Assessment report Part II – CZECHIA

# ADMINISTRATIVE INFORMATION

|  |  |
| --- | --- |
| CT number | **2023-504773-20-00** |
| Member State Concerned | Italy Belgium Croatia Czechia Denmark Spain Greece Poland Hungary |
| Title of the study | Otevřené jednoramenné klinické hodnocení fáze 3 hodnotící účinnost, bezpečnost, snášenlivost, farmakokinetiku a imunogenicitu nitrožilně podávaného vedolizumabu při léčbě pediatrických pacientů s aktivní chronickou pouchitidou  **An Open Label Single-Arm Phase 3 Study to Evaluate the Efficacy, Safety, Tolerability, Pharmacokinetics, and Immunogenicity of Vedolizumab Intravenous in the Treatment of Pediatric Subjects with Active Chronic Pouchitis** |
| Name of sponsors | Takeda Development Center Americas Inc. |
| IMPs (repeat for PR1, PR2…..) | Substance (name/ code): AMOXICILLIN SODIUM, CLAVULANIC ACID/SUB00503MIG, SUB06642MIG, , CIPROFLOXACIN HYDROCHLORIDE, CIPROFLOXACIN/SUB01316MIG, SUB07470MIG, , VEDOLIZUMAB/SUB30452, , METRONIDAZOLE/SUB08922MIG, , VANCOMYCIN/SUB05076MIG, , RIFAMYCIN SODIUM/SUB04246MIG,  Marketing authorisation status (MA number, MS where authorised etc): -/null, -/null, EU/1/14/923/001/EU, -/null, -/null, -/null  Modified in relation to MA: |

|  |  |
| --- | --- |
| Has Part I been submitted prior to the submission of Part II?  *If Yes*  Is there already a conclusion on part I?  Is the CT already approved in any member state ? | Yes  No  Yes  No  Yes  No |

# General information

|  |  |
| --- | --- |
| Is the CT a low-interventional trial?[[1]](#footnote-1) | Yes  No |
| First in man , Phase I , II , III , IV NA | |
| Is the CT a cluster trial[[2]](#footnote-2) | Yes  No |
| Is the CT intended to be performed in more than one member states? | Yes  No |
| Does the CT involve more than one site in the concerned member states? | Yes  No |
| Does the CT include healthy volunteers? | Yes  No |
| Does the CT include female?  Male? | Yes  No  Yes  No |
| Age group  Adults (18-64 years)  Elderly (>= 65 years)  < 18 years  In Utero  Preterm Newborn Infants (up to gestational age < 37 weeks)  Newborns (0-27 days)  Infants and toddlers (28 days - 23 months)  Children (2-11 years)  Adolescents (12-17 years) | Yes  No  Yes  No  Yes  No  Yes  No  Yes  No  Yes  No  Yes  No  Yes  No |
| Does the CT include vulnerable persons?  *If yes*  Minors  Incapacitated subjects  Pregnant women  Breastfeeding women  Subjects in emergency situations  Other groups If yes specify: ............................................................. | Yes  No  Yes  No  Yes  No  Yes  No  Yes  No  Yes  No  Yes  No |
| Are there study-specific procedures and/or interventions beyond the drug application?  *If yes*  Specify: ............................................ | Yes  No |

# Informed Consent fORM

***(Repeat for ICF1, ICR2 ….)***

|  |  |  |
| --- | --- | --- |
| Date/version of Informed Consent Form | ICF\_Main\_Adult\_CZE\_Czech, v1.0\_12Jan2024 | |
| Does the Informed Consent Form contain the correct title  of the CT? | | Yes  No |
| Does the Informed Consent Form contain placeholder for the dated signature of the person performing the interview? | | Yes  No |
| Does this placeholder indicate the qualification of the person performing the interview | | Yes  No |
| Does the Informed Consent Form contain a placeholder for  for the dated signature of the subject  for the dated signature of legally designated representative?  for the dated signature and name for an impartial witness (in case of a subject is not able to sign (temporarily disabled or illiterate)? | | Yes  No  NA  Yes  No  NA  Yes  No  NA |
| Does the Informed Consent Form contain a placeholder for the assent from minor (capable of forming an opinion) | | Yes  No  NA |
| Does the subject or the legally designated representative declare that the information is understood? | | Yes  No  NA |
| Does the subject or the legally designated representative confirm whether a copy of the Informed Consent Form (or the record) has been retained? | | Yes  No  NA |
| Does the subject or the legally designated representative declare that the information is understood? | | Yes  No |
| *Additional items may be added according to national requirements*  For example  Does the subject or the legally designated representative confirm whether a copy of the Informed Consent Form (or the record) has been retained? | | Yes  No |

