



Clinical trial results:

A Phase IIa, randomized, double-blind, placebo-controlled study of HIV-1 Vaccines MVA.HTI and ChAdOx1.HTI with TLR7 agonist vesatolimod (GS-9620) in early treated HIV-1 infection

Summary

| | |
|--------------------------|------------------|
| EudraCT number | 2018-002125-30 |
| Trial protocol | ES |
| Global end of trial date | 16 December 2022 |

Results information

| | |
|--------------------------------|----------------|
| Result version number | v1 (current) |
| This version publication date | 12 August 2023 |
| First version publication date | 12 August 2023 |

Trial information

Trial identification

| | |
|-----------------------|-----------|
| Sponsor protocol code | AELIX-003 |
|-----------------------|-----------|

Additional study identifiers

| | |
|------------------------------------|---|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | - |
| WHO universal trial number (UTN) | - |

Notes:

Sponsors

| | |
|------------------------------|---|
| Sponsor organisation name | AELIX Therapeutics |
| Sponsor organisation address | Parc Científic de Barcelona, C/ Baldri i Reixac, 4-8, Barcelona, Spain, 08028 |
| Public contact | Jordi Naval, AELIX Therapeutics, 34 934031339, jnaval@aelixtherapeutics.com |
| Scientific contact | Jordi Naval, AELIX Therapeutics, 34 934031339, jnaval@aelixtherapeutics.com |

Notes:

Paediatric regulatory details

| | |
|--|----|
| Is trial part of an agreed paediatric investigation plan (PIP) | No |
| Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial? | No |
| Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial? | No |

Notes:

Results analysis stage

| | |
|--|------------------|
| Analysis stage | Final |
| Date of interim/final analysis | 21 June 2023 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 03 October 2022 |
| Global end of trial reached? | Yes |
| Global end of trial date | 16 December 2022 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

To evaluate the safety of the CCMM (ChAdOx1.HTI + MVA.HTI) + Vesatolimod regimen during Period 1 (week 0 to 48) in early treated HIV 1 infection

Protection of trial subjects:

This study was conducted in compliance with the ethical principles that have their origin in the Declaration of Helsinki, protocol, ICH harmonised tripartite guideline E6(R2): GCP, and all applicable AEMPS requirements. A written informed consent (including separate consent for the intensive PK substudy if applicable and potential updated or new information related to COVID 19, which could impact the study risk-benefit assessment) in compliance with AEMPS regulations was obtained from each participant.

Background therapy:

The most frequently taken concomitant medications (that were ongoing on or after the first dose of the IMP) were COVID-19 vaccines (31 [93.9%] participants in the CCMM + vesatolimod group and 17 [100%] participants in the placebo group), paracetamol (21 [63.6%] participants in the CCMM + vesatolimod group and 13 [76.5%] participants in the placebo group), and ibuprofen (16 [48.5%] participants in the CCMM + vesatolimod group and 7 [41.2%] participants in the placebo group).

Evidence for comparator:

Matching placebo

| | |
|---|-------------|
| Actual start date of recruitment | 20 May 2019 |
| Long term follow-up planned | No |
| Independent data monitoring committee (IDMC) involvement? | Yes |

Notes:

Population of trial subjects

Subjects enrolled per country

| | |
|--------------------------------------|-----------|
| Country: Number of subjects enrolled | Spain: 50 |
| Worldwide total number of subjects | 50 |
| EEA total number of subjects | 50 |

Notes:

Subjects enrolled per age group

| | |
|---|---|
| In utero | 0 |
| Preterm newborn - gestational age < 37 wk | 0 |
| Newborns (0-27 days) | 0 |
| Infants and toddlers (28 days-23 months) | 0 |

| | |
|---------------------------|----|
| Children (2-11 years) | 0 |
| Adolescents (12-17 years) | 0 |
| Adults (18-64 years) | 50 |
| From 65 to 84 years | 0 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details:

Approximately 57 participants were planned to be enrolled in the study. After providing informed consent, participants were randomly assigned in a 2:1 ratio using an IRT to receive CCMM + vesatolimod or placebo.

Pre-assignment

Screening details:

The study screened participants living with HIV who had initiated ART within 180 days (6 months) of the estimated date of HIV 1 acquisition and who had achieved virological suppression for at least 1 year. A total of 65 participants were assessed for eligibility and 50 participants enrolled in the study.

Period 1

| | |
|------------------------------|---|
| Period 1 title | Period 1 |
| Is this the baseline period? | Yes |
| Allocation method | Randomised - controlled |
| Blinding used | Double blind |
| Roles blinded | Subject, Investigator, Monitor, Data analyst, Carer, Assessor |

Blinding implementation details:

Study treatments taken during this study were double-blind. Period 1 (48 weeks) during which participants received blinded investigational medicinal product (IMP) and continued their antiretroviral therapy (ART regimen).

