Assessment report Part II – CZECHIA

1) ADMINISTRATIVE INFORMATION

CT number	2023-505268-12-00
Member State Concerned	Czechia
Title of the study	Multicentrické, randomizované, dvojitě zaslepené, kontrolované klinické hodnocení fáze III k posouzení účinnosti, bezpečnosti a snášenlivosti dvou úvodních podání přípravku COMP360 u účastníků s depresí rezistentní vůči léčbě **A Phase III, multicentre, randomised, double-blind, controlled study to investigate the efficacy, safety, and tolerability of two initial administrations of COMP360 in participants with treatment-resistant depression**
Name of sponsors	Compass Pathfinder Limited
IMPs (repeat for PR1, PR2…..)	Substance (name/ code): PSILOCYBINE/SUB10158MIG, Marketing authorisation status (MA number, MS where authorised etc): 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 ☒
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 ☐

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

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: Whole Blood, Urine, Serum	

3) INFORMED CONSENT FORM
(Repeat for ICF1, ICR2 ….)

Date/version of Informed Consent Form	SIS-ICF_Main ICF, V 2.0_12Mar2024
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? Does the information sheet adequately explain that withdrawal of	Yes ☒ No ☐

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, 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?	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	Yes ☐ No ☐

any time by the subject or his or her legally designated representative?

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 ☐
	Yes ☐ No ☐
Are the arrangements for recruitment of subjects adequate?	Yes ☐ No ☐

Questions/queries:

8) SUITABILITY OF THE INVESTIGATOR

1) MUDr. Martin Brunovský, Ph.D. 2) MUDr. Alexander Nawka, Ph.D. 3) MUDr. Mgr. Marek Perez, Ph.D., MBA 4) MUDr. Tomáš Páleníček, Ph.D. 5) MUDr. Luboš Janů, Ph.D. 6) MUDr. Slavomír Pietrucha	
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

1) MUDr. Martin Brunovský, Ph.D.
2) MUDr. Alexander Nawka, Ph.D.
3) MUDr. Mgr. Marek Perez, Ph.D., MBA
4) MUDr. Tomáš Páleníček, Ph.D.
5) MUDr. Luboš Janů, Ph.D.
6) MUDr. Slavomír Pietrucha

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 ☐
1) Psyon s.r.o., Čistovická 249/11, Praha 2) INEP medical s.r.o., Křížkova 264/22, 186 00 Praha 3) MPMeditrine s.r.o., Opavská 962/39, 708 00 Ostrava 4) Národní ústav Duševního zdraví, Topolova 748, 250 67 Klecany 5) A-Shine s.r.o., Šumavská 2, 301 00 Plzeň 6) Neuroterapie KH s.r.o, Boženy Jandlové 2132/3, 143 00	Yes ☒ No ☐

Praha	
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,	

Conclusion

1) Psyon s.r.o., Čistovická 249/11, Praha
2) INEP medical s.r.o., Křížkova 264/22, 186 00 Praha
3) MPMeditrine s.r.o., Opavská 962/39, 708 00 Ostrava
4) Národní ústav Duševního zdraví, Topolova 748, 250 67 Klecany
5) A-Shine s.r.o., Šumavská 2, 301 00 Plzeň
6) Neuroterapie KH s.r.o, Boženy Jandlové 2132/3, 143 00

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

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

1) Psyon s.r.o., Čistovická 249/11, Praha - MUDr. Martin Brunovský, Ph.D.
2) INEP medical s.r.o., Křížkova 264/22, 186 00 Praha - MUDr. Alexander Nawka, Ph.D.
3) MPMeditrine s.r.o., Opavská 962/39, 708 00 Ostrava - MUDr. Mgr. Marek Perez, Ph.D., MBA
4) Národní ústav Duševního zdraví, Topolova 748, 250 67 Klecany - MUDr. Tomáš Páleníček, Ph.D.
5) A-Shine s.r.o., Šumavská 2, 301 00 Plzeň - MUDr. Luboš Janů, Ph.D.
6) Neuroterapie KH s.r.o, Boženy Jandlové 2132/3, 143 00 Praha - MUDr. Slavomír Pietrucha

