Adaptimmune LLC

Abbreviated STATISTICAL ANALYSIS PLAN

Protocol Number: ADP 0011-001
Protocol Version: 7
eCRF version: Annotated eCRFs - ADP-0011-001 - 2017-07-26.pdf
Protocol Date: 7 February 2017

Protocol title: A Phase I/IIa, Open Label, Clinical Trial Evaluating the Safety and Efficacy of Autologous T Cells Expressing Enhanced TCRs Specific for NY-ESO-1 in Patients with Recurrent or Treatment Refractory Ovarian Cancer

Indication: Ovarian cancer
Treatment: NY-ESO-1^{c259}-T

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1. OVERVIEW

This abbreviated statistical analysis plan (SAP) describes the safety and tolerability of autologous genetically modified T cells transduced to express the high affinity NY-ESO-1c259 TCR in HLA-A*0201, A*0205, and/or A*0206 subjects who have a diagnosis of recurrent epithelial ovarian, primary peritoneal or fallopian tube carcinoma with refractory or platinum resistant disease and/or have received ≥ 2 lines of chemotherapy, as performed for Study ADP-0011-001, based on study protocol Version 7, dated 7 February, 2017. Listings are based on data collected in the EDC study database, and based on the eCRF template version dated 26 July 2017. Data collected outside of the EDC system are not covered by this SAP.

2. POPULATIONS

The ITT population is defined as all subjects who enroll into the study. Subjects prior to protocol version 5 are eligible subjects with screening informed consent. These subjects are all subjects in the SREG dataset. All listings, except the listing on persistence data, will be based on the ITT population. The mITT is defined as all subjects who received any dose of T-cells. Persistence data will be listed for the mITT population.

3. LISTINGS CONVENTIONS

A list of listings will be provided. Footnotes will be used as needed to clarify the information that is presented in the tables and listings. Unless otherwise requested by Adaptimmune, the term ‘subject’ will be used in all listings in accordance with CDISC standards.

The general layout of listings will be as follows:

Listing 16.2_x

<Title>

Col 1 Col 2 Col 3 etc

<Any footnotes>

File Name: <pathname for SAS program>

All listings will use landscape orientation. Margins will be at least 2.0 cm at the top and bottom and at least 0.8 cm on the left and right, excluding headers and footers, in accordance with electronic Common Technical Document (eCTD) guidelines. Font will be Courier New, with an 8-point font size in most cases. Page numbering will be sequential within each listing. Column headers should be in initial capital letters. Units for numeric data will be included when appropriate.

Programming Conventions:

Data listings may be created from different SAS programs. A single program may produce multiple data listings from the same dataset (e.g., all clinical chemistry data listings may be generated by a single program).

Data listings will provide all data collected on the corresponding eCRF page. If there are too many fields to be fit into a single page, data should be grouped logically and the listings will be generated as Part I, Part II, etc.

Data listings should include all subjects with data. However, if only subjects who meet a certain condition are listed (e.g., subjects with SAEs) and no subjects meet the condition, the data listing will so indicate.

The sort order for data presented in data listings, unless otherwise requested by Adaptimmune, will be subject ID as the first column, followed by other columns. Within a subject, data will be listed in chronological order.

Whenever possible, formatted values will be displayed (i.e., decoded). In instances where it is necessary to use coded data, the decode must appear as a footnote.

Acronyms used in Listing titles or column or row headings must appear in full form in a footnote. Column headings can be shortened where needed with explanatory footnotes.

Where applicable, calendar date and study day of evaluations/events will be provided in the data listings, where study day is relative to the date of the first T cell infusion.

Definitions:

Study Day

If an event occurs prior to t-cell infusion then:

Study Day of the event = date of event – date of the first T cell infusion

If an event occurs post T-cell infusion then:

Study Day of the event = date of event – date of the first T cell infusion + 1

Time in Study

Time in study = date of last visit – date of screening informed consent + 1

4. PRELIMINARY LIST OF LISTINGS TO BE PROGRAMMED

4.1. Data Listings

Number	Title
16.2.1.1	**Subject Disposition**
16.2.4.1	**Demographics and Baseline Characteristics**
16.2.4.3	**Disease History**
16.2.6.1	**Target and Non-target Lesions**
16.2.6.2	**Index and Non-index Lesions**
16.2.6.3	**New Lesion Assessments**
16.2.6.4	**irRC Tumor Assessment by PI**
16.2.6.5	**CA-125**

Number	Title
16.2.7.1	**Adverse Events**
16.2.7.3	**Serious Adverse Events**
16.2.8.4.3	**Persistence (may contain data on dosed subjects only)**

In addition, the following summary tables will be prepared by the sponsor's biometrics team internally:

1. Demographics – mITT (i.e. all treated)
2. Baseline characteristics (height at screening, weight at baseline, ECOG at baseline) – mITT (i.e. all treated)
3. Overall Summary of Adverse Events for ADP-0011-001 Ovarian Study -- Population: mITT Subjects; Period: start of lymphodepletion to end of interventional phase
4. Summary of AEs and Related AEs by Preferred Term and Grade for ADP-0011-001 Ovarian Study; Population: mITT Subjects; Period: start of lymphodepletion to end of interventional phase
5. Summary of SAEs and Related SAEs by Preferred Term for ADP-0011-001 Ovarian Study; Population: mITT Subjects; Period: start of lymphodepletion to end of interventional phase