Unblinded Roles: Pharmacist+ unblinded Study nurses, uCTM and uCRA

Arms

| | |
|------------------------------|--------------------|
| Are arms mutually exclusive? | Yes |
| Arm title | CCMM + Vesatolimod |

Arm description:

ChAdOx1.HTI is an immunotherapeutic medicinal product that contains genetically modified organisms (ChAdOx1). MVA.HTI is an investigational immunological product (vaccine) of a biological/biotechnological origin that contains genetically modified organisms (MVA). Vesatolimod (also known as GS-9620) is an orally administered toll-like receptor 7 (TLR7) agonist currently in clinical development for the treatment and remission of HIV-1 infection.

| | |
|--|--------------------------|
| Arm type | Experimental |
| Investigational medicinal product name | ChAdOx1.HTI |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Suspension for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

ChAdOx1.HTI vaccine was delivered as one 0.5 mL IM injection, taken at Weeks 0 and 12.

| | |
|--|--------------------------|
| Investigational medicinal product name | MVA.HTI |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Suspension for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

MVA.HTI vaccine was delivered as one 0.5 mL IM injection, taken at Weeks 24 and 36.

| | |
|--|--------------------|
| Investigational medicinal product name | Vesatolimod |
| Investigational medicinal product code | |
| Other name | GS-9620 |
| Pharmaceutical forms | Film-coated tablet |

| | |
|--------------------------|----------|
| Routes of administration | Oral use |
|--------------------------|----------|

Dosage and administration details:

Vesatolimod was administered orally at the study site with approximately 240 mL of water after an overnight fast or after fasting period of at least 8 hours. Participants were not allowed to consume water 1 hour before and 2 hours after dosing. Vesatolimod was delivered as three 2-mg tablets and was taken at Weeks 26, 28, 30, 32, 34, 38, 40, 42, 44, and 46.

| | |
|------------------|---------|
| Arm title | Placebo |
|------------------|---------|

Arm description:

The placebos matched to ChAdOx1.HTI and MVA.HTI were commercially available sterile saline solution (sodium chloride 0.9%).

| | |
|--|---------------------|
| Arm type | Placebo |
| Investigational medicinal product name | ChAdOx1.HTI placebo |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

ChAdOx1.HTI placebo (0.9% NaCl solution for injection) was delivered as one 0.5 mL IM injection and was taken at Weeks 0 and 12.

| | |
|--|-------------------|
| Investigational medicinal product name | MVA.HTI placebo |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

MVA.HTI (0.9% NaCl solution for injection) was delivered as one 0.5 mL IM injection and was taken at Weeks 24 and 36.

| | |
|--|---------------------|
| Investigational medicinal product name | Vesatolimod placebo |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Film-coated tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Vesatolimod placebo was administered orally at the study site with approximately 240 mL of water after an overnight fast or after fasting period of at least 8 hours. Participants were not allowed to consume water 1 hour before and 2 hours after dosing. Vesatolimod placebo tablet was delivered as three 2-mg placebo tablets and was taken at Weeks 26, 28, 30, 32, 34, 38, 40, 42, 44, and 46.

| Number of subjects in period 1 | CCMM + Vesatolimod | Placebo |
|---------------------------------------|-----------------------|---------|
| Started | 33 | 17 |
| Completed | 30 | 17 |
| Not completed | 3 | 0 |
| Withdrawal by participant | 2 | - |
| Investigator decision | 1 | - |

Period 2

| | |
|------------------------------|---|
| Period 2 title | Period 2 (ATI) |
| Is this the baseline period? | No |
| Allocation method | Randomised - controlled |
| Blinding used | Double blind |
| Roles blinded | Subject, Investigator, Monitor, Data analyst, Carer, Assessor |

Blinding implementation details:

Participants were allowed to proceed to Period 2 if they met ATI requirements and had received at least 3 doses of vaccine/placebo and at least 3 doses of vesatolimod/placebo. During Period 2 (up to 24 weeks) participants discontinued their ART regimen (ATI period) and were monitored for pVL and CD4 counts.

Arms

| | |
|------------------------------|--------------------|
| Are arms mutually exclusive? | Yes |
| Arm title | CCMM + Vesatolimod |

Arm description:

ChAdOx1.HTI is an immunotherapeutic medicinal product that contains genetically modified organisms (ChAdOx1). MVA.HTI is an investigational immunological product (vaccine) of a biological/biotechnological origin that contains genetically modified organisms (MVA).

| | |
|--|--------------------------|
| Arm type | Experimental |
| Investigational medicinal product name | ChAdOx1.HTI |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Suspension for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

In Period 2 (Week 48 to Week 72), all participants discontinued ART at/after the Week 48 visit. HIV-1 plasma viremia levels were monitored weekly and CD4 counts were monitored monthly. During this period subjects did not receive study drug/ placebo.

| | |
|--|--------------------------|
| Investigational medicinal product name | MVA.HTI |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Suspension for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

In Period 2 (Week 48 to Week 72), all participants discontinued ART at/after the Week 48 visit. HIV-1 plasma viremia levels were monitored weekly and CD4 counts were monitored monthly. During this period subjects did not receive study drug/ placebo.

| | |
|--|--------------------|
| Investigational medicinal product name | Vesatolimod |
| Investigational medicinal product code | |
| Other name | GS-9620 |
| Pharmaceutical forms | Film-coated tablet |
| Routes of administration | Oral use |

Dosage and administration details:

In Period 2 (Week 48 to Week 72), all participants discontinued ART at/after the Week 48 visit. HIV-1 plasma viremia levels were monitored weekly and CD4 counts were monitored monthly. During this period subjects did not receive study drug/ placebo.

| | |
|------------------|---------|
| Arm title | Placebo |
|------------------|---------|

Arm description:

The placebos matched to ChAdOx1.HTI and MVA.HTI were commercially available sterile saline solution (sodium chloride 0.9%).

| | |
|----------|---------|
| Arm type | Placebo |
|----------|---------|

| | |
|--|---------------------|
| Investigational medicinal product name | ChAdOx1.HTI placebo |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

