attempting to continue to make outcomes better by combining these drugs with other immunotherapy medications, chemotherapy, and/or radiation. While this article has discussed a lot of potential side effects, importantly these drugs, including in head and neck cancer, have been generally well tolerated, with only a minority experiencing significant side effects. Importantly, in the large study where Nivolumab was compared to chemotherapy in HNSCC, that led to the approval of Nivolumab by the FDA, patients treated with Nivolumab had less side effect overall and less severe side effects compared to those treated with chemotherapy. Additionally, treatment with Nivolumab improved patients' quality of life more than chemotherapy in this clinical trial. The different spectrum of side effects and generally good tolerance of these drugs compared to traditional chemotherapy, also allows physicians to offer these to patients that may have lasting side effects from prior treatment for their HNSCC. That being said, as this article highlights, immune related adverse events can become severe if not recognized and treated early. Therefore, vigilance and good communication by both patient and physician is imperative for safe and successful treatment of head and neck cancer with anti-PD-1 monoclonal antibodies.

*Editors Note: Dr. Dan Zandberg obtained his MD from Jefferson Medical College and his internal medicine residency at the George Washington Univ. Medical Center. He is currently at the University of Pittsburgh Medical Center Hillman Cancer Center, as Associate Professor of Medicine, Director of the head and neck and thyroid cancer disease sections for the division of hematology/oncology, and co-director of the UPMC Hillman head and neck cancer research program.*

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## April Awareness Arrives!

2018 April Awareness was a hit this year! Countless oral cancer screenings, awareness displays, health fairs and other events were a part of the big picture, which kicked off in early April with the lighting of Niagara Falls in SPOHNC colors. Thank you to the Niagara Falls Illumination Board for this great honor, and for helping to raise awareness of oral, head and neck cancer.

Other special illuminations included the campus of Penn. State Hershey Medical Center, where the facility was lit in SPOHNC colors for the entire month of April. Thank you Patrice Saurman, Penn Hershey SPOHNC Chapter Facilitator for arranging for this amazing tribute to all those affected by the diagnosis and treatment of oral, head and neck cancer.

New this year was a very unique event in Hickman, Nebraska – the Animal Run. This year's run was the 35<sup>th</sup> annual event. Directed over the last 30 years by Scott Weiskamp, this is the first time that SPOHNC has been the recipient of its fundraising efforts.

Scott is a recent survivor of head and neck cancer. Each year, the run proceeds are designated to a different cause. Over the course of 35 years, they have raised over \$125,000 to benefit families/charities. This year was the largest fundraiser ever, at just over \$12,000.

108 runners & 9 canines ran with their master at this year's event. The monies raised will benefit the American Cancer Society and SPOHNC. Many volunteers were essential to the day running so smoothly. Hickman area businesses supported the run with gifts and prizes and major sponsor, Lincoln Running Co. provided lots of give-away's to runners after the race.

While Valentines Day is known to bring out the "lover" in all of us, the SPOHNC chapter in Greenville, SC takes it one step further every February with its annual "Caregiver Appreciation Celebration." Survivors invite family members, friends, doctors, preachers, therapists: anyone who really made a difference in their lives over the past year.

The evening begins with a potluck, and everyone enjoys sampling dishes that other members have created to "slide down easily" when eating is a challenge. Food sharing is followed by story sharing, and even those whose swallowing hasn't been affected by radiation can get lumps in their throats (and tears in their eyes) as patients recount special acts of kindness that came their way during treatment and even years afterward.

Honorees receive a special commemorative mug. Although the SPOHNC logo always makes an appearance, the design on the opposite side changes yearly. The 2018 edition features an effervescent version of the burgundy and white Oral, Head & Neck Cancer Awareness Ribbon and a quote from Mother Teresa: "It is not how much you do, but how much *love* you put in the doing." Expressing gratitude to those who have loved us best through tough times has proven to be powerful medicine as we heal and deal with the challenges of cancer survivorship.

Many of our SPOHNC Chapters have taken advantage of the opportunity to hear an unbranded presentation about Immunotherapy, provided by Bristol-Myers Squibb. The presentation, given by clinical liaisons across the country, explains this fairly new and exciting cancer treatment in laymens terms, and Chapters who already participated were very impressed with the clinicians expertise. "Everyone left the meeting feeling educated and most importantly, encouraged. Medicine is changing so rapidly and this presentation gave us much to be hopeful for." - **Linda Clyne, SPOHNC Greenville, SC Chapter Facilitator**. If your Chapter is interested, please contact SPOHNC for further information, at [info@spohnc.org](mailto:info@spohnc.org).

