Assessment report Part II – SM-5 – CZECHIA

# ADMINISTRATIVE INFORMATION

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| CT number  | **2023-506906-38-00** |
| Member State Concerned | Italy Portugal Romania Spain Sweden Netherlands Poland Slovakia Belgium Bulgaria Croatia Czechia Denmark France Germany Greece Hungary  |
| Title of the study | Multicentrické, randomizované, otevřené klinické hodnocení fáze 3 hodnotící bezpečnost a účinnost epcoritamabu + rituximabu a lenalidomidu (R2 ) ve srovnání s chemoimunoterapií u dříve neléčeného folikulárního lymfomu (EPCORE™FL-2)**A Phase 3, Multicenter, Randomized, Open-Label Trial to Evaluate the Safety and Efficacy of Epcoritamab + Rituximab and Lenalidomide (R2) compared to Chemoimmunotherapy in Previously Untreated Follicular Lymphoma (EPCORE™FL-2)** |
| Name of sponsors | AbbVie Deutschland GmbH & Co. KG |
| IMPs (repeat for PR1, PR2…..) | Substance (name/ code): VINCRISTINE SULFATE/SUB05101MIG, , CYCLOPHOSPHAMIDE/SUB06859MIG, , LENALIDOMIDE/SUB25389, , BENDAMUSTINE HYDROCHLORIDE/SUB00696MIG, , LENALIDOMIDE/SUB25389, , RITUXIMAB/SUB12570MIG, , EPCORITAMAB/SUB204090, , EPCORITAMAB/SUB204090, , RITUXIMAB/SUB12570MIG, , TOCILIZUMAB/SUB20313, , OBINUTUZUMAB/SUB32751, , DOXORUBICIN HYDROCHLORIDE/SUB01827MIG, , PREDNISONE/SUB10020MIG, Marketing authorisation status (MA number, MS where authorised etc): PL 04515/0008/XI, PL 00116/0387/XI, EU/1/07/391/001/EU, PL 08553/0571/XI, EU/1/07/391/009/EU, EU/1/16/1167/002/EU, null/null, null/null, EU/1/16/1167/001/EU, EU/1/08/492/001/EU, EU/1/14/937/001/EU, PL 00057/ 0970/XI, 043410048/ITModified in relation to MA: |

# FINAL Decision

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| The SM-5 is approvableThe SM is not approvableThe SM is approvable subjects to conditions  | [x] [ ] [ ]  |

**In case of approval**

**The approval SM-5 is valid for the following trial sites and investigators**

1. prof. MUDr. David Belada, Ph.D., IV. Interní hematologicka klinika Fakultni nemocnice Hradec Králové, Sokolská 581, 500 05 Hradec Králové
2. doc. MUDr. Andrea Janiková, Ph.D., Interni hematologická a onkologická klinika Fakultni nemocnice Brno, Jihlavská 20, 625 00 Brno
3. doc. MUDr. Jan Novák, Ph.D., Interni hematologická klnika FNKV a 3. LF UK, Fakultni nemocnice Kralovské Vinohrady, Šrobárova 50, 100 34 Praha 10
4. prof. MUDr. Michael Doubek, Ph.D., Interní hematologická a onkologická klinika, Fakultní nemocnice Brno, Jihlavská 340/20, 625 00 Brno

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

1. L1\_M22-003 CZ ICF Main all arms\_MS\_redline, verze 1.1.1, 2Jul2024
2. L1\_M22-003 CZ ICF Main Czech all arms\_Public, verze 1.1.1, 2Jul2024
3. L1\_M22-003 CZ ICF Optional Czech \_Public, verze 1.1.1, 2Jul2024
4. L1\_M22-003 CZ ICF Optional Czech\_redlines, verze 1.1.1, 2Jul2024
5. L1\_M22-003 CZ ICF Preg Part Czech \_Public, verze 2.0, 16Jul2024
6. L1\_M22-003 CZ ICF Preg Part Czech\_redlines, verze 2.0, 16Jul2024
7. L1\_M22-003 CZ ICF Privacy Czech \_Public, 16 Jul 2024
8. L1\_M22-003 CZ ICF Privacy Czech\_redlines, 16 Jul 2024
9. M1\_M22-003 CZ CV PI Doubek, 5 Aug 2024
10. M2\_M22-003 CZ Declaration of Interest Doubek, 5 Aug 2024
11. K2\_M22-003 CZ Recruitment Material\_Recruitment Brochure\_Public, V1.0\_22May2024

**In Olomouc – 27-09-2024**