Assessment report Part II – CZECHIA

## 1) ADMINISTRATIVE INFORMATION

| | |
|---|---|
| CT number | **2023-506558-20-00** |
| Member State Concerned | Italy Bulgaria Czechia Spain France Germany |
| Title of the study | **Phase 3, randomized, double-blind, placebo-controlled, parallel-group, 3-arm, multinational, multicenter study to evaluate the efficacy and safety of amlitelimab by subcutaneous injection in participants aged 12 years and older with moderate-to-severe atopic dermatitis on background topical corticosteroids - EFC17561 – SHORE**<br><br>Randomizované, dvojitě zaslepené, placebem kontrolované, s paralelními skupinami a 3 rameny, mezinárodní multicentrické klinické hodnocení fáze 3 k posouzení účinnosti a bezpečnosti podkožně podávaného amlitelimabu podávaného současně s lokálními kortikosteroidy u pacientů od 12 let se středně těžkou až těžkou atopickou dermatitidou |
| Name of sponsors | Sanofi-Aventis Research & Development |
| IMPs (repeat for PR1, PR2…..) | Substance (name/ code): TACROLIMUS/SUB10797MIG, , AMLITELIMAB/SUB219075, , N/A/N/A, , -/-, , AMLITELIMAB/SUB219075, , PIMECROLIMUS/SUB16457MIG,<br>Marketing authorisation status (MA number, MS where authorised etc): -/null, null/null, N/A/IS, -/null, null/null, -/null<br>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 ☐ NA ☐ |

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

| | |
|---|---|
| Does the CT involve more than one site in the concerned member states? | Yes ☐ No ☐ NA ☐ |
| 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<br>If yes specify: ..... | Yes ☐ No ☒ |
| Are there study-specific procedures and/or interventions beyond the drug application? | Yes ☒ No ☐ |
| *If yes* | |
| Specify: Blood, tissue (skin biopsy), urine, upper respiratory tract (nasopharyngeal or oropharyngeal) exudate | |

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

| | |
|---|---|
| Date/version of Informed Consent Form | 1ICF_CZ_13Feb2024 |

| | |
|---|---|
| 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<br><br>for the dated signature of the subject<br><br>for the dated signature of legally designated representative?<br><br>for the dated signature and name for an impartial witness (in case of a subject is not able to sign (temporarily disabled or illiterate)? | <br><br>Yes ☒ No ☐ NA ☐<br><br>Yes ☒ No ☐ NA ☐<br><br>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*<br><br>For example<br><br>Does the subject or the legally designated representative confirm whether a copy of the Informed Consent Form (or the record) has been retained? | <br><br><br><br>Yes ☒ No ☐ |

**Conclusion**

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

**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 | |

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| 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 ☐NA ☐ |
| 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) | |

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| In the case of a trial with minors.<br>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.<br>Is there Informed Consent documents adequately paying attentions to the information needs of these subjects? | Yes ☐ No ☐NA ☐ |
| In the case of a trial in an emergency situation<br>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 ☐ |

**Conclusion**

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

**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:<br>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:<br>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

1) MUDr. Andrea Vocílková (Praglandia s.r.o.)
2) MUDr. Sylva Zajícová (CCR Ostrava s.r.o.)
3) prof. MUDr. Petr Arenberger (Sanatorium Profesora Arenbergera)
4) MUDr. Petra Brodská (Dermafit Centrum s.r.o.)
5) MUDr. Marie Selerová (Nemocnice AGEL Nový Jičín a.s.)

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|---|---|
| 6) MUDr. Romana Nyklová-Skřivánková (AGE Centrum s.r.o.) | |
| 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. Andrea Vocílková (Praglandia s.r.o.)
2) MUDr. Sylva Zajícová (CCR Ostrava s.r.o.)
3) prof. MUDr. Petr Arenberger (Sanatorium Profesora Arenbergera)
4) MUDr. Petra Brodská (Dermafit Centrum s.r.o.)
5) MUDr. Marie Selerová (Nemocnice AGEL Nový Jičín a.s.)
6) MUDr. Romana Nyklová-Skřivánková (AGE Centrum s.r.o.)