Lewis and Amy Beilman and their wonderful friends of the Grand Haven community in Palm Coast Northeast, Florida, have done it again! The 6<sup>th</sup> Annual Move to Music event took place on Saturday,

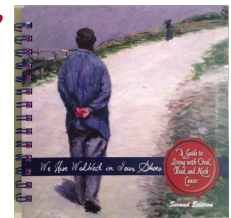
April 21<sup>st</sup> and a good time was had by all. Music, food, exercise and lots of exciting raffle prizes kept over 100 friends busy for a morning and afternoon. Look for the annual video, to be posted on our website soon!

Several other Chapters have held events and as we await their exciting news and details, we promise to share it in an upcoming issue of "News from SPOHNC." If you were part of something to help raise awareness, let us know – send us some photos and a few paragraphs. We want to tell your story!

SPOHNC extends its sincerest appreciation to all of our volunteers who helped to raise awareness, give back and make a difference.



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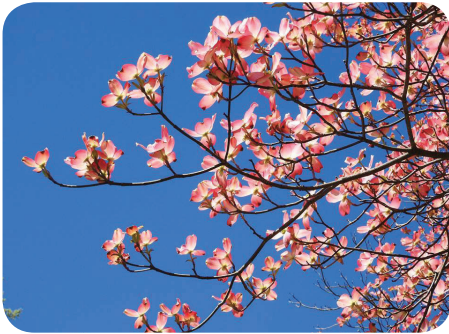


photo courtesy of PJ Jordan, Caregiver

## Delicious Spring Smoothie from “Eat Well Stay Nourished A Recipe and Resource Guide For Coping With Eating Challenges”

*Compiled and Edited by Nancy E. Leupold, Survivor, Founder & President Emeritus*

### **Pomegranate Smoothie (from Volume Two)**

- 1 c. pomegranate or tart cherry juice
- 1 c. full fat plain yogurt
- 2 Tbsp. honey
- ½ c. crushed ice

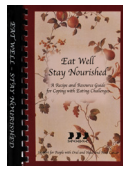


Combine all ingredients and mix in blender until smooth. Enjoy! *Serves 1 / 430 calories per serving.*

Note – Manukah honey has been shown to soothe the mouth sores.  
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~ Hillary M. New York

### **Eat Well Stay Nourished A Recipe and Resource Guide for Coping With Eating Challenges**

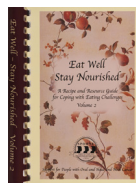


*compiled by Nancy E. Leupold, Survivor, Founder and President Emeritus*

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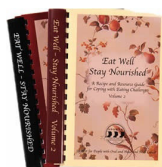
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SPOHNC would like to welcome Kristen B. Pytynia, MD to our Medical Advisory Board. The Medical Advisory Board functions as the Review Board for all feature articles published in “News from SPOHNC.”



Dr. Pytynia comes to us highly recommended by her colleague, Jeffrey Myers, MD, PhD, FACS. Dr. Myers is the son of our own Eugene Myers, MD, FACS, FRCS,

Edin (Hon) a highly respected member of SPOHNC’s Board of Directors.

Dr. Pytynia an associate professor in the division of Head and Neck Surgery and Section Chief, Head and Neck Surgery Regional Care Centers at MD Anderson Cancer Center. She specializes in surgical therapy of malignant lesions of the head and neck, including skin cancers, mucosal squamous cell cancers, salivary malignancies and thyroid cancer. Dr. Pytynia has her MPH and is interested in outcomes research for patients with head and neck cancer.

### *Inspire Someone Today*

***SPOHNC is seeking your story, to share with those who are just beginning their cancer journey.***



*To find out how you can help a newly diagnosed patient, contact Chris at SPOHNC at 1-800-377-0928, x4 or email [c.leonardis@spohnc.org](mailto:c.leonardis@spohnc.org).*

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*~ Patti D.*

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## **TIME FOR SHARING... A Survivor's Story** **My Journey to Finding a Clinical Trial -** **Never Stop Asking Questions; Never Accept Unreasonable Answers**

I'd like to tell you about my journey leading up to the trial, which I feel is an important part of the whole experience. Tenacity, a positive approach, and a willingness to find the best chances are essential in the course of any treatment.

