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Dear Laryngology colleagues:

It is with great excitement that I announce the opening of a new prospective clinical trial for adults (>18 years) with aggressive recurrent respiratory papillomatosis at the National Institutes of Health in Bethesda, MD. In this trial, we will treat patients with an anti-PD-L1 antibody (a checkpoint inhibitor) called Avelumab, which is designed to unleash T-lymphocyte killing of papillomatous cells infected with the HPV virus. We are attempting to apply what is at the forefront of cancer immunotherapy to RRP (this is the same class of drugs that Jimmy Carter received for his brain cancer), as an alternative to frequent surgical debulking.

Aside from offering adult patients with severe RRP an alternative option in the form of a clinical trial, we will also be performing important, cutting edge science designed to determine which parts of HPV the immune system is responding to, whether these are enhanced with immunotherapy, and whether the entire mucosal tract can be cleared of persistent HPV infection after treatment.

Please help me in discussing this trial with any adult RRP patient you have that has required frequent surgical debulking, and with other physicians who care for this disorder in your regional community. Not only does this trial offer these patients an alternative, it offers us the chance to make significant strides in understanding how checkpoint inhibitor immunotherapy affects the immune system. This trial has the potential to fundamentally change how we treat RRP and other benign HPV-driven disease in the future!

This trial would require patients to travel to Bethesda, MD multiple times over a several month period, but we have the resources to financially support patient travel to and from Bethesda, MD for the trial.

If you have any questions, please feel free to contact me at: clint.allen@nih.gov

If you have a patient that is interested and wishes to learn more about the trial, please have them call Deborah Allen or Erin Ferraro (protocol nurse coordinators) at **301-451-8904** or visit clinicaltrials.gov and search for trial number NCT02859454.

Thank you, and I hope we can pull together as a Laryngology community to max out enrollment in this important NIH clinical trial.

Best regards,

A handwritten signature in black ink, appearing to read "Clint T. Allen", written in a cursive style.

Clint T. Allen, MD

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