In Period 2 (Week 48 to Week 72), all participants discontinued ART at/after the Week 48 visit. HIV-1 plasma viremia levels were monitored weekly and CD4 counts were monitored monthly. During this period subjects did not receive study drug/ placebo.

| | |
|--|-------------------|
| Investigational medicinal product name | MVA.HTI placebo |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

In Period 2 (Week 48 to Week 72), all participants discontinued ART at/after the Week 48 visit. HIV-1 plasma viremia levels were monitored weekly and CD4 counts were monitored monthly. During this period subjects did not receive study drug/ placebo.

| | |
|--|---------------------|
| Investigational medicinal product name | Vesatolimod placebo |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Film-coated tablet |
| Routes of administration | Oral use |

Dosage and administration details:

In Period 2 (Week 48 to Week 72), all participants discontinued ART at/after the Week 48 visit. HIV-1 plasma viremia levels were monitored weekly and CD4 counts were monitored monthly. During this period subjects did not receive study drug/ placebo.

| Number of subjects in period 2 | CCMM + Vesatolimod | Placebo |
|--------------------------------|--------------------|------------------|
| Started | 30 | 17 |
| Entered Period 2 | 30 | 17 |
| Discontinued Period 2 | 0 ^[1] | 0 ^[2] |
| Completed | 30 | 17 |

Notes:

[1] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Three (9.1%) participants in the CCMM + vesatolimod group did not complete active treatment (Period 1). All participants who entered Period 2 completed the period.

[2] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: All participants in the placebo group completed active treatment (Period 1). All participants who entered Period 2 completed the period.

Period 3

| | |
|------------------------------|-----------------------------|
| Period 3 title | Period 3 (ART reinitiation) |
| Is this the baseline period? | No |
| Allocation method | Randomised - controlled |
| Blinding used | Double blind |

| | |
|---------------|---|
| Roles blinded | Subject, Investigator, Monitor, Data analyst, Carer, Assessor |
|---------------|---|

Blinding implementation details:

Participants who met the requirements for restarting ART during Period 2 moved into Period 3 after restarting ART, whether during Period 2 or at the completion of Period 2 (i.e., at Week 72) underwent Week 72 procedures. During Period 3 (12 weeks) participants were monitored following the restart of their ART.

Arms

| | |
|------------------------------|-----|
| Are arms mutually exclusive? | Yes |
|------------------------------|-----|

| | |
|------------------|--------------------|
| Arm title | CCMM + Vesatolimod |
|------------------|--------------------|

Arm description:

ChAdOx1.HTI is an immunotherapeutic medicinal product that contains genetically modified organisms (ChAdOx1). MVA.HTI is an investigational immunological product (vaccine) of a biological/biotechnological origin that contains genetically modified organisms (MVA).

| | |
|--|--------------------------|
| Arm type | Experimental |
| Investigational medicinal product name | ChAdOx1.HTI |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Suspension for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

In Period 3 (Week 72 to Week 84), all participants who restarted their ART during Period 2, whether during Period 2 or after completing Period 2 (i.e., at the Week 72 visit), had their viral load monitored at 4 and 12 weeks after restarting ART (Week 76 and Week 84). During this period subjects did not receive study drug/ placebo.

| | |
|--|--------------------------|
| Investigational medicinal product name | MVA.HTI |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Suspension for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

In Period 3 (Week 72 to Week 84), all participants who restarted their ART during Period 2, whether during Period 2 or after completing Period 2 (i.e., at the Week 72 visit), had their viral load monitored at 4 and 12 weeks after restarting ART (Week 76 and Week 84). During this period subjects did not receive study drug/ placebo.

| | |
|--|--------------------|
| Investigational medicinal product name | Vesatolimod |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Film-coated tablet |
| Routes of administration | Oral use |

Dosage and administration details:

In Period 3 (Week 72 to Week 84), all participants who restarted their ART during Period 2, whether during Period 2 or after completing Period 2 (i.e., at the Week 72 visit), had their viral load monitored at 4 and 12 weeks after restarting ART (Week 76 and Week 84). During this period subjects did not receive study drug/ placebo.

| | |
|------------------|---------|
| Arm title | Placebo |
|------------------|---------|

Arm description:

The placebos matched to ChAdOx1.HTI and MVA.HTI were commercially available sterile saline solution (sodium chloride 0.9%).

| | |
|--|---------------------|
| Arm type | Placebo |
| Investigational medicinal product name | ChAdOx1.HTI placebo |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

In Period 3 (Week 72 to Week 84), all participants who restarted their ART during Period 2, whether during Period 2 or after completing Period 2 (i.e., at the Week 72 visit), had their viral load monitored at 4 and 12 weeks after restarting ART (Week 76 and Week 84). During this period subjects did not receive study drug/ placebo.

| | |
|--|-------------------|
| Investigational medicinal product name | MVA.HTI placebo |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

In Period 3 (Week 72 to Week 84), all participants who restarted their ART during Period 2, whether during Period 2 or after completing Period 2 (i.e., at the Week 72 visit), had their viral load monitored at 4 and 12 weeks after restarting ART (Week 76 and Week 84). During this period subjects did not receive study drug/ placebo.

| | |
|--|---------------------|
| Investigational medicinal product name | Vesatolimod placebo |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Film-coated tablet |
| Routes of administration | Oral use |

Dosage and administration details:

In Period 3 (Week 72 to Week 84), all participants who restarted their ART during Period 2, whether during Period 2 or after completing Period 2 (i.e., at the Week 72 visit), had their viral load monitored at 4 and 12 weeks after restarting ART (Week 76 and Week 84). During this period subjects did not receive study drug/ placebo.

| Number of subjects in period 3 | CCMM + Vesatolimod | Placebo |
|---------------------------------------|-------------------------------|------------------|
| Started | 30 | 17 |
| Enter Period 3 | 30 | 17 |
| Discontinued Period 3 | 0 ^[3] | 1 ^[4] |
| Completed the Study | 30 | 16 |
| Completed | 30 | 16 |
| Not completed | 0 | 1 |
| Withdrawal by participant | - | 1 |

Notes:

[3] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: All participants who entered Period 3 completed the study.

