ClinicalTrials.gov ID: NCT03502330

Title: APX005M With Nivolumab and Cabiralizumab in Advanced Melanoma, Non-small Cell Lung Cancer or Renal Cell Carcinoma

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Principal Investigator:	Harriet Kluger, MD	**HIC #:**	2000021757
Funding Source:	Bristol Myers Squibb and Apexigen Inc.		

CONSENT FOR CONTINUED PARTICIPATION IN A RESEARCH PROJECT

YALE UNIVERSITY SCHOOL OF MEDICINE – YALE-NEW HAVEN HOSPITAL

Study Title: A Phase I/Ib Study of APX005M in Combination with Nivolumab and Cabiralizumab in Patients with Advanced Melanoma, Non-small Cell Lung Cancer or Renal Cell Carcinoma Whose Disease Has Progressed on Anti-PD-1/PD-L1 Therapy

Principal Investigator: Harriet Kluger, MD
Principal Investigator's Phone Number: 203-200-6622
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Principal Investigator's Mailing Address: PO BOX 20856, New Haven, CT 06520
Funding Source: Bristol Myers Squibb and Apexigen, Inc.

Continuing Treatment Beyond Progression

Invitation to Participate and Description of Project

All parts of the informed consent that you have signed before for the main study remain valid, as does your consent to it, except any that are specifically revised by this document.

Continuing Treatment beyond Disease Progression
With most anti-cancer drugs, an increase in the size or number of tumors detected with CT or MRI scans or a physical exam is a signal that your disease has progressed and that you should consider switching to another therapy. However, an early increase in the size or number of tumors may not always be a sign of disease progression. Because of this possibility, you will have the option of continuing to receive study drug even after a scan in the course of receiving study drug shows an increase in the size or number of your tumors. A later scan will help to determine whether the increase was caused by real progression of your disease. Additional tests may help determine the cause for the increase in the size or number of your tumors and may be required to allow you to continue in the study.

You may have other potentially beneficial approved treatments available to you. These treatments may include those that may shrink tumors, delay progression of cancer, provide symptom relief, or prolong your life. The option to continue the study drugs in spite of an apparent increase in tumor size should be carefully discussed with your study doctor. There are risks of continuing to treatment beyond an apparent increase in tumor size because of the possibility that it represents true progression of your disease. In that case, you may be exposed to an ongoing risk of side effects caused by the study drugs and delay the initiation of other treatment options that may have demonstrated benefit in clinical trials. In addition, your cancer may progress to the point that you are no longer able to receive other potentially effective therapies. If you show true progression of your disease, you will be discontinued from the study and the study doctor will ask you to visit the office for follow up exams.

APPROVED BY THE YALE UNIVERSITY IRB 2/7/2020

Principal Investigator:	Harriet Kluger, MD	**HIC #:**	2000021757
Funding Source:	Bristol Myers Squibb and Apexigen Inc.		

Questions/Information
If you or your representative(s) have any questions regarding the information above, you should contact your study doctor at the telephone number on page one of this form.

Signature Acknowledgement of Treatment Continuation after Possible Disease Worsening

This signature page applies only to subjects after possible disease worsening has occurred for the first time while receiving treatment and only after the study doctor determines that continued treatment is possible.

I understand that because of the nature of this experimental treatment, I may be able to continue treatment after apparent disease worsening. My study doctor has explained that other approved therapies may be available to me, which may include those that may shrink tumors, delay progression of cancer, provide symptom relief, or prolong life. I understand that continuing to take study treatment may delay the start of treatment with these other therapies.

Study Participant (print name)	Signature	Date
Person obtaining consent (print name)	Signature	Date
Person obtaining consent (print name) – only if applicable, otherwise blank	Signature	Date
Interpreter/ Witness (print name) – only if applicable, otherwise blank	Signature	Date

If after you have signed this form you have any questions about your privacy rights, please contact the Yale Privacy Officer at (203) 432-5919.

If you have further questions about this project or if you have a research-related problem, you may contact the Principal Investigator, Dr. Harriet Kluger, at (203) 200-6622. If you would like to talk with someone other than the researchers to discuss problems, concerns, and questions you may have concerning this research, or to discuss your rights as a research subject, you may contact the Yale Human Investigation Committee at (203) 785-4688.

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