Assessment report Part II – CZECHIA

# ADMINISTRATIVE INFORMATION

|  |  |
| --- | --- |
| CT number | **2024-510944-30-00** |
| Member State Concerned | Slovakia Austria Italy Latvia Croatia Portugal Czechia Spain France Germany Poland Hungary |
| Title of the study | RANDOMIZOVANÁ, DVOJITĚ MASKOVANÁ, PIVOTNÍ MULTICENTRICKÁ STUDIE FÁZE 2/3 SE 3 RAMENY HODNOTÍCÍ ÚČINNOST A BEZPEČNOST INTRAVITREÁLNĚ PODANÉHO PŘÍPRAVKU EYE103 VE SROVNÁNÍ S INTRAVITREÁLNĚ PODANÝM RANIBIZUMABEM (0,5 MG) U ÚČASTNÍKŮ S DIABETICKÝM MAKULÁRNÍM EDÉMEM  ***A RANDOMIZED, DOUBLE-MASKED, MULTI-CENTER, 3-ARM PIVOTAL PHASE 2/3 STUDY TO EVALUATE THE EFFICACY AND SAFETY OF INTRAVITREAL EYE103 COMPARED WITH INTRAVITREAL RANIBIZUMAB (0.5MG) IN PARTICIPANTS WITH DIABETIC MACULAR EDEMA*** |
| Name of sponsors | Eyebiotech Limited |
| IMPs (repeat for PR1, PR2…..) | Substance (name/ code): RANIBIZUMAB/SUB22314, , FLUORESCEIN SODIUM/SUB13905MIG, , EYE103/SUB323744,  Marketing authorisation status (MA number, MS where authorised etc): EU/1/06/374/004/EU, 6375757.00.00/DE, 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: blood | Yes  No |

# Informed Consent fORM

***(Repeat for ICF1, ICR2 ….)***

|  |  |  |
| --- | --- | --- |
| Date/version of Informed Consent Form | SIS and ICF Adult\_CZE\_V2.0\_15Oct2024 | |
| 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.

**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  NA  Yes  No  NA  Yes  No  NA |

**Conclusion**

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

**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  Yes  No |

**Questions/queries:**

# SUITABILITY OF THE INVESTIGATOR

|  |  |
| --- | --- |
| 1. MUDr. Jan Ernest, Ph.D., Axon Clinical s.r.o., Ševce Matouše 26, 140 00 Praha 2. MUDr. Jan Studnička, Visus spol. s r.o., Němcové 738, 547 01 Náchod 3. MUDr. Vladimir Korda, Ph.D., MBA, Oftex s.r.o., Rokycanova 2798, Zelené Předměsti, 530 02 Pardubice 4. prof. MUDr. Alexandr Stepanov, Ph.D., MBA, FEBO, Oblastni nemocnice Mladá Boleslav a.s., Oftalmologická klinika, Třída Václava Klementa 147, 293 01 Mladá Boleslav 5. MUDr. Jan Hamouz, Fakultní nemocnice Královské Vinohrady, Oftalmologická klinika, Šrobárova 1150/50, 100 00 Praha |  |
| 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  NA  Yes  No  Yes  No |

**Conclusion**

1. MUDr. Jan Ernest, Ph.D., Axon Clinical s.r.o., Ševce Matouše 26, 140 00 Praha
2. MUDr. Jan Studnička, Visus spol. s r.o., Němcové 738, 547 01 Náchod
3. MUDr. Vladimir Korda, Ph.D., MBA, Oftex s.r.o., Rokycanova 2798, Zelené Předměsti, 530 02 Pardubice
4. prof. MUDr. Alexandr Stepanov, Ph.D., MBA, FEBO, Oblastni nemocnice Mladá Boleslav a.s., Oftalmologická klinika, Třída Václava Klementa 147, 293 01 Mladá Boleslav
5. MUDr. Jan Hamouz, Fakultní nemocnice Královské Vinohrady, Oftalmologická klinika, Šrobárova 1150/50, 100 00 Praha

**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?   1. Axon Clinical s.r.o., Ševce Matouše 26, 140 00 Praha 2. Visus spol. s r.o., Němcové 738, 547 01 Náchod 3. Oftex s.r.o., Rokycanova 2798, Zelené Předměsti, 530 02 Pardubice 4. Oblastni nemocnice Mladá Boleslav a.s., Třída Václava Klementa 147, 293 01 Mladá Boleslav 5. Fakultní nemocnice Královské Vinohrady, Šrobárova 1150/50, 100 00 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)  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**