**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) Praglandia s.r.o., Ostrovského 253/3, 150 00 Praha<br>2) CCR Ostrava s.r.o., 28. října 3348/65, 702 00 Moravská Ostrava<br>3) Sanatorium Profesora Arenbergera, Bolzanova 1604/7, 110 01 Praha<br>4) Dermafit Centrum s.r.o., Manětinská 1499/17, 323 00 Plzeň<br>5) Nemocnice AGEL Nový Jičín a.s., Purkyňova 2138/16, 741 01 Nový Jičín<br>6) AGE Centrum s.r.o., Na Šibeniku 914/1, 779 00 Olomouc | Yes ☒ No ☐ |
| 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?<br>(issued by the head of the clinic/institution at the clinical trial site | |

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| or by some other responsible person, according to the system in the Member State concerned) | |
| 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**

1) Praglandia s.r.o., Ostrovského 253/3, 150 00 Praha
2) CCR Ostrava s.r.o., 28. října 3348/65, 702 00 Moravská Ostrava
3) Sanatorium Profesora Arenbergera, Bolzanova 1604/7, 110 01 Praha
4) Dermafit Centrum s.r.o., Manětinská 1499/17, 323 00 Plzeň
5) Nemocnice AGEL Nový Jičín a.s., Purkyňova 2138/16, 741 01 Nový Jičín
6) AGE Centrum s.r.o., Na Šibeniku 914/1, 779 00 Olomouc

## 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 ☐ NA ☒ |
| 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

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|---|---|
| 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. Praglandia s.r.o., Ostrovského 253/3, 150 00 Praha - MUDr. Andrea Vocílková
2. CCR Ostrava s.r.o., 28. října 3348/65, 702 00 Moravská Ostrava - MUDr. Sylva Zajícová
3. Sanatorium Profesora Arenbergera, Bolzanova 1604/7, 110 01 Praha – prof. MUDr. Petr Arenberger
4. Dermafit Centrum s.r.o., Manětinská 1499/17, 323 00 Plzeň - MUDr. Petra Brodská
5. Nemocnice AGEL Nový Jičín a.s., Purkyňova 2138/16, 741 01 Nový Jičín - MUDr. Marie Selerová
6. AGE Centrum s.r.o., Na Šibeniku 914/1, 779 00 Olomouc - MUDr. Romana Nyklová-Skřivánková

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

1. L1-sis-icf-assent-child-12-14y-cs, EFC17561_2main(12-14y)_CZ _17May2024
2. L1-sis-icf-assent-child-15-17y-cs, EFC17561_2main(15-17y)_CZ_17May2024
3. L1-sis-icf-future-sample-use-cs, 1FSU_CZ_13Feb2024
4. L1-sis-icf-gdpr-adult-cs, Doplňující informace GDPR – 15-Feb-2024
5. L1-sis-icf-gdpr-parents-cs, Doplňující informace GDPR – 15-Feb-2024
6. L1-sis-icf-main-adult-cs, ICF_2CZ_17May2024
7. L1-sis-icf-optional-procedures-15-17y-cs,EFC17561_1volitelné procedury (15-17y)_2CZ_ 17May2024
8. L1-sis-icf-optional-procedures-adult-cs, EFC17561_1volitelné procedury adult_2CZ_17May2024
9. L1-sis-icf-optional-procedures-parents-cs, EFC17561_1volitelné procedury rodiče_2CZ_ 17May2024
10. L1-sis-icf-parents-cs, 2Parent ICF_CZ_17May2024
11. L1-sis-icf-partner-pregnancy-cs, 1PP_CZ_14Feb2024 CCZE-QU-FOR-0119837 – V5.0 – 15-Oct-2023
12. L2-other-subject-information-material-patient-info-adolescents-cs, Verze 2.0 z února 2024
13. L2-other-subject-information-material-patient-info-adult-cs, V 2.0 z února 2024
14. M1-cv-investigator-arenbergerpetr-sanatorium-profesora-arenbergera-cs, 2 Mar 2023
15. M1-cv-investigator-brodskapetra-dermafit-centrum-cs, 5 Dec 2023
16. M1-cv-investigator-nyklovaskrivankovaromana-age-centrum-cs, 5 Dec 2023
17. M1-cv-investigator-selerovamarie-nemocnice-agel-cs, 4 Dec 2023
18. M1-cv-investigator-vocilkovaandrea-praglandia-cs, 10 Dec 2023
19. M1-cv-investigator-zajicovasylva-ccr-ostrava-cs, 4 Dec 2023
20. M2-doi-investigator-arenbergerpetr-sanatorium-profesora- arenbergera-cs, 5 Dec 2023
21. M2-doi-investigator-brodskapetra-dermafit-centrum-cs, 7 Dec 2023
22. M2-doi-investigator-nyklovaskrivankovaromana-age-centrum-cs, 05 Dec 2023
23. M2-doi-investigator-selerovamarie-nemocnice-agel-cs, 4 Dec 2023
24. M2-doi-investigator-vocilkovaandrea-praglandia-cs, 5 Dec 2023
25. M2-doi-investigator-zajicovasylva-ccr-ostrava-cs, 4 Dec 2023