[4] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Only 1 (5.9%) participant in the placebo group discontinued from the study during Period 3 due to withdrawal by participant.

Baseline characteristics

Reporting groups

| | |
|---|--------------------|
| Reporting group title | CCMM + Vesatolimod |
| Reporting group description: | |
| ChAdOx1.HTI is an immunotherapeutic medicinal product that contains genetically modified organisms (ChAdOx1). MVA.HTI is an investigational immunological product (vaccine) of a biological/biotechnological origin that contains genetically modified organisms (MVA). Vesatolimod (also known as GS-9620) is an orally administered toll-like receptor 7 (TLR7) agonist currently in clinical development for the treatment and remission of HIV-1 infection. | |
| Reporting group title | Placebo |
| Reporting group description: | |
| The placebos matched to ChAdOx1.HTI and MVA.HTI were commercially available sterile saline solution (sodium chloride 0.9%). | |

| Reporting group values | CCMM + Vesatolimod | Placebo | Total |
|--|--------------------|-----------|-------|
| Number of subjects | 33 | 17 | 50 |
| Age categorical | | | |
| Units: Subjects | | | |
| Adults (18-64 years) | 33 | 17 | 50 |
| Age continuous | | | |
| Units: years | | | |
| arithmetic mean | 38.4 | 36.8 | |
| standard deviation | ± 8.77 | ± 12.42 | - |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 0 | 0 | 0 |
| Male | 33 | 17 | 50 |
| HLA with potential for superior viral control (Corrected) | | | |
| Baseline was defined as the last nonmissing assessment prior to the first administration of any IMP. A total of 10 (20.0%) participants (6 [18.2%] in the CCMM + vesatolimod group and 4 [23.5%] in the placebo group) had potential for superior viral control due to the presence of human leukocyte antigen (HLA allele(s)) associated with natural control of HIV. Median time since HIV acquisition to screening visit was 43.08 months (41.79 months in the CCMM + vesatolimod group and 46.45 months in the placebo group). | | | |
| Units: Subjects | | | |
| Yes | 6 | 4 | 10 |
| No | 27 | 13 | 40 |
| Time from HIV acquisition to ART initiation | | | |
| Time from HIV acquisition to ART initiation = the ART initiation date — the estimated date of HIV-1 acquisition. | | | |
| Units: days | | | |
| median | 61.0 | 86.0 | |
| full range (min-max) | 7 to 170 | 16 to 167 | - |

Subject analysis sets

| | |
|----------------------------|---------------|
| Subject analysis set title | ITT set |
| Subject analysis set type | Full analysis |

Subject analysis set description:

ITT set was defined as all randomized participants who took at least one dose of IMP. Numbers were based on planned treatment group.

| | |
|----------------------------|-----------------|
| Subject analysis set title | Safety set |
| Subject analysis set type | Safety analysis |

Subject analysis set description:

Safety set was defined as all randomized participants who took at least one dose of IMP. Numbers were based on actual treatment group.

| Reporting group values | ITT set | Safety set | |
|--|----------|------------|--|
| Number of subjects | 50 | 50 | |
| Age categorical | | | |
| Units: Subjects | | | |
| Adults (18-64 years) | 17 | 33 | |
| Age continuous | | | |
| Units: years | | | |
| arithmetic mean | 37.9 | 37.9 | |
| standard deviation | ± 10.06 | ± 10.06 | |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 0 | 0 | |
| Male | 50 | 50 | |
| HLA with potential for superior viral control (Corrected) | | | |
| Baseline was defined as the last nonmissing assessment prior to the first administration of any IMP. A total of 10 (20.0%) participants (6 [18.2%] in the CCMM + vesatolimod group and 4 [23.5%] in the placebo group) had potential for superior viral control due to the presence of human leukocyte antigen (HLA allele(s)) associated with natural control of HIV. Median time since HIV acquisition to screening visit was 43.08 months (41.79 months in the CCMM + vesatolimod group and 46.45 months in the placebo group). | | | |
| Units: Subjects | | | |
| Yes | 10 | 10 | |
| No | 40 | 40 | |
| Time from HIV acquisition to ART initiation | | | |
| Time from HIV acquisition to ART initiation = the ART initiation date — the estimated date of HIV-1 acquisition. | | | |
| Units: days | | | |
| median | 67.0 | 67.0 | |
| full range (min-max) | 7 to 170 | 7 to 170 | |