1. Axon Clinical s.r.o., Ševce Matouše 26, 140 00 Praha - MUDr. Jan Ernest, Ph.D.
2. Visus spol. s r.o., Němcové 738, 547 01 Náchod - MUDr. Jan Studnička
3. Oftex s.r.o., Rokycanova 2798, Zelené Předměsti, 530 02 Pardubice - MUDr. Vladimir Korda, Ph.D., MBA
4. Oblastni nemocnice Mladá Boleslav a.s., Oftalmologická klinika, Třída Václava Klementa 147, 293 01 Mladá Boleslav - prof. MUDr. Alexandr Stepanov, Ph.D., MBA, FEBO
5. Fakultní nemocnice Královské Vinohrady, Oftalmologická klinika, Šrobárova 1150/50, 100 00 Praha - MUDr. Jan Hamouz

**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  NA |

**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 |  |

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

**List of trial sites and investigators**

1. Axon Clinical s.r.o., Ševce Matouše 26, 140 00 Praha - MUDr. Jan Ernest, Ph.D.
2. Visus spol. s r.o., Němcové 738, 547 01 Náchod - MUDr. Jan Studnička
3. Oftex s.r.o., Rokycanova 2798, Zelené Předměsti, 530 02 Pardubice –

MUDr. Vladimir Korda, Ph.D., MBA

1. Oblastni nemocnice Mladá Boleslav a.s., Oftalmologická klinika, Třída Václava Klementa 147, 293 01 Mladá Boleslav - prof. MUDr. Alexandr Stepanov, Ph.D., MBA, FEBO
2. Fakultní nemocnice Královské Vinohrady, Oftalmologická klinika, Šrobárova 1150/50, 100 00 Praha - MUDr. Jan Hamouz

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

1. K1\_Recruitment arrangements, March 2023
2. L1\_SIS and ICF Adult\_CZE\_V2.0\_15Oct2024
3. L1\_SIS and ICF Pregnant partner\_CZ, ICF\_Pregnant Partner\_Czech\_V1.0\_03Jul-2024
4. L1\_SIS and ICF Privacy notice\_CZ, Privacy notice ICF\_ Czech\_V1.0\_10-Jul-2024
5. M2\_DoI Investigator Stepanov\_Klaudians Hospital, 11 Jul 2024
6. M2\_DoI Investigator Studnička\_Visus spol, 11 Jul 2024
7. M2\_DoI Investigator Ernest\_Axon Clinical, 17 Jul 2024
8. M2\_DoI Investigator Hamouz\_Hamouz Ocni Rakovnik, 10 Jul 2024
9. M2\_DoI Investigator Korda\_Oftex, 15 Jul 2024
10. M2\_GCP Investigator Ernest\_Axon Clinical, 30 Mar 2023
11. M2\_GCP Investigator Hamouz\_Hamouz Ocni Rakovnik, 4 Mar 2024
12. M2\_GCP Investigator Korda\_Oftex, 30 Oct 2023
13. M2\_GCP Investigator Stepanov\_Klaudians Hospital, 12 May 2024
14. M2\_GCP Investigator Studnička\_Visus spol, 1 Feb 2024
15. M1\_CV Investigator Ernest\_Axon Clinical, 17 Jun 2024
16. M1\_CV Investigator Hamouz\_Hamouz Ocni Rakovnik, 14 Jun 2024
17. M1\_CV Investigator Korda\_Oftex, 13 Jun 2024
18. M1\_CV Investigator Stepanov\_Klaudians Hospital, 16 Apr 2024
19. M1\_CV Investigator Studnička\_Visus spol, 26 Feb 2024
20. N1\_Site suitability form Axon Clinical, 16 Jul 2024
21. N1\_Site suitability form Klaudians Hospital, 16 Jul 2024
22. N1\_Site suitability form Ocni Klinika, 10 Jul 2024
23. N1\_Site suitability form Visus spol, 11 Jul 2024
24. N1\_Site suitability form\_Oftex, 15 Jul 2024
25. O1\_Trial participant insurance certificate, 3 Jul 2024
26. O1\_Trial participant insurance policy
27. P1\_Compensation trial participants investigator funding and other arrangements, V1.0\_24-Apr-2024
28. P1\_Compensation trial participants investigator funding and other arrangements\_Budget, v 1.0, 4 Jul 2024
29. R1\_Compliance on the collection and use of personal data, 15 May 2024
30. S1\_Compliance on the collection use and storage of biological samples, V1.0\_24-Jun-2024

**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.

Pavel Stuška, ThLic., PhD.

MUDr. Renata Lubičová

Ing. Jakub Král

Iveta Sudolská

Věra Bartlová

**In Prague October 24th, 2024**

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)