Assessment report Part II – SM-1 – CZECHIA

# ADMINISTRATIVE INFORMATION

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| CT number | **2023-505712-37-00** |
| Member State Concerned | Italy Belgium Czechia Romania Spain France Germany Norway Poland Hungary |
| Title of the study | **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)**  Adaptivní, randomizované, nezaslepené klinické hodnocení fáze 2/3, jehož cílem je porovnat neoadjuvantní a adjuvantní léčbu přípravkem V940 (mRNA-4157) v kombinaci s pembrolizumabem (MK-3475) oproti standardní léčbě, a monoterapii pembrolizumabem u účastníků s resekabilním lokálně pokročilým kožním spinocelulárním karcinomem (LA cSCC) |
| Name of sponsors | Merck Sharp & Dohme LLC |
| IMPs (repeat for PR1, PR2…..) | Substance (name/ code): PEMBROLIZUMAB/SUB167136, , MRNA-4157/SUB299909,  Marketing authorisation status (MA number, MS where authorised etc): EU/1/15/1024/002/EU, null/null  Modified in relation to MA: |

# FINAL Decision

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| --- | --- |
| The SM-1 is approvable  The SM is not approvable  The SM is approvable subjects to conditions |  |

**In case of approval**

**The approval SM-1 is valid for the following trial sites and investigators**

1. Fakultní nemocnice Královské Vinohrady, Dermatovenerologická klinika, Šrobárova 1150/50, 100 34 Praha 10 - prof. MUDr. Petr Arenberger, Ph.D., DrSc., MBA, FCMA
2. Všeobecná Fakultní nemocnice Praha, Dermatovenerologická klinika, U Nemocnice 499/2, 128 08 Praha 2 - MUDr. Ivana Krajsová, MBA

**List of documents on the basis of which the decision was made:**

1. L1\_ICF\_Main consent\_CZE, v. 3\_10 Jul 2024
2. L1\_ICF\_Main consent\_CZE\_CS\_TC, v. 3\_10 Jul 2024
3. L1\_ICF\_Optional\_prescreening\_CZE, v.2\_10 Jul 2024
4. L1\_ICF\_Optional\_prescreening\_CZE\_CS\_TC, v.2\_10 Jul 2024
5. Q1\_Payment details\_CZE, v 1.2, 16 Jan 2023
6. Q1\_Proof of payment\_CZE, 24 Jul 2024
7. K2\_Recruitment Doc Adjuvant Brochure\_CZE, V 00.1
8. K2\_Recruitment Doc Patient Brochure\_CZE, V 00.1

In Prague -