My journey began at my 2 yr CT scan checkup. The scans showed 2 small nodes (about 1/4" diameter) in the right lung. I've been told that head and neck cancer recurrence usually shows up around the two-year mark, so having a clean scan at that time period was what we were hoping for. But not this time for me!

My oncologist ordered a biopsy to determine if the nodes were cancerous. The biopsy process itself was fairly straightforward. For me, it was supposed to be an outpatient procedure; however it didn't end up there. The procedure—to have a small needle inserted into the lung just below my clavicle while awake (in a twilight state)—should have taken about 45 minutes.

An Interventional Radiologist does the procedure with an assistant and another person reviews the specimen immediately to determine if it's acceptable or not. In my case, after they took several samples and removed the needle, my lung partially collapsed. They inserted a chest tube and I was able to enjoy a 3-day hospital stay with twice-a-day chest X-rays. Critically aware of how much radiation was given to me in the first treatment go-around, I was determined to convince x-ray technicians to cover my neck while in the hospital recovering from the collapsed lung. They said it was not the protocol and that it could block part of the lung. I told them they must cover my neck or get out! I never had the same technicians and had to do this twice a day for 3 days until they complied with my persistence. At the end of it all, I was right to insist on what I knew was best for my body. Each x-ray was acceptable.

They determined that the specimens were "inconclusive," and the hospital thoracic surgeon suggested another biopsy. I told him we would confer with my oncologist, who recommended a 3 month wait to see if the spots got bigger...and they did. So they performed another lung biopsy. This time, going in from the side, they took good

specimens and my lung did not collapse! The tests came back as squamous cell cancer (metastatic), and the oncologist recommended a clinical trial, since—in his words—I already had enough radiation.

Here's where the rubber meets the road: My oncologist asked me to research trials and let him know which ones I'd be interested in. I really thought this request was very strange, but I did as asked. He gave me the website ([www.ClinicalTrials.gov](http://www.ClinicalTrials.gov)) and off I went. It was a headache at first because of all the medical terminology. Using keywords like "squamous cell" "head and neck" and "recurrence" helped limit the results. If I remember correctly, I believe there were about 70 listed. To point out a very positive aspect, if you do a search now, there are over 200 Head and Neck cancer trials.

*Search, type of cancer, Refined Search, State, Search Result - Head and Neck 220, Head and Neck Recurrence 18, Head and Neck Recurrence, Squamous cell 10 Head and Neck Recurrence, Squamous cell PA 3*

So I did more research. I picked out 7 trials and gave my doctor the information. A few days later my doctor called me to go through each one like picking out fruit... "not good... not this one, maybe later..." Better yet, more like the story of Goldilocks and the Three Bears. He selected one and said, "This trial is for you. It's on the leading edge of research these days. I really believe this is the one to use." He also said that any of the trials WILL want me because I was asymptomatic (no other health issues other than the cancer) which would be very helpful to the overall statistics.

The trials web site provides many key pieces of information that you'll need in determining which trial. The hospital and location are a good place to start. Since many trials span from as few as several months to 2 years, it's logical to first look at the trial location. My trial was listed at Fox Chase in Philly and Johns Hopkins in Baltimore. We also decided to go to Sloan Kettering in New York City as recommended by my

cancer buddy Jim Hepfer. I can't stress enough the importance of having a cancer buddy and reaching out for help. Jim was extremely helpful to us from day one! My coworker Kevin knew about Jim's cancer and treatment and suggested that I reach out to him. That was a true blessing! Not only did Jim help me during treatment he also took the time from his business and escorted my wife, Lorrie and I to NYC and through the Sloan Kettering review process. Jim is also the one who introduced me to the great SPOHNC Chapter support group at Hershey.

I am naming these key people to highlight the point of reaching out for help. If I had not done so, my options would have been limited, and I would not have had many pieces of non-medical information that many of us need to understand and cope with the whole process. In other words, seek help to feel less in the dark about the process. Never stop looking, never stop asking questions, and never accept unreasonable answers!

At this point, we could begin contacting each treatment center to set up review appointments. It turned out that there were no trials for me at Sloan-Kettering at that time, but we had our first encounter with the review process. Our heads were spinning with all the information. The review process was similar at Fox Chase and Johns Hopkins. We selected Johns Hopkins, because it was an easier drive during the winter months, and the trial was going to last 2 years.

The first thing is to really know all about your cancer history. Know the cancer type, also know the medical terms and know any other specific factors. For me it was head & neck cancer, HPV P-16 positive, Squamous cell, Stage 4. Initial treatment - Radiation & 1 dose of Cisplatin, 3 doses of Cetuximab (Erbix). Recurrence at 24 month CT scan.

