Assessment report Part II – CZECHIA

1) 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?	Yes ☒ No ☐
If Yes	
Is there already a conclusion on part I?	Yes ☐ No ☐
Is the CT already approved in any member state ?	Yes ☐ No ☐

2) GENERAL INFORMATION

Is the CT a low-interventional trial?[1]	Yes ☐ No ☒
First in man ☐, Phase I ☐, II ☐, III ☒, IV☐ NA☐	
Is the CT a cluster trial[2]	Yes ☐ No ☒

[1] If yes – other demands for damage compensation, cfr. Art. 76
[2] If yes – other demands for informed consent, cfr. Art. 30

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?	Yes ☒ No ☐
Male?	Yes ☒ No ☐
Age group	
Adults (18-64 years)	Yes ☒ No ☐
Elderly (>= 65 years)	Yes ☒ No ☐
< 18 years	
In Utero	Yes ☒ No ☐
Preterm Newborn Infants (up to gestational age < 37 weeks)	Yes ☐ No ☒
Newborns (0-27 days)	Yes ☐ No ☒
Infants and toddlers (28 days - 23 months)	Yes ☐ No ☒
Children (2-11 years)	Yes ☒ No ☐
Adolescents (12-17 years)	Yes ☒ No ☐
Does the CT include vulnerable persons?	Yes ☒ No ☐
If yes	
Minors	Yes ☐ No ☐
Incapacitated subjects	Yes ☐ No ☐
Pregnant women	Yes ☐ No ☒
Breastfeeding women	Yes ☐ No ☒
Subjects in emergency situations	Yes ☐ No ☒
Other groups If yes specify:	Yes ☐ No ☐
Are there study-specific procedures and/or interventions beyond the drug application?	Yes ☐ No ☒
If yes	
Specify:	

3) 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:

4) 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 ?	Yes ☒ No ☐
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 ☐
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,	Yes ☒ No ☐
the follow-up measures if the participation of the subject in the clinical trial is discontinued	Yes ☒ No ☐
Post trial treatment options	Yes ☒ No ☐ NA ☐
Does the information sheet provide information about the damage compensation according to national law of concerned member state	Yes ☒ No ☐ NA ☐
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 ☐
Does the information sheet provide	
the EU trial number	Yes ☒ No ☐

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 ☐
Does the information sheet provide adequate information about planned personal data collection and processing	Yes ☒ No ☐
Does the information sheet provide adequate information about planned collection, storage and future use of biological samples?	Yes ☒ No ☐
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)	

In the case of a trial with minors. Is there Informed Consent documents adequately paying attentions to the information needs of these subjects?	Yes ☒ No ☐
In the case of a trial with incapacitated subjects. Is there Informed Consent documents adequately paying attentions to the information needs of these subjects?	Yes ☒ No ☐
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 ☐

Conclusion

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

If not

Questions/queries:

5) 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	Yes ☒ No ☐
Further detailed points must filled in by member states at national level	Yes ☒ No ☐
For example	

Are the rules for the collection, storage and future use of biological samples of the subject fulfilled?	Yes ☒ No ☐
Is the procedure to pseudonymise the data correct?	Yes ☒ No ☐
Are Initials omitted?	Yes ☒ No ☐
Is there no placeholder for the complete birthday?	Yes ☒ No ☐
Will the coding number maintained in the hand of the investigator or of a trustee?	Yes ☒ No ☐
Is described how long the data will be stored?	Yes ☒ No ☐
Is there a comprehensive description of the aims and scope of data collection?	Yes ☒ No ☐
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 ☐

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?	Yes ☒ No ☐
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 ☐

Questions/queries:

6) COMPENSATION

Is there no undue influence, including that of a financial nature, exerted on subjects to participate in the clinical trial	Yes ☐ No ☒
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 ☒

Questions/queries:

7) RECRUITMENT

Is the procedure for inclusion of subjects described in detail in the protocol or a separate document	Yes ☒ No ☐

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

Questions/queries:

8) SUITABILITY OF THE INVESTIGATOR

V Uvalu 84/1, Motol (Mitrová Katarína)	
Is there an informative CV?	Yes ☒ No ☐
Is previous experience obtained from work with clinical trials described?	Yes ☒ No ☐
Is previous experience obtained from work with patient care described?	Yes ☒ No ☐
Have certificates describing adequate ICH/GPV training been submitted?	Yes ☒ No ☐
Has a financial disclosure been submitted?	Yes ☒ No ☐
Have institutional affiliations, that might influence the impartiality of the investigators been presented?	Yes ☒ No ☐
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 ☐

Conclusion

V Uvalu 84/1, Motol (Mitrová Katarína)

Reason:

9) SUITABILITY OF THE FACILITIES

Has a list of the planned clinical trial sites with name and position of the principal investigators	Yes ☒ No ☐
and the planned number of subjects at the sites been submitted?	Yes ☒ No ☐
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)	Yes ☒ No ☐
Does this statement adequately describe	
the suitability of facilities,	Yes ☒ No ☐
the equipment,	Yes ☒ No ☐
the human resources	Yes ☒ No ☐
the expertise of the site,	Yes ☒ No ☐

Conclusion

V Uvalu 84/1, Motol (Mitrová Katarína)

Reason:

10) PROOF OF INSURANCE COVER OR INDEMNIFICATION

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

Questions/queries:

11) FINANCIAL AND OTHER ARRANGEMENTS

Is there a description confirming adequate financing of the clinical trial is ensured?	Yes ☐ No ☐
Are financial transactions and compensation paid to subjects	Yes ☐ No ☐

adequate?	
Are financial transactions and compensation paid to the investigator/site for participating in the clinical trial adequate?	Yes ☐ No ☐
Are any other agreement between the sponsor and the site adequate?	Yes ☐ No ☐

Questions/queries:

12) LIST OF QUESTIONS TO THE SPONSOR/

13) ASSESMENT OF THE SPONOR´S RESPONSE

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

14) 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