26. M3-gcp-investigator-arenbergerpetr-sanatorium-profesora-arenbergera-en, 17 Aug 2022
27. M3-gcp-investigator-brodskapetra-dermafit-centrum-en, 14 Jun 2023
28. M3-gcp-investigator-nyklovaskrivankovaromana-age-centrum-en, 20 Jun 2023
29. M3-gcp-investigator-selerovamarie-nemocnice-agel-en, 4 Sep 2023
30. N1-site-suitability-form-age-centrum-cs, 05 Dec 2023
31. N1-site-suitability-form-ccr-ostrava-cs, 4 Dec 2023
32. N1-site-suitability-form-dermafit-centrum-cs, 5 Dec 2023
33. N1-site-suitability-form-nemocnice-agel-cs, 23 Nov 2023
34. N1-site-suitability-form-praglandia-cs, 5 Dec 2023
35. N1-site-suitability-form-sanatorium-profesora-arenbergera-cs, 5 Dec 2023
36. N2-registration2-nonstate-praglandia-cs, 9 Mar 2022
37. N2-registration-nonstate-age-centrum-cs, 7 Mar 2023
38. N2-registration-nonstate-ccr-ostrava-cs, 15 Aug 2023
39. N2-registration-nonstate-dermafit-centrum-cs, 29 Aug 2023
40. N2-registration-nonstate-nemocnice-agel-cs, 7 Jun 2023
41. N2-registration-nonstate-praglandia-cs, 18 Aug 2021
42. N2-registration-nonstate-sanatorium-profesora-arenbergera-cs, 9 Apr 2024
43. O1-trial-participant-insurance-certificate-cs, 7 Dec 2023
44. O2-proof-of-coverage-sanofi-en-commitment, 1 Jan 2024
45. P1-financial-arrangements-en, 28 Jun 2023
46. P1-financial-arrangements-trial-participants-cz
47. R1-compliance-on-the-collection-and-use-of-personal-data-cs, 13 Feb 2024
48. S1-compliance-biological-samples-en, v5.0, 12 Feb 2024
49. K2-recruitment-material-brochure-cs, Verze 2.0 ze dne 01/11/2023
50. K2-recruitment-material-dear-patient-letter-cs, Verze 4.0 ze dne 01/11/2023
51. K2-recruitment-material-dr-to-dr-letter-cs, Verze 4.0 ze dne 01/11/2023
52. K2-recruitment-material-flyer-cs, Verze 1.0 ze dne 25/07/2023
53. K2-recruitment-material-poster-with-compensation-cs, Verze 1.0 ze dne 25/07/2023
54. K2-recruitment-material-poster-without-compensation-cs, Verze 1.0 ze dne 25/07/2023
55. K1-recruitment-arrangements-en, v1.0, 5 Dec 2023
56. d4-patient-facing-material-questionnaire-cdlqi-cs-2023-506558-20
57. d4-patient-facing-material-questionnaire-dlqi-cs-2023-506558-20
58. d4-patient-facing-material-questionnaire-hads-cs-2023-506558-20
59. d4-patient-facing-material-questionnaire-poem-cs-2023-506558-20
60. d4-patient-facing-material-questionnaire-pp-nrs-cs-2023-506558-20
61. d4-patient-facing-material-questionnaire-sd-nrs-cs-2023-506558-20
62. d4-patient-facing-material-questionnaire-sp-nrs-cs-2023-506558-20
63. d4-patient-facing-material-questionnaire-TCS-TCI-cs-2023-506558-20

**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 7th June 2024**