Here are a few of the details that are important to know about before beginning the Trial process: Appointment scheduling, Trial Phase (1, 2, or 3), Travel time, Trial Paperwork ([Trial details](#), [HIPPA](#), [eligibility](#)).

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dose, course of treatment, risks and possible side effects, what is paid for and what insurance covers, Blood tests, Review of biopsy – The biopsy chain of ownership is a big deal if the biopsy is done locally. Each treatment center will want to analyze the specimen. So each center needs to provide tracking to the original owner of the specimen. If the time frame between the biopsy and trial acceptance is too long, the protocol may require another biopsy to be done, which is what happened to me. So they did a THIRD biopsy!

My experience seems to have been unique from the get go. Others have had their oncologists refer them to a cancer research hospital for assessment. Even when we visited Sloan Kettering, the doctor provided us with hope that they would help us. Since there was no trial for recurrent head and neck cancer at that time, it was left to us to search further. Unfortunately, the doctor was not forthcoming in pointing us toward a specific treatment center or trial. It was up to us to find one. Again, I found that really strange. I want to stress how important it is to continue to ask questions and seek your own answers. If I hadn't persevered at this stage, I may have lost the opportunity to be included in the trial that was my best chance for recovery. I am hopeful that this approach has changed and that doctors are now more forthcoming. I am certain that if we stressed this issue with our oncologist, he would have made some arrangement, but it's unclear as to why he has us do the research.

Once I had decided on Johns Hopkins and provided a blood sample I waited for the call about when treatment would begin. The trial protocol was to begin treatment within 10 days from sign up. Once you sign the document, the clock starts, and they will sign it, noting the exact time it was signed. Dates and times are one of the necessary details of a trial. Again, my situation went sideways. My coordinator had a family emergency, which delayed the process by 2 days. Then, they couldn't find a doctor to do the biopsy because of the tumor location. By the time a doctor agreed to do the biopsy, 10 days had gone by. Then the biopsy specimen was sent to the wrong lab, so we lost another 2 days. Unbeknownst to us, I was down to the last day to be included in the trial. My doctor at Johns Hopkins had to personally make a case to the drug company running the trial for me to be included before it closed. Finally, at 6:30 pm Monday night my trial doctor called me with the good news: I was to be at Johns Hopkins the

next morning at 7 am to begin the trial. I was the last person in the United States to be accepted into the phase 1b trial for the immunotherapy drug now known as Keytruda (It may also be called PEMBRO in the future). The phase 1b trial focuses on the effectiveness, tolerability and safety of the drug dose.

To put this in perspective, I would not have been eligible for phase 2 of the drug trial, which required the patient to have failed at multiple rounds of traditional chemotherapy. This was my best—and only—trial option available at that time. I've given you all these crazy details for only one reason. Persistence. Not only on my part but also my doctor at Johns Hopkins. If she had not pushed the trial leader and the interventional radiologist and the lab, I would not have been in this trial, which turned out to be a lifesaver for me.

My treatment was every 21 days, 200 ml infusion which took approximately 30 minutes. However, drive time, blood test, nurse coordinator meeting and doctor visit took up a fair amount of the day. The day was even longer every 8 weeks when it included a CT scan.

You'll meet some amazing people during treatment days; café attendants, hospital workers, nurses, infusion specialists, doctor's and other patients. Overall, each treatment day was somewhat routine with few deviations. My doctor now refers to me as the "poster boy" for Keytruda. I was the only one in the Head and Neck trial who had a complete response and made it through the whole trial. The tumors began shrinking after 2 months and had completely dissolved after 9 months. I have been off the trial for 10 months now and all scans have been clear. At my last appointment, September 12, I officially heard the words "In Remission" for the first time. NO CANCER!!!

Some follow up points – New trials and treatment techniques are being developed all the time. Personalized and targeted therapies are on the horizon. At the time I was researching my treatment options, the doctor at Sloan-Kettering Hospital told us about T-cell engineering. It was just being talked about as one of the newest immunotherapy methods. That

was in late 2013 and early 2014. Now only 3 years later we see this has become a reality. So I cannot over-emphasize the importance of perseverance in your resolve.

To highlight a few;

- Genomic Profiling is a laboratory method that is used to learn about all the genes in a person or in a specific cell type, and the way those genes interact with each other and with the environment. Genomic profiling may be used to find out why some people get certain diseases while others do not, or why people react in different ways to the same drug. It may also be used to help develop new ways to diagnose, treat, and prevent diseases, such as cancer. Also called genomic characterization.

