Date: 15 April, 2024

RESPONSE TO THE RFI, CT-2023-505712-37-00-IN-007

EU Trial Number	2023-505712-37
Universal Trial Number	U1111-1292-3589
Protocol Code	V940-007
Protocol Title	A Phase 2/3, adaptive, randomized, open-label, clinical study to evaluate neoadjuvant and adjuvant V940 (mRNA-4157) in combination with pembrolizumab (MK-3475) versus standard of care, and pembrolizumab monotherapy in participants with resectable locally advanced cutaneous squamous cell carcinoma (LA cSCC) (INTerpath-007)
Sponsor	Merck Sharp & Dohme LLC
Country	Czech Republic

Dear Sir/Madam

On behalf of the Sponsor, Merck Sharp & Dohme LLC, I am hereby sending you our response to the Request for Information during **Assessment** that was sent to us on **05-Apr-2024** with reference **CT-2023-505712-37-00-IN-007**.

The following change to the application was made in answer of below consideration:

Part II – Czech Republic:

- Section Subject information and informed consent form:

Consideration # 1: Main ICF has been updated in answer to RFI:

- **L1_ICF_Main consent_CZE_CS_not pub_Version Czech v2_15APR2024 (CZE V940-007_v.00_Czech v.2_15APR2024)**
- **L1_ICF_Main consent_CZE_CS_for pub_Version Czech v2R_15APR2024**
- **L1_ICF_Main consent_CZE_CS_TC_not pub_Version Czech v2_15APR2024**

Sincerely,
MSD Czech Republic – Clinical Operations Manager