# Bob Enrolls in Clinical Trial Testing NeoAdjuvant Therapy for Melanoma

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After 14 years working in a Las Vegas hospital, and an additional five at the National Institutes of Health, Robert "Bob" Hill knew the importance of putting patients first — a philosophy he applied to his own melanoma journey. After being diagnosed with Stage 3 melanoma, Bob chose to enroll in a clinical trial at Georgetown University, comparing the effectiveness of treating melanoma with pembrolizumab before or after surgery, what doctors call neo-adjuvant and adjuvant therapy respectively.

It all started in January, 2019 when Bob showed his primary care doctor a mole on his arm. He'd noticed it about a year before, but had become increasingly concerned as it seemed to be slowly growing. His doctor referred him to Dr. Henshaw, a surgeon, who ordered further testing.

Eventually Bob's growing mole was diagnosed as Stage 3 melanoma. He quickly found himself, with his daughter by his side, in the office of medical oncologist Suthee Rapisuwon, MD.

## Treating Stage 3 Melanoma

Stage 3 melanoma means the cancer has already spread from its origin, or primary site, to nearby lymph nodes. Historically, patients with Stage 3 melanoma were treated with surgery — and then were closely monitored for recurrence. Unfortunately, up to 60% of patients with Stage 3 disease treated with only surgery will relapse within 3 years.[1] Reducing this relapse rate is a high priority for clinicians, and in 1995 interferon was approved as the first melanoma 'adjuvant therapy' by the FDA.

Adjuvant therapy is delivered after a primary treatment, in this case surgery, and is intended to reduce the risk of melanoma returning. While interferon is able to reduce the risk of melanoma recurrence by about 10%, it also carries significant risk of side effects for patients.[1] Due to this, it never took off as an adjuvant therapy. However in 2015, with the approval of ipilimumab, a wave of more effective and easier to tolerate options started to earn FDA approval. Now, there are five options for adjuvant therapy related to melanoma in the United States.

Recently however, researchers have become interested in flipping the adjuvant model on its head — what they call neoadjuvant therapy — by starting with a systemic treatment like immunotherapy, then performing surgery, and then continuing the immunotherapy for some time afterwards. Preliminary data looks promising — and researchers hope that it may even be more effective than adjuvant therapy — but they can only know for sure by conducting clinical trials.

## Bob Enrolls in Clinical Trial

For Bob, he really was in the right place at the right time.

“Dr. Rapisuwon presented me with the concept of a clinical trial where they would give me infusions of a drug before surgery,” recalls Bob. “While nothing is guaranteed, Dr. Rapisuwon was very hopeful that this might be the best option for me.”

After carefully considering all options, Bob and his daughter agreed. Bob enrolled in the trial and received his first infusion of pembrolizumab on June 27, 2019.

As part of the trial, he would receive a total of three infusions — each three weeks apart — before surgery. Then, after he’d healed from the surgery, he’d continue receiving pembrolizumab for an additional 15 cycles.

Researchers would then compare how Bob and other patients who were on the ‘neoadjuvant’ arm of the trial compared to a group of patients who would receive the same drug for 18 cycles, but only after surgery.

“I’m lucky, my daughter has a PhD in microbiology and had even run clinical trials before, so I really benefited from her experience and knew that clinical trials are often the best choice for patients,” says Bob. “I also was glad that in some way, this is bigger than me — and that findings from this study would help other people in the future. That hit home for me.”

After three rounds of pembrolizumab infusions, Bob could tell the immunotherapy was working. “I could feel the tumors on my arm just shrink away,” says Bob. “I even considered not moving forward with the surgery at all, but ultimately decided that my doctors knew best.”

The surgery was successful, with no real complications, but recovery was still difficult. “I never really had side effects from the infusions, but recovering from the surgery has easily been the hardest part of this. I describe it like a shark bite — a great white — even today, it itches and is uncomfortable.

Today, Bob has completed three rounds of his post-operative infusions and will continue to be treated with pembrolizumab every three weeks throughout 2020. He’s also so grateful for the high quality care that he receives at Georgetown University and is optimistic for his future.

“I’m very hopeful that this is going to work,” says Bob. “It was amazing to see the tumors shrink over time; and if this helps other people in the future, that’s even better.”

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