End points

End points reporting groups

| | |
|---|--------------------|
| Reporting group title | CCMM + Vesatolimod |
| Reporting group description: ChAdOx1.HTI is an immunotherapeutic medicinal product that contains genetically modified organisms (ChAdOx1). MVA.HTI is an investigational immunological product (vaccine) of a biological/biotechnological origin that contains genetically modified organisms (MVA). Vesatolimod (also known as GS-9620) is an orally administered toll-like receptor 7 (TLR7) agonist currently in clinical development for the treatment and remission of HIV-1 infection. | |
| Reporting group title | Placebo |
| Reporting group description: The placebos matched to ChAdOx1.HTI and MVA.HTI were commercially available sterile saline solution (sodium chloride 0.9%). | |
| Reporting group title | CCMM + Vesatolimod |
| Reporting group description: ChAdOx1.HTI is an immunotherapeutic medicinal product that contains genetically modified organisms (ChAdOx1). MVA.HTI is an investigational immunological product (vaccine) of a biological/biotechnological origin that contains genetically modified organisms (MVA). | |
| Reporting group title | Placebo |
| Reporting group description: The placebos matched to ChAdOx1.HTI and MVA.HTI were commercially available sterile saline solution (sodium chloride 0.9%). | |
| Reporting group title | CCMM + Vesatolimod |
| Reporting group description: ChAdOx1.HTI is an immunotherapeutic medicinal product that contains genetically modified organisms (ChAdOx1). MVA.HTI is an investigational immunological product (vaccine) of a biological/biotechnological origin that contains genetically modified organisms (MVA). | |
| Reporting group title | Placebo |
| Reporting group description: The placebos matched to ChAdOx1.HTI and MVA.HTI were commercially available sterile saline solution (sodium chloride 0.9%). | |
| Subject analysis set title | ITT set |
| Subject analysis set type | Full analysis |
| Subject analysis set description: ITT set was defined as all randomized participants who took at least one dose of IMP. Numbers were based on planned treatment group. | |
| Subject analysis set title | Safety set |
| Subject analysis set type | Safety analysis |
| Subject analysis set description: Safety set was defined as all randomized participants who took at least one dose of IMP. Numbers were based on actual treatment group. | |

Primary: Proportion of participants who developed solicited Grade 3 or 4 local reactions in the 7-day period following administration of IMPs during Period 1

| | |
|---|---|
| End point title | Proportion of participants who developed solicited Grade 3 or 4 local reactions in the 7-day period following administration of IMPs during Period 1 ^[1] |
| End point description: The incidence of Grade 3 or 4 solicited local reactions in the CCMM + vesatolimod group was higher than in the placebo group. 95% CI of the proportion was calculated based on the exact method and was (5.1, 31.9) for CCMM + vesatolimod group and (0.0, 19.5) for placebo group. Diary event severity was assessed by the participant. AE severity was assessed by the investigator, Grade 1 was presented as 'Mild', Grade 2 was presented as 'Moderate'; Grade 3,4 or death were presented as 'Severe'. | |
| End point type | Primary |

End point timeframe:

From administration of IMP within the 7 days following IMP dosing (during Period 1)

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No statistical analyses have been provided for safety end points since data was summarized using descriptive statistics.

| End point values | CCMM + Vesatolimod | Placebo | Safety set | |
|-----------------------------|-----------------------|-----------------|----------------------|--|
| Subject group type | Reporting group | Reporting group | Subject analysis set | |
| Number of subjects analysed | 33 | 17 | 50 | |
| Units: number of subjects | | | | |
| Grade 3 | 5 | 0 | 5 | |
| Grade 4 | 1 | 0 | 1 | |

Statistical analyses

No statistical analyses for this end point

Primary: Proportion of participants who developed solicited Grade 3 or 4 systemic reactions in the 7-day period following administration of IMPs during Period 1

| | |
|-----------------|--|
| End point title | Proportion of participants who developed solicited Grade 3 or 4 systemic reactions in the 7-day period following administration of IMPs during Period 1 ^[2] |
|-----------------|--|

End point description:

The incidence of Grade 3 solicited systemic reactions in the CCMM + vesatolimod group was higher than in the placebo group, whereas all Grade 4 solicited systemic reactions were reported in the placebo group. Ten (30.3%) participants in the CCMM + vesatolimod group had 40 and 3 (17.6%) participants in the placebo group had twenty Grade 3 solicited systemic reactions during Period 1. 95% CI of the proportion was calculated based on the exact method and was (15.6, 48.7) for CCMM + vesatolimod group and (3.8, 43.4) for placebo group.

Diary event severity is assessed by the participant. AE severity was assessed by the investigator, Grade 1 was presented as 'Mild', Grade 2 was presented as 'Moderate'; Grade 3,4 or death were presented as 'Severe'.

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

From administration of IMP within the 7 days following IMP dosing (during Period 1)

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No statistical analyses have been provided for safety end points since data was summarized using descriptive statistics.

| End point values | CCMM + Vesatolimod | Placebo | Safety set | |
|-----------------------------|-----------------------|-----------------|----------------------|--|
| Subject group type | Reporting group | Reporting group | Subject analysis set | |
| Number of subjects analysed | 33 | 17 | 50 | |
| Units: number of subjects | | | | |
| Grade 3 | 10 | 3 | 13 | |
| Grade 4 | 0 | 2 | 2 | |

Statistical analyses

No statistical analyses for this end point

Primary: Proportion of participants who developed treatment-emergent SAEs during Period 1

| | |
|-----------------|---|
| End point title | Proportion of participants who developed treatment-emergent SAEs during Period 1 ^[3] |
|-----------------|---|

End point description:

The serious TEAE was considered severe and was reported as recovered/resolved. The median duration for the serious TEAE during Period 1 was 10 days (range: 10.0 to 10.0). It was considered not related to the IMP.

