INFORMED CONSENT FORM FOR OPTIONAL BIOPSIES

TITLE:	**A PHASE II, SINGLE-ARM STUDY OF ATEZOLIZUMAB IN PATIENTS WITH LOCALLY ADVANCED, UNRESECTABLE STAGE III NON-SMALL CELL LUNG CANCER WHO HAVE NOT PROGRESSED AFTER PLATINUM-BASED CONCURRENT CHEMORADIATION**
PROTOCOL NUMBER:	MO43156
SPONSOR:	F. Hoffmann-La Roche Ltd
STUDY DOCTOR:	Assist. Prof. Martina Vrankar, MD, PhD Phone number: _____
NAME OF INSTITUTION:	Institute of Oncology Ljubljana
INSTITUTION ADDRESS:	Zaloška cesta 2, 1000 Ljubljana, Slovenia
NAME OF ETHICS COMMITTEEE:	Republic of Slovenia National Medical Ethics Committee
ETHICS COMMITTEE APPROVAL DATE:	{Date}

You are being asked to undergo optional biopsies to allow for tumor tissue samples to be collected as part of Study MO43156. You will undergo the optional biopsies at the time of response and/or radiographic disease progression (if clinically feasible). The samples will be used for tests to find out how variations in biomarkers (such as cancer- or immune-specific proteins or genes) affect your disease or your response to study drug.

To understand this procedure and its potential risks, refer to Section 2.2 of the main consent.

You will not receive any direct benefit from undergoing the optional biopsies. However, information from these procedures may benefit other patients with non-small cell lung cancer or a similar condition in the future. You will not be paid for undergoing the optional biopsies.

Undergoing the optional biopsies is your choice. No matter what you choose, it will not affect your participation in the main study or the regular care you receive from your doctors.

You will undergo the optional biopsies at the time of response and/or radiographic disease progression. To understand this procedure and its potential risks, refer to Section 2.2 of the main consent.

Your tumor tissue samples and information related to the biopsies will be kept under the same level of privacy used for the main study. Samples will be stored for up to 15 years after the final study results have been reported. Your samples will undergo biomarker testing, which may involve analysis of your genome (DNA). Information on genome testing is provided in Section 2.4 of the main consent. Handling of genetic information is described in Section 2.6 of the main consent.

You can change your mind about participating. If you want to withdraw your consent for the optional biopsies, tell your study doctor that you no longer want to participate.

Signature

I confirm that I have read this consent form, or it has been read to me. I understand the information presented and have had my questions answered. I understand that I will be given a copy of all 3 pages of this form after it has been signed and dated. I willingly consent to undergo optional biopsies.

Patient name (print)	
If applicable – Name of patient's legally authorized representative (print)	Relationship to patient
Patient signature or signature of patient's legally authorized representative	Date

I, the undersigned, have fully explained this informed consent to the patient named above and/or the patient's legally authorized representative.

Name of person conducting informed consent discussion (print)

Signature of person conducting informed consent discussion | Date

Witness name [a] (print)

Witness signature [a] | Date

Witness name [a] (print)

Witness signature [a] | Date

[a] If the investigator or Institutional Review Board or Ethics Committee deems a witness signature is necessary (as per ICH Guidelines, Good Clinical Practice [E6], 4.8.9, or local regulations).