**Conclusion**

If all points are addressed Yes): The Inform Consent Form fulfils the conditions in art. 29, 1.

If not

**Questions/queries:**

# Written Information

|  |  |
| --- | --- |
| Is the Information sheet sufficiently comprehensive, concise, clear, relevant, and understandable to a layperson? | Yes  No |
| Does the information sheet describe adequately nature, objectives, benefits, implications, risks, and inconveniences, of the clinical trial? | Yes  No |
| Does the information sheet adequately describe  the subject's rights and guarantees regarding his or her protection, in particular his or her right to refuse to participate and the right to withdraw from the clinical trial at any time without any resulting detriment and without having to provide any justification ?  Does the information sheet adequately explain that withdrawal of the informed consent will not affect the results of activities already carried out and the use of data obtained, based on informed consent, before its withdrawal? | Yes  No  Yes  No |
| Does the information sheet adequately describe  the conditions under which the clinical trial is to be conducted, including the expected duration of the subject's participation in the clinical trial? | Yes  No |
| Does the information sheet adequately describe  the possible treatment alternatives,  the follow-up measures if the participation of the subject in the clinical trial is discontinued  Post trial treatment options | Yes  No  Yes  No  Yes  No  NA |
| Does the information sheet provide information about the damage compensation according to national law of concerned member state  *Further detailed points to be filled in at a national level*  *If NA*  Does the information sheet adequately inform that no particular arrangements for damage compensation are in place | Yes  No  NA  Yes  No |
| Does the information sheet provide  the EU trial number  information about the availability of the clinical trial results (that the summary of the results of the clinical trial and a summary presented in terms understandable to a layperson will be made available in the EU database) | Yes  No  Yes  No |
| Does the information sheet provide adequate information about planned personal data collection and processing  Does the information sheet provide adequate information about planned collection, storage and future use of biological samples?  *Further detailed points must filled in by member states at national level*  (in accordance with Regulation (EC) No 45/2001 and **national data protection legislation** implementing Regulation (EU) 2016/679, respectively) | Yes  No  Yes  No |

|  |  |
| --- | --- |
| In the case of a trial with minors.  Is there Informed Consent documents adequately paying attentions to the information needs of these subjects?  In the case of a trial with incapacitated subjects.  Is there Informed Consent documents adequately paying attentions to the information needs of these subjects?  In the case of a trial in an emergency situation Are there Informed Consent documents to obtain consent from the subject and/or legally designated representative to continue the participation of the subject in the CT after the intervention? | Yes  No  Yes  No  Yes  No |

**Conclusion**

If all points are addressed Yes: The written information fulfils the conditions in art. 28 and 29

If not

**Questions/queries:**

# Protection of personal Data

|  |  |
| --- | --- |
| Has a statement been submitted by the sponsor or his or her representative that data will be collected and processed in compliance with Regulation (EC) No 45/2001 and **national data protection legislation** implementing Regulation (EU) 2016/679, respectively  *Further detailed points must filled in by member states at national level*  For example  Are the rules for the collection, storage and future use of biological samples of the subject fulfilled?  Is the procedure to pseudonymise the data correct?  Are Initials omitted?  Is there no placeholder for the complete birthday?  Will the coding number maintained in the hand of the investigator or of a trustee?  Is described how long the data will be stored?  Is there a comprehensive description of the aims and scope of data collection?  Is there an indication, whether the data will be transferred to a so called “third party country” with a reduced level of data protection? | Yes  No  Yes  No  Yes  No  Yes  No  Yes  No  Yes  No  Yes  No  Yes  No  Yes  No  Yes  No |
| Will the subject (or his or her legally designated representative) be asked to consent to the use of his or her data and/or biological samples outside the protocol of the clinical trial for other scientific purposes?  *If Yes*  Will the subject be informed that this consent may be withdrawn at any time by the subject or his or her legally designated representative? | Yes  No  Yes  No |