- Molecular Tumor Boards are meetings where physicians caring for patients with cancer and other providers meet to discuss specific patients and advise one another on the best treatment plans. The board includes expert physicians and world-class scientists, including medical oncologists, surgeons, radiation therapists, researchers, geneticists and pathologists.

- GPS Cancer is a molecular scan that has been developed to aid personalized cancer therapy. Available through NantHealth, the technology integrates whole-genome DNA and transcriptome sequencing with qualitative proteomics through mass spectrometry to generate a molecular profile of an individual patient's cancer and assessment of protein pathway function. GPS Cancer is also an enabling technology for the Cancer Breakthroughs 2020 initiative, which aims to facilitate the development of combination immunotherapy approaches against cancer.

- CRISPR is an abbreviation of Clustered Regularly Interspaced Short Palindromic Repeats. In the field of genome engineering, the term "CRISPR" is often used loosely to refer to the various systems that can be programmed to target specific stretches of genetic code and to edit DNA at precise locations, as well as for other purposes, such as for new diagnostic tools.

- KYMRIA<sup>TM</sup> is a prescription cancer treatment used in patients up to 25 years old who have acute lymphoblastic leukemia (ALL) that is either relapsing or refractory (did not go into remission with other leukemia treatments). KYMRIA is made from your own white blood cells. This drug

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**Connect with SPOHNC's "group" on Facebook**

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uses the T-cell replacement approach. To date, it has results of 75+ % in young age patients.

• Philadelphia Coalition for a Cure (PC4C) and Children's Hospital of Orange County (CHOC) are partnering on a clinical research initiative to aid in the diagnosis of adult and pediatric brain tumors. The collaboration will leverage molecular profiling platform to help inform treatment decision-making. Data resulting from the partners' studies will be shared with the global research community. PC4C includes members from the Children's Hospital of Philadelphia (CHOP), the Hyundai Cancer Institute at CHOC and departments within the University of Pennsylvania, Temple University, Drexel University College of Medicine, Thomas Jefferson University, and Cooper Medical School of Rowan University.

PC4C, CHOP, CHOC, and the leading adult Philadelphia institutions are defining a new clinical and research collaborative ecosystem that partners leading academic centers, commercial partners, and payers in order to do what needs to be done on behalf of patients—identify therapies and

accelerate discovery.

• Cancer MoonShot 2020," a historic national coalition of pharmaceutical companies, biotechs, major payers, community oncologists and academia.

Here are 10 points about this initiative:  
1. Cancer MoonShot 2020 is a 4-year initiative to accelerate the development of immunotherapies to treat cancer by the start of the next decade.

2. The program is named "MoonShot" because it tries to do for cancer what the United States achieved in the 1960s when humans flew to the moon for the first time.

3. The coalition recognizes that every patient's cancer is different. Treatments that work in one person may not work in others.

4. Based on this assumption, Cancer MoonShot 2020 strives to leverage all of our knowledge and technology to radically change how cancer is treated.

5. The alliance will accelerate access to next-generation immunotherapy cancer care by encouraging more collaboration among drug makers, biotech companies, insurers and researchers.

6. At the center of the initiative is "QUILT," which stands for Quantitative, Integrative Lifelong Trial.

7. QUILT will involve sequencing the genomes of 100,000 cancer patients, assigning 20,000 patients to next-generation immunotherapy by the year 2020.

8. The trial will include patients with 20 types of cancer, including breast, lung, prostate and pancreatic.

9. The ultimate goal of the initiative is a vaccine-based immunotherapy tailored to the unique tumor signature of individual patients.

10. A group of physicians, researchers, and industry leaders met with Vice President Biden in December 2015 to discuss this new approach.

Please remember, never stop looking for another treatment, never stop asking questions and never accept unreasonable answers.

~ Jeffrey Shoop

Jeffery.shoop@gmail.com

See SPOHNC's Clinical Trial finding service for head and neck cancer at <https://app.emergingmed.com/spohnc>

Visit [Clinicaltrials.gov](http://Clinicaltrials.gov) · NCT03083873 · US sites only



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*TIL Therapy is an investigational therapy and has not been approved for any indication by the Food and Drug Administration (FDA) or any other regulatory agency. The safety and efficacy of this therapy has not been determined.*

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that you are there..."*

*~ Lewis & Amy B.  
SPOHNC Palm Coast NE, FL  
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