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

From administration of IMP up to 48 weeks (during Period 1)

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No statistical analyses have been provided for safety end points since data was summarized using descriptive statistics.

| End point values | CCMM + Vesatolimod | Placebo | Safety set | |
|----------------------------------|-----------------------|-----------------|----------------------|--|
| Subject group type | Reporting group | Reporting group | Subject analysis set | |
| Number of subjects analysed | 33 | 17 | 50 | |
| Units: subjects | | | | |
| number (confidence interval 95%) | 1 (0.1 to 15.8) | 0 (0 to 19.5) | 1 (0.1 to 10.6) | |

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse events (including SAEs) would be collected beginning from the time the participant signs the ICF and until the completion of the study.

Adverse event reporting additional description:

ChAdOx1.HTI, MVA.HTI, and vesatolimod were found to be generally safe and well-tolerated, no new safety signal detected.

A TEAE is defined as any event not present before exposure to IMP or any event already present that worsens in either intensity or frequency after exposure to IMP.

| | |
|-----------------|------------|
| Assessment type | Systematic |
|-----------------|------------|

Dictionary used

| | |
|--------------------|--------|
| Dictionary name | MedDRA |
| Dictionary version | 23.0 |

Reporting groups

| | |
|-----------------------|--------------------|
| Reporting group title | CCMM + Vesatolimod |
|-----------------------|--------------------|

Reporting group description:

ChAdOx1.HTI is an immunotherapeutic medicinal product that contains genetically modified organisms (ChAdOx1). MVA.HTI is an investigational immunological product (vaccine) of a biological/biotechnological origin that contains genetically modified organisms (MVA). Vesatolimod (also known as GS-9620) is an orally administered toll-like receptor 7 (TLR7) agonist currently in clinical development for the treatment and remission of HIV-1 infection.

| | |
|-----------------------|---------|
| Reporting group title | Placebo |
|-----------------------|---------|

Reporting group description:

The placebos matched to ChAdOx1.HTI and MVA.HTI were commercially available sterile saline solution (sodium chloride 0.9%).

| Serious adverse events | CCMM + Vesatolimod | Placebo | |
|---|-----------------------|----------------|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 1 / 33 (3.03%) | 0 / 17 (0.00%) | |
| number of deaths (all causes) | 0 | 0 | |
| number of deaths resulting from adverse events | 0 | 0 | |
| Hepatobiliary disorders | | | |
| Cholangitis | | | |
| subjects affected / exposed | 1 / 33 (3.03%) | 0 / 17 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

Frequency threshold for reporting non-serious adverse events: 5 %

| Non-serious adverse events | CCMM + Vesatolimod | Placebo | |
|---|-------------------------------|-------------------|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 32 / 33 (96.97%) | 17 / 17 (100.00%) | |
| Vascular disorders | | | |
| Varicose vein | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 1 / 17 (5.88%) | |
| occurrences (all) | 0 | 1 | |
| General disorders and administration site conditions | | | |
| Injection site pain | | | |
| subjects affected / exposed | 29 / 33 (87.88%) | 5 / 17 (29.41%) | |
| occurrences (all) | 64 | 9 | |
| Influenza like illness | | | |
| subjects affected / exposed | 12 / 33 (36.36%) | 4 / 17 (23.53%) | |
| occurrences (all) | 40 | 5 | |
| Fatigue | | | |
| subjects affected / exposed | 11 / 33 (33.33%) | 4 / 17 (23.53%) | |
| occurrences (all) | 17 | 17 | |
| Asthenia | | | |
| subjects affected / exposed | 5 / 33 (15.15%) | 5 / 17 (29.41%) | |
| occurrences (all) | 11 | 12 | |
| Injection site induration | | | |
| subjects affected / exposed | 7 / 33 (21.21%) | 2 / 17 (11.76%) | |
| occurrences (all) | 10 | 3 | |
| Injection site erythema | | | |
| subjects affected / exposed | 6 / 33 (18.18%) | 2 / 17 (11.76%) | |
| occurrences (all) | 6 | 3 | |
| Malaise | | | |
| subjects affected / exposed | 5 / 33 (15.15%) | 1 / 17 (5.88%) | |
| occurrences (all) | 7 | 1 | |
| Pyrexia | | | |
| subjects affected / exposed | 4 / 33 (12.12%) | 2 / 17 (11.76%) | |
| occurrences (all) | 5 | 2 | |
| Chills | | | |
| subjects affected / exposed | 4 / 33 (12.12%) | 1 / 17 (5.88%) | |
| occurrences (all) | 4 | 3 | |
| Injection site reaction | | | |

| | | | |
|---|-----------------------|----------------------|--|
| subjects affected / exposed occurrences (all) | 3 / 33 (9.09%) 5 | 1 / 17 (5.88%) 1 | |
| Injection site pruritus subjects affected / exposed occurrences (all) | 1 / 33 (3.03%) 1 | 1 / 17 (5.88%) 1 | |
| Vaccination site pain subjects affected / exposed occurrences (all) | 0 / 33 (0.00%) 0 | 2 / 17 (11.76%) 2 | |
| Injection site bruising subjects affected / exposed occurrences (all) | 0 / 33 (0.00%) 0 | 1 / 17 (5.88%) 1 | |
| Injection site warmth subjects affected / exposed occurrences (all) | 0 / 33 (0.00%) 0 | 1 / 17 (5.88%) 1 | |
| Reproductive system and breast disorders Testicular pain subjects affected / exposed occurrences (all) | 0 / 33 (0.00%) 0 | 1 / 17 (5.88%) 1 | |
| Respiratory, thoracic and mediastinal disorders Nasal congestion subjects affected / exposed occurrences (all) | 5 / 33 (15.15%) 16 | 6 / 17 (35.29%) 9 | |
| Cough subjects affected / exposed occurrences (all) | 3 / 33 (9.09%) 3 | 1 / 17 (5.88%) 1 | |
| Rhinorrhoea subjects affected / exposed occurrences (all) | 0 / 33 (0.00%) 0 | 2 / 17 (11.76%) 2 | |
| Psychiatric disorders Anxiety subjects affected / exposed occurrences (all) | 3 / 33 (9.09%) 3 | 4 / 17 (23.53%) 4 | |
| Insomnia subjects affected / exposed occurrences (all) | 1 / 33 (3.03%) 1 | 1 / 17 (5.88%) 1 | |
| Affective disorder | | | |