**Questions/queries:**

# Compensation

|  |  |
| --- | --- |
| Is there no undue influence, including that of a financial nature, exerted on subjects to participate in the clinical trial  In trials with incapacitated subjects, minors, pregnant or breastfeeding subjects:  Are no incentives or financial inducements given to the subjects or their legally designated representatives, except for compensation for expenses and loss of earnings directly related to the participation in the clinical trial; | Yes  No  Yes  No |

**Questions/queries:**

# Recruitment

|  |  |
| --- | --- |
| Is the procedure for inclusion of subjects described in detail in the protocol or a separate document  Is clearly described of what the first act of recruitment is?  Is the recruitment of subjects planned to be done through advertisement  If yes:  Have copies of the advertising material been submitted, including any printed materials, and audio or visual recordings.  Has an outline of the procedures proposed for handling responses to the advertisement been submitted?  Have copies of communications used to invite subjects to participate in the clinical trial been submitted? Have arrangements for information or advice to the respondents found not to be suitable for inclusion in the clinical trial been described?  Does the person performing the interview has the required qualification according to the law of concerned member states  Are the arrangements for recruitment of subjects adequate? | Yes  No  Yes  No  Yes  No    Yes  No  Yes  No  Yes  No  Yes  No  Yes  No |

**Questions/queries:**

# SUITABILITY OF THE INVESTIGATOR

|  |  |
| --- | --- |
| V Uvalu 84/1, Motol (Mitrová Katarína ) |  |
| Is there an informative CV?  Is previous experience obtained from work with clinical trials described?  Is previous experience obtained from work with patient care described?  Have certificates describing adequate ICH/GPV training been submitted?  Has a financial disclosure been submitted?  Have institutional affiliations, that might influence the impartiality of the investigators been presented?  *Further detailed points may be filled in by member states at national level*  For example  Is the investigator qualified in accordance with national Low? *(medical doctor as defined in national law, or a person following a profession which is recognised in the Member State concerned)* | Yes  No  Yes  No  Yes  No  Yes  No  Yes  No  Yes  No  Yes  No |

**Conclusion**

**V Uvalu 84/1, Motol (Mitrová Katarína )**

**Reason:**

# SUITABILITY OF THE FACILITIES

|  |  |
| --- | --- |
| Has a list of the planned clinical trial sites with  name and position of the principal investigators  and the planned number of subjects at the sites  been submitted?  V Uvalu 84/1, Motol (Mitrová Katarína )  Has a written statement been submitted describing the suitability of the clinical trial sites adapted to the nature and use of the investigational medicinal product?  (issued by the head of the clinic/institution at the clinical trial site or by some other responsible person, according to the system in the Member State concerned)  Does this statement adequately describe  the suitability of facilities,  the equipment,  the human resources  the expertise of the site, | Yes  No  Yes  No  Yes  No    Yes  No  Yes  No  Yes  No  Yes  No |

**Conclusion**

V Uvalu 84/1, Motol (Mitrová Katarína )

**Reason:**

# PROOF OF INSURANCE COVER OR INDEMNIFICATION

|  |  |
| --- | --- |
| Is the arrangement for damage compensation in accordance to **national law**?  *Further detailed points must be filled in at the national level* | Yes  No |

**Questions/queries:**

# FINANCIAL AND OTHER ARRANGEMENTS

|  |  |
| --- | --- |
| Is there a description confirming adequate financing of the clinical trial is ensured?  Are financial transactions and compensation paid to subjects adequate?  Are financial transactions and compensation paid to the investigator/site for participating in the clinical trial adequate?  Are any other agreement between the sponsor and the site adequate? | Yes  No  Yes  No  Yes  No  Yes  No |

**Questions/queries:**

# LIST OF questions TO THE SPONSOR/

# Assesment of the Sponor´s Response

|  |  |
| --- | --- |
| Are all queries resolved?  If not specify:  .......................................................................................... | Yes  No |

