A phase 1b/2a open label study to evaluate anti-tumor efficacy and safety of rhIL-7-hyFc (NT-I7) in combination with anti-PD-L1 (atezolizumab) in patients with anti-PD-1/PD-L1 naïve or relapsed/refractory high-risk skin cancers

NCT03901573

19 January 2023

ADDENDUM TO THE INFORMED CONSENT FORM
Study Treatment Beyond Disease Progression

Study Title: A Phase 1b/2a, Open Label Study to Evaluate Anti-Tumor Efficacy and Safety of rhIL-7-hyFc (NT-I7) in Combination with Anti-PD-L1 (Atezolizumab) in Patients with Anti-PD-1/PD-L1 Naïve or Relapsed/Refractory High-Risk Skin Cancers

Protocol #: NIT-106 (ION-02)

Protocol Version Date: Amendment 5, v1.0_19JAN23

Sponsor: NeoImmuneTech, Inc.

Study Doctor: <<investigator>>
<<firm name>>
<<street address>>, <<city>>, <<state>> <<zip>>

Telephone Number: <<000-000-0000>>

After Office Hours: <<000-000-0000>>

You are a participant in NIT-106 (ION-02) study, and the study doctor or study staff has asked you to read and sign this *Addendum to the Informed Consent Form.* Everything in the main study consent form you signed before still applies to your participation in this study, unless otherwise noted in this form.

This form describes additional information about the study. If you have any questions about or do not understand something in this form, you should ask the study doctor or study staff. You should also discuss your participation with anyone you choose in order to better understand this study and your options.

What is the purpose of this addendum?

Studies in patients with other types of cancer have shown a delayed response to study treatment when they continue study treatment despite initial disease progression. We are asking you to read and sign this *Addendum to the Informed Consent Form* because your cancer has grown or spread and meets the definition of Progressive Disease based on imaging scan results. Continued study treatment is optional. You could choose to receive other options to treat your high-risk skin cancer after disease progression with the study treatment. For example:

- You may choose to receive the standard treatment for your cancer, including surgery, chemotherapy, radiation therapy, or targeted therapies (such as BRAF or MEK inhibitors for BRAF-mutant melanoma).
- You may choose to take part in a different study, if one is available.
- You may choose not to be treated for your cancer.
- You may choose to receive comfort care. This type of care helps reduce pain, tiredness, appetite problems, and other problems caused by the cancer. It does not treat the cancer directly, but instead tries to improve how you feel. Comfort care tries to keep you as active and comfortable as possible.

Please talk to us about your choices before you decide if you want to continue study treatment.

Your information will continue to be used and shared as described in the main study consent form.

Do I have to continue in this study?

Your decision to continue in the study and to receive the experimental study treatment is voluntary. You do not have to be in the study any longer if you don't want to, and you can change your mind at any time. There will be no penalty to you, and you won't lose any benefits. If you want to stop being in the study, tell the study doctor or study staff. If you leave the study, the study doctor and study staff will still be able to use your information that they have already collected.

Who can answer my questions about this study?

In the event of an emergency, dial 911 immediately.

If you require emergency care, be sure to tell the emergency care provider about your participation in this study. Contact the study doctor or study staff as soon as possible.

You can ask questions about the study at any time. You can call the study doctor or study staff at any time if you have any concerns or complaints. You should call the study doctor or study staff at the phone number listed on page 1 of this form if you have questions about the study procedures, study costs (if any), study payment (if any), or if you get hurt or sick during the study.

[*Use the language below if you are using a local IRB]*

If you have questions about your rights as a research participant, you should contact <<IRB Name>> at <<IRB phone number>>.

[*Use the language below if you are using the central IRB*]

Advarra® reviewed this study. Advarra® is a group of people who review research studies to protect the rights and welfare of research participants. Review by Advarra® does not mean that the study is without risks. If you have questions about your rights as a research participant, if you are not able to resolve your concerns with the study doctor or study staff, if you have a complaint, or if you have general questions about what it means to be in a research study, you can call Advarra® or visit the Advarra® website at www.advarra.com.

Advarra® is located in Columbia, Maryland.
Office hours are 8:30 AM to 8:00 PM Eastern Time, Monday through Friday.
Ask to speak with a Study Subject Advisor at 877-992-4724 (toll free).

CONSENT

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

I agree to allow the collection, use, and sharing of my information as described in the main study consent form.

By signing this form, I do not give up any of my legal rights that I have as a research participant. I will get a signed copy of this addendum to the informed consent form.

If you have read this addendum or had it explained to you and you understand the information in this form, please sign your name below.

Participant's name (print)	Participant's signature	Date (dd-MMM-yyyy)

Researcher's Statement & Signature

I have discussed the addendum with the person signing above. A copy of the signed addendum will be given to the participant.

Study staff conducting consent discussion (print)	Signature of study staff conducting consent discussion	Date (dd-MMM-yyyy)

WITNESS STATEMENT

As an impartial third party, I witnessed the entire consent discussion and the signature of the individual providing consent on this form.

Printed Name of Witness

Signature of Witness

Date (dd-MMM-yyyy)