| | | | |
|---|------------------------|------------------------|--|
| subjects affected / exposed occurrences (all) | 0 / 33 (0.00%) 0 | 1 / 17 (5.88%) 1 | |
| Substance abuse subjects affected / exposed occurrences (all) | 0 / 33 (0.00%) 0 | 1 / 17 (5.88%) 1 | |
| Investigations Mycoplasma test positive subjects affected / exposed occurrences (all) | 0 / 33 (0.00%) 0 | 1 / 17 (5.88%) 1 | |
| Injury, poisoning and procedural complications Procedural pain subjects affected / exposed occurrences (all) | 0 / 33 (0.00%) 0 | 2 / 17 (11.76%) 2 | |
| Vaccination complication subjects affected / exposed occurrences (all) | 1 / 33 (3.03%) 1 | 1 / 17 (5.88%) 1 | |
| Limb injury subjects affected / exposed occurrences (all) | 0 / 33 (0.00%) 0 | 1 / 17 (5.88%) 1 | |
| Penis injury subjects affected / exposed occurrences (all) | 0 / 33 (0.00%) 0 | 1 / 17 (5.88%) 1 | |
| Nervous system disorders Headache subjects affected / exposed occurrences (all) | 16 / 33 (48.48%) 38 | 10 / 17 (58.82%) 21 | |
| Tension headache subjects affected / exposed occurrences (all) | 1 / 33 (3.03%) 2 | 2 / 17 (11.76%) 2 | |
| Dizziness subjects affected / exposed occurrences (all) | 2 / 33 (6.06%) 2 | 0 / 17 (0.00%) 0 | |
| Migraine with aura subjects affected / exposed occurrences (all) | 0 / 33 (0.00%) 0 | 1 / 17 (5.88%) 1 | |
| Myoclonus | | | |

| | | | |
|---|----------------------|-----------------------|--|
| subjects affected / exposed occurrences (all) | 0 / 33 (0.00%) 0 | 1 / 17 (5.88%) 1 | |
| Blood and lymphatic system disorders Lymphadenopathy subjects affected / exposed occurrences (all) | 3 / 33 (9.09%) 3 | 3 / 17 (17.65%) 4 | |
| Lymph node pain subjects affected / exposed occurrences (all) | 0 / 33 (0.00%) 0 | 1 / 17 (5.88%) 1 | |
| Ear and labyrinth disorders Deafness unilateral subjects affected / exposed occurrences (all) | 0 / 33 (0.00%) 0 | 1 / 17 (5.88%) 1 | |
| Ear pain subjects affected / exposed occurrences (all) | 0 / 33 (0.00%) 0 | 1 / 17 (5.88%) 1 | |
| Eye disorders Conjunctivitis allergic subjects affected / exposed occurrences (all) | 0 / 33 (0.00%) 0 | 1 / 17 (5.88%) 1 | |
| Photopsia subjects affected / exposed occurrences (all) | 0 / 33 (0.00%) 0 | 1 / 17 (5.88%) 1 | |
| Gastrointestinal disorders Nausea subjects affected / exposed occurrences (all) | 6 / 33 (18.18%) 6 | 6 / 17 (35.29%) 11 | |
| Diarrhoea subjects affected / exposed occurrences (all) | 5 / 33 (15.15%) 6 | 6 / 17 (35.29%) 7 | |
| Abdominal pain subjects affected / exposed occurrences (all) | 3 / 33 (9.09%) 4 | 2 / 17 (11.76%) 2 | |
| Proctalgia subjects affected / exposed occurrences (all) | 2 / 33 (6.06%) 3 | 1 / 17 (5.88%) 1 | |
| Dyspepsia | | | |

| | | | |
|---|------------------|-----------------|--|
| subjects affected / exposed | 1 / 33 (3.03%) | 1 / 17 (5.88%) | |
| occurrences (all) | 1 | 1 | |
| Haemorrhoids | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 2 / 17 (11.76%) | |
| occurrences (all) | 0 | 2 | |
| Toothache | | | |
| subjects affected / exposed | 1 / 33 (3.03%) | 1 / 17 (5.88%) | |
| occurrences (all) | 1 | 1 | |
| Vomiting | | | |
| subjects affected / exposed | 1 / 33 (3.03%) | 1 / 17 (5.88%) | |
| occurrences (all) | 1 | 2 | |
| Constipation | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 1 / 17 (5.88%) | |
| occurrences (all) | 0 | 1 | |
| Odynophagia | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 1 / 17 (5.88%) | |
| occurrences (all) | 0 | 1 | |
| Oropharyngeal pain | | | |
| subjects affected / exposed | 2 / 33 (6.06%) | 2 / 17 (11.76%) | |
| occurrences (all) | 3 | 2 | |
| Skin and subcutaneous tissue disorders | | | |
| Rash | | | |
| subjects affected / exposed | 2 / 33 (6.06%) | 0 / 17 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed | 11 / 33 (33.33%) | 1 / 17 (5.88%) | |
| occurrences (all) | 12 | 3 | |
| Myalgia | | | |
| subjects affected / exposed | 9 / 33 (27.27%) | 2 / 17 (11.76%) | |
| occurrences (all) | 12 | 4 | |
| Back pain | | | |
| subjects affected / exposed | 4 / 33 (12.12%) | 2 / 17 (11.76%) | |
| occurrences (all) | 5 | 2 | |
| Muscle spasms | | | |