# FINAL Decision

|  |  |
| --- | --- |
| The Clinical trial is approvable  The Clinical trial is not approvable  The Clinical trial is approvable subjects to conditions |  |

**In case of approval**

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

**List of trial sites and investigators**

1. MUDr. Katarína Mitrová, Ph.D., Pediatrická klinika, Fakultní nemocnice Motol, V Úvalu 84/1, 150 00 Praha

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

1. K1\_Vedolizumab-3041\_Recruitment and Informed consent procedure\_CZE\_v1.0\_30Jan2024\_NotPublic
2. K1\_Vedolizumab-3041\_Recruitment and Informed consent procedure\_CZE\_v1.0\_30Jan2024\_Placeholder
3. L1\_Vedolizumab-3041\_ICF\_Assent\_12\_14\_CZE\_Czech\_v1\_0\_12Jan2024\_Public
4. L1\_Vedolizumab-3041\_ICF\_Assent\_15\_17\_CZE\_Czech\_v1\_0\_12Jan2024\_Public
5. L1\_Vedolizumab-3041\_ICF\_Optional\_FutureResearch\_Adult\_CZE\_Czech\_v1\_0\_12Jan2024\_Public
6. L1\_vedolizumab\_3041\_ICF\_Optional\_FutureResearch\_Parental\_CZE\_Czech\_v1\_0\_12Jan2024\_Public
7. L1\_Vedolizumab-3041\_ICF\_PP\_CZE\_Czech\_v1\_0\_12Jan2024\_Public
8. L1\_Vedolizumab-3041\_ICF\_Main\_Parental\_CZE\_Czech\_v1\_0\_12Jan2024\_Public
9. L1\_Vedolizumab-3041\_ICF\_Main\_Adult\_CZE\_Czech\_v1\_0\_12Jan2024\_Public
10. L1\_Vedolizumab-3041\_ICF\_GDPR\_Adult\_CZE\_Czech\_v1\_0\_12Jan2024\_Public
11. L1\_Vedolizumab-3041\_ICF\_GDPR\_Parental\_CZE\_Czech\_v1\_0\_12Jan2024\_Public
12. 17. ICF\_Assent\_12\_14\_CZE\_Czech\_v1\_0\_ 27.5.2024
13. 18. ICF\_Assent\_15\_17\_CZE\_Czech\_v1\_0\_27.5.2024
14. 22. ICF\_Main\_Parental\_CZE\_Czech\_v1\_0\_27.5.2024
15. L2\_Vedolizumab-3041\_Patient\_Card\_CZE\_Czech\_v1\_0\_0\_26Oct2023\_Public
16. L2\_Vedolizumab-3041\_Appointment\_Card\_CZE\_Czech\_v1\_0\_02Nov2023\_Public
17. L2\_Vedolizumab-3041\_Stickers\_CZE\_v1\_0\_26Oct2023\_Public
18. L2\_Vedolizumab-3041\_Thank\_You\_Card\_CZE\_Czech\_v1\_0\_02Nov2023\_Public
19. L2\_Vedolizumab-3041\_Visit\_Passport\_CZE\_Czech\_v1\_0\_02Nov2023\_Public
20. L2\_Vedolizumab-3041\_Brochure\_CZE\_Czech\_v1\_0\_01Feb2024\_Public
21. L2\_Vedolizumab-3041\_Parent Letter\_CZE\_Czech\_v1\_0\_01Feb2024\_Public
22. L2\_Vedolizumab-3041\_Video\_CZE\_Czech\_V1\_0\_01Feb2024\_Public
23. L2\_Vedolizumab-3041\_Visit Guide\_CZE\_Czech\_V1\_0\_01Feb2024\_Public
24. L2\_Vedolizumab-3041\_Visit Guide-Passport\_CZE\_Czech\_V1\_0\_01Feb2024\_Public
25. L2\_Vedolizumab-3041\_Application\_Screen\_eDiary\_v1\_21Feb2024\_Public
26. L2\_Vedolizumab-3041\_QRG\_v1\_CZE\_Czech\_22Feb2024\_Public
27. L2\_Vedolizumab-3041\_Slate\_Screen\_EQ\_5D\_Y\_v1\_21Feb2024\_Public