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

1. K2_HH Factsheet, v 4.0, 7 Dec 2023
2. K2_Images, v3.0_1 Feb 2024
3. K2_LB BRV_Tnoversion
4. K2_LB BV_Tnoversion
5. K2_LB MoA_Tnoversion
6. K2_LB MV, Videos v1.0, 04-Oct-2022
7. K2_LB PE_Tnoversion
8. K2_LB RCH_Tnoversion
9. K2_MP Consent Navigator, 19-May-2023 v1.0 Czech
10. K2_MP Notif CfT
11. K2_MP Patient Portal, Protocol v3.0, 13-Feb-2023
12. K2_PAG Copy, v3.0, 1 Feb 2024
13. K2_PFS
14. K2_PIS, V3.0_06MAR2023_Czech (Czech Republic)_12MAY2023
15. K2_PL, V3.0_ 12MAY2023
16. K2_PN, v5.0, 21Jul2021
17. K2_Poster, V3.0, 06MAR2023
18. K2_Print Ads Copy, v2.0, 06OCT2022
19. K2_Print Ads, V2.0_27SEP2022(2
20. K2_QSG, v2.0 15Jul2022
21. K2_Telephone PS Script, V2.0 10. listopadu 2023
22. K2_Web text for sites, v3.0_1Feb2024
23. K2_Website Copy, v4.0_1Feb2024
24. L1_SIS-ICF_GDPR ICF, V2.0_12. března 2024
25. L1_SIS-ICF_Main ICF, V 2.0_12Mar2024
26. L1_SIS-ICF_Medical Record RF, V1.0, 18Oct2023
27. L1_SIS-ICF_Optional Biomarker, V 3.0, 21Mar2023

28. L1_SIS-ICF_Pre-Screening ICF, V 2.0, 21. března 2023
29. L2_Subject Card. verze 2.0, 17. března 2021
30. M1_CV PI Nawka_INEP Medical, 16 Oct 2023
31. M1_CV PI Pietrucha_Neuroterapie KH, 21 Mar 2024
32. M1_CV PI_ Janu_A-Shine, 12 Oct 2023
33. M1_CV_PI Brunovsky_PSYON, 25 Oct 2023
34. M1_CV_PI Palenicek, 2 Nov 2023
35. M1_CV_PI_Perez_MPMeditrine, 28 Mar 2023
36. M2_ DoI_PI Nawka_INEP Medical, 12 Oct 2023
37. M2_DoI_PI Brunovsky_PSYON, 18 Oct 2023
38. M2_DoI_PI Perez_MPMeditrine, 28 Mar 2024
39. M2_DoI_PI_Janu_A-Shine, 12 Oct 2023
40. M2_DoI_PI_Palenicek_NUDZ, 11 Oct 2023
41. M2_PI DoI_PI Pietrucha_Neuroterapie KH, 21 Mar 2024
42. N1_Site Registration_A-Shine, 19 Nov 2021
43. N1_Site Registration_INEP Medical, 28 Mar 2018
44. N1_Site Registration_MPMeditrine, 19 Nov 2014
45. N1_Site Registration_Neuroterapie KH, 17 Dec 2020
46. N1_Site Registration_PSYON, 26 Aug 2022
47. N1_Site Suitability_A-Shine, 3 Nov 2023
48. N1_Site Suitability_INEP Medical, 17 Oct 2023
49. N1_Site Suitability_MPMeditrine, 28 Mar 2024
50. N1_Site Suitability_Neuroterapie, 21 Mar 2024
51. N1_Site Suitability_NUDZ, 24 Oct 2023
52. N1_Site Suitability_PSYON, 25 Oct 2023
53. O1_Insurance certificate, 13 Dec 2023
54. O2_Insurance Policy_Amendment 1, 10 Aug 2023
55. O2_Insurance Policy
56. P1_Compensation for pts, CZ v1_19Oct2023
57. R1_Compl National Data Protect, 3 Oct 2023
58. S1_Compl Use Bio samples, 28 Jan 2022
59. K1_Recruit-ICF procedure, V 3.0, 5.5.2022
60. K2_Advocacy FS, 9 Jan 2024
61. K2_Brochure, 9 Jan 2024
62. K2_Caregiver Info, 12 May 2023
63. K2_COMP6BQ, 9 Aug 2022
64. K2_COMPEQ
65. K2_COMPES
66. K2_Core
67. K2_Digital MC, 12 Jan 2024
68. K2_Flyer, 12 May 2023

