DISCLOSURE

REDACTED STATISTICAL ANALYSIS PLAN AMENDMENT

MEDI4736-NHL-001

A PHASE 1/2, OPEN LABEL, MULTICENTER STUDY TO ASSESS THE SAFETY AND TOLERABILITY OF DURVALUMAB (ANTI-PD-L1 ANTIBODY) AS MONOTHERAPY AND IN COMBINATION THERAPY IN SUBJECTS WITH LYMPHOMA OR CHRONIC LYMPHOCYTIC LEUKEMIA

The "FUSION NHL-001" Study

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STATISTICAL ANALYSIS PLAN

AMENDMENT 1

A PHASE 1/2, OPEN-LABEL, MULTICENTER STUDY TO ASSESS THE SAFETY AND TOLERABILITY OF DURVALUMAB (ANTI-PD-L1 ANTIBODY) AS MONOTHERAPY AND IN COMBINATION THERAPY IN SUBJECTS WITH LYMPHOMA OR CHRONIC LYMPHOCYTIC LEUKEMIA

STUDY DRUG:	MEDI4736
PROTOCOL NUMBER:	MEDI4736-NHL-001
FINAL PROTOCOL DATE:	06 Nov 2015
PROTOCOL AMENDMENT No. 1 DATE:	04 May 2017
PROTOCOL AMENDMENT No 2 DATE:	14 Dec 2017

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SIGNATURE PAGE

STATISTICAL ANALYSIS PLAN (SAP) AND SAP AMENDMENT APPROVAL SIGNATURE PAGE	
SAP TITLE	MEDI4736-NHL-001 Statistical Analysis Plan
SAP VERSION, DATE	Version 2.0 (Amendment 1), 23 Apr 2019
SAP AUTHOR	
PROTOCOL TITLE	A Phase 1/2, open-label, multicenter study to assess the safety and tolerability of durvalumab (anti-PD-L1 antibody) as monotherapy and in combination therapy in subjects with lymphoma or chronic lymphocytic leukemia
INVESTIGATIONAL PRODUCT	MEDI4736
PROTOCOL NUMBER	MEDI4736-NHL-001
PROTOCOL VERSION, DATE	Amendment No. 2, 14 Dec 2017
SIGNATURE STATEMENT	By my signature, I indicate I have reviewed this SAP and find its contents to be acceptable.
Statistical Therapeutic Area Head	
Signature	
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Lead Clinical Resear	
Signature	
Printed Name	
Lead Product Safety Physician	
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Statistical Therapeutic Area Head Signature Printed Name Date	
Lead Clinical Research Signature Printed Name	
Lead Product Safety Physician Signature Printed Name Date	

Reason of the amendment

This statistical analysis plan (SAP) amendment details the Efficacy Evaluable Population in the case of subjects do not have a post-baseline response assessment before death.

Efficacy Evaluable Population

Per SAP version 1.0, section 4.2.2, the Efficacy Evaluable Population is defined as follow:

Efficacy Evaluable (EE) Population (for the dose-finding, dose-confirmation, and dose-expansion part) is defined as all subjects who complete at least 1 cycle of their assigned treatment, have baseline, and at least 1 post-baseline tumor response assessment. Subjects will be analyzed according to their initial treatment arm and dose level allocation.

Changed to

Efficacy Evaluable (EE) Population (for the dose-finding, dose-confirmation, and dose-expansion part) is defined as all subjects who complete at least 1 cycle of their assigned treatment, have baseline, and at least 1 post-baseline tumor response assessment.

A subject who died before Cycle 4 Day 1 (i.e. before the first IWG or IWCLL response assessment scheduled per protocol) and without having done any unscheduled post-baseline IWG or IWCLL response assessment will be included in the Efficacy Evaluable Population.

Subjects will be analyzed according to their initial treatment arm and dose level allocation.

Rational:

The first efficacy assessment is performed at Cycle 4 Day 1, any subject who died before and without having done any unscheduled post-baseline IWG or IWCLL response assessment cannot have a post baseline assessment and should not be excluded from the Efficacy Evaluable Population for that criterion.