28. M1\_CV\_PI\_Mitrova\_Katarina\_FN Motol\_CZE\_17Jan2024\_NotPublic
29. M1\_CV\_PI\_Mitrova\_Katarina\_FN Motol\_CZE\_17Jan2024\_Placeholder
30. M2\_Vedolizumab-3041\_Declaration\_of\_Interest\_Mitrova\_Katarina\_PI\_FN Motol\_CZE\_16Jan2024\_NotPublic
31. M2\_Vedolizumab-3041\_Declaration\_of\_Interest\_Mitrova\_Katarina\_PI\_FN Motol\_CZE\_16Jan2024\_Placeholder
32. N1\_Vedolizumab\_3041\_Statement\_of\_Suitability\_CZE\_Mitrova\_Katarina\_16Jan2024\_NotPublic
33. N1\_Vedolizumab\_3041\_Statement\_of\_Suitability\_CZE\_Mitrova\_Katarina\_16Jan2024\_Placeholder
34. N2\_Vedolizumab-3041\_List\_of\_participating sites\_CZE\_11Jan2024\_NotPublic
35. N2\_Vedolizumab-3041\_List\_of\_participating sites\_CZE\_11Jan2024\_Placeholder
36. O1\_Vedolizumab-3041\_Insurance\_Certificate\_CZE\_English\_01Dec2023\_NotPublic
37. O1\_Vedolizumab-3041\_Insurance\_Certificate\_CZE\_English\_01Dec2023\_Placeholder
38. O2\_Vedolizumab-3041\_Insurance\_Policy\_CZE\_English\_04Jul2019\_NotPublic
39. O2\_Vedolizumab-3041\_Insurance\_Policy\_CZE\_English\_04Jul2019\_Placeholder
40. O2\_Vedolizumab-3041\_Insurance\_Terms and Conditions\_CZE\_Czech\_26May2021\_NotPublic
41. O2\_Vedolizumab-3041\_Insurance\_Terms and Conditions\_CZE\_Czech\_26May2021\_Placeholder
42. O2\_Vedolizumab-3041\_Insurance\_Terms and Conditions\_CZE\_English\_26May2021\_NotPublic
43. O2\_Vedolizumab-3041\_Insurance\_Terms and Conditions\_CZE\_English\_26May2021\_Placeholder
44. P1\_Vedolizumab-3041\_Compensation\_for\_Trial\_Participants\_CZE\_14Sep2023
45. R1\_Vedolizumab-3041\_Data\_Protection\_Declaration\_CZE\_06Feb2024\_NotPublic
46. R1\_Vedolizumab-3041\_Data\_Protection\_Declaration\_CZE\_06Feb2024\_Placeholder
47. S1\_Vedolizumab-3041\_Use\_of\_Biological\_Samples\_Declaration\_CZE\_05Feb2024\_NotPublic
48. S1\_Vedolizumab3041\_Use\_of\_Biological\_Samples\_Declaration\_CZE\_05Feb2024\_Placeholde

**List of members of the ethic committee participating in the decision**

MUDr. Jindřiška Burešová (chairman)

doc. MUDr. Jiřina Zapletalová, Ph.D.

prof. MUDr. et Mgr. Jiří Minařík, Ph.D.

MUDr. Libor Kvapil

MUDr. Josef Srovnal, Ph.D.

Anna Holá

MUDr. et PhDr. Lenka Hansmanová, Ph.D.

PharmDr. Tomáš Anděl, Ph.D.

doc. MUDr. Libuše Stárková, CSc.

prof. MUDr. Karel Indrák, DrSc.

MUDr. Karel Cwiertka, Ph.D.

MUDr. Jan Strojil, Ph.D.

Iveta Sudolská

Věra Bartlová

1. If yes – other demands for damage compensation, cfr. Art. 76 [↑](#footnote-ref-1)
2. If yes – other demands for informed consent, cfr. Art. 30 [↑](#footnote-ref-2)