D4_COMP 006_Patient Facing Documentation_Part 2_CZ_04Apr2024_NFP
D4_COMP006_EQ5D5L_Pv1.1_CZE_nodate_NFP,
D4_COMP006_PHQ9_PvXX_CZE_nodate_NFP,
D4_COMP006_GAD7_Pv1.0_CZE_nodate_NFP,
D4_COMP006_SDS_Pv3.0_CZE_nodate_NFP,
D4_COMP006_mDESS_Pv1.0_CZE_30Jun2022_NFP,
D4_COMP006_TIC-P_Pv1.0_CZE_30Jun2022_NFP,
D4_COMP006_5D-ASC_Pv1.0_CZE_30Jun2022_NFP,
D4_COMP006_EBI_Pv1.0_CZE_30Jun2022_NFP,
D4_COMP006_DSST S_Pv4.0_CZE_05Sep2022_NFP,
D4_COMP006_STAR-P_Pv1.0_CZE_30Jun2022_NFP,
D4_COMP006_Rapport,PPS_Pv1.0_CZE_30Jun2022_NFP,
D4_COMP006_BEQ_Pv1.0_CZE_08Jul2022_NFP,
D4_COMP006_CGI-S_Pv1.0_CZE_27Jun2022_NFP,
D4_COMP006_C-SSRS B_Pv5.1_CZE_V X-Y_NFP,
D4_COMP006_C-SSRS BS_Pv5.1_CZE_V X-Y_NFP,
D4_COMP006_C-SSRS SLV_Pv5.1_CZE_V X-Y_NFP,
D4_COMP006_MGH-ATRQ_Pv1.0_CZE_27Jun2022_NFP,
D4_COMP006_SIGMA-STD_Pv1.0_CZE_16Jun2022_NFP,
D4_COMP006_SIGMA-SLE_Pv1.0_CZE_16Jun2022_NFP,
D4_COMP006_BPRS_Pv1.0_CZE_27Jun2022_NFP,
D4_COMP006_MINI_Pv7.0.2_CZE_02Jan2022_NFP,

D4_COMP006_EQ5D5L_Sv1.0_CZE_07Oct2022_NFP,
D4_COMP006_PHQ9_Sv1.0_CZE_13Oct2022_NFP,
D4_COMP006_GAD7_Sv1.0_CZE_03Oct2022_NFP,
D4_COMP006_SDS_SMv1.0_CZE_22Sep2022_NFP,
D4_COMP006_SDS_Sv1.0_CZE_03Oct2022_NFP,
D4_COMP006_mDESS_SMv1.0_CZE_03Oct2022_NFP,
D4_COMP006_mDESS_Sv1.0_CZE_22Sep2022_NFP,
D4_COMP006_TIC-P_Sv1.0_CZE_07Oct2022_NFP,
D4_COMP006_5D-ASC_Sv2.0_CZE_07Oct2022_NFP,
D4_COMP006_EBI_Sv1.0_CZE_08Sep2022_NFP,
D4_COMP006_STAR-P_Sv1.0_CZE_08Sep2022_NFP,
D4_COMP006_DSST_SMv1.0_CZE_07Nov2022_NFP,
D4_COMP006_DSST_Sv1.0_CZE_07Nov2022_NFP,
D4_COMP006_RPPS_Sv1.0_CZE_08Sep2022_NFP,
D4_COMP006_BPRS_Sv1.0_CZE_08Sep2022_NFP,
D4_COMP006_CGI-S_Sv1.0_CZE_08Sep2022_NFP,
D4_COMP006_C-SSRS SLV_SMv1.0_CZE_07Oct2022_NFP,
D4_COMP006_C-SSRS SLV_Sv1.0_CZE_08Sep2022_NFP,
D4_COMP006_MGH-ATRQ_SMv1.0_CZE_03Oct2022_NFP,
D4_COMP006_MGH-ATRQ_Sv1.0_CZE_13Oct2022_NFP,
D4_COMP006_C-SSRS,BS_SMv1.0_CZE_07Oct2022_NFP,
D4_COMP006_QSG_Sv2.0_CZE_03Aug2022_NFP,
D4_COMP006_STAR-C_Sv1.0_CZE_11Apr2023_NFP

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

In Prague 13 June 2024