| | | | |
|-----------------------------------|-----------------|-----------------|--|
| subjects affected / exposed | 0 / 33 (0.00%) | 1 / 17 (5.88%) | |
| occurrences (all) | 0 | 1 | |
| Musculoskeletal pain | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 1 / 17 (5.88%) | |
| occurrences (all) | 0 | 1 | |
| Pain in extremity | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 1 / 17 (5.88%) | |
| occurrences (all) | 0 | 1 | |
| Rotator cuff syndrome | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 1 / 17 (5.88%) | |
| occurrences (all) | 0 | 1 | |
| Temporomandibular joint syndrome | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 1 / 17 (5.88%) | |
| occurrences (all) | 0 | 1 | |
| Infections and infestations | | | |
| COVID-19 | | | |
| subjects affected / exposed | 9 / 33 (27.27%) | 7 / 17 (41.18%) | |
| occurrences (all) | 9 | 7 | |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 6 / 33 (18.18%) | 4 / 17 (23.53%) | |
| occurrences (all) | 6 | 5 | |
| Nasopharyngitis | | | |
| subjects affected / exposed | 5 / 33 (15.15%) | 2 / 17 (11.76%) | |
| occurrences (all) | 7 | 3 | |
| Syphilis | | | |
| subjects affected / exposed | 3 / 33 (9.09%) | 2 / 17 (11.76%) | |
| occurrences (all) | 3 | 2 | |
| Proctitis gonococcal | | | |
| subjects affected / exposed | 2 / 33 (6.06%) | 2 / 17 (11.76%) | |
| occurrences (all) | 2 | 2 | |
| Tonsillitis | | | |
| subjects affected / exposed | 1 / 33 (3.03%) | 2 / 17 (11.76%) | |
| occurrences (all) | 1 | 2 | |
| Bronchitis | | | |
| subjects affected / exposed | 2 / 33 (6.06%) | 0 / 17 (0.00%) | |
| occurrences (all) | 2 | 0 | |

| | | |
|------------------------------------|----------------|----------------|
| Folliculitis | | |
| subjects affected / exposed | 1 / 33 (3.03%) | 1 / 17 (5.88%) |
| occurrences (all) | 1 | 1 |
| Hordeolum | | |
| subjects affected / exposed | 1 / 33 (3.03%) | 1 / 17 (5.88%) |
| occurrences (all) | 1 | 1 |
| Oral herpes | | |
| subjects affected / exposed | 1 / 33 (3.03%) | 1 / 17 (5.88%) |
| occurrences (all) | 1 | 1 |
| Oropharyngeal gonococcal infection | | |
| subjects affected / exposed | 1 / 33 (3.03%) | 1 / 17 (5.88%) |
| occurrences (all) | 1 | 1 |
| Pharyngeal chlamydia infection | | |
| subjects affected / exposed | 1 / 33 (3.03%) | 1 / 17 (5.88%) |
| occurrences (all) | 1 | 1 |
| Tinea versicolour | | |
| subjects affected / exposed | 1 / 33 (3.03%) | 1 / 17 (5.88%) |
| occurrences (all) | 1 | 1 |
| Urethritis gonococcal | | |
| subjects affected / exposed | 2 / 33 (6.06%) | 0 / 17 (0.00%) |
| occurrences (all) | 2 | 0 |
| Furuncle | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 1 / 17 (5.88%) |
| occurrences (all) | 0 | 1 |
| Gastroenteritis shigella | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 1 / 17 (5.88%) |
| occurrences (all) | 0 | 1 |
| Genital herpes simplex | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 1 / 17 (5.88%) |
| occurrences (all) | 0 | 1 |
| Gonorrhoea | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 1 / 17 (5.88%) |
| occurrences (all) | 0 | 1 |
| Latent syphilis | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 1 / 17 (5.88%) |
| occurrences (all) | 0 | 1 |

| | | | |
|------------------------------------|----------------|-----------------|--|
| Oral candidiasis | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 1 / 17 (5.88%) | |
| occurrences (all) | 0 | 1 | |
| Pharyngitis | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 1 / 17 (5.88%) | |
| occurrences (all) | 0 | 2 | |
| Proctitis chlamydial | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 1 / 17 (5.88%) | |
| occurrences (all) | 0 | 1 | |
| Ureaplasma infection | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 1 / 17 (5.88%) | |
| occurrences (all) | 0 | 1 | |
| Viral infection | | | |
| subjects affected / exposed | 0 / 33 (0.00%) | 1 / 17 (5.88%) | |
| occurrences (all) | 0 | 1 | |
| Metabolism and nutrition disorders | | | |
| Decreased appetite | | | |
| subjects affected / exposed | 3 / 33 (9.09%) | 3 / 17 (17.65%) | |
| occurrences (all) | 5 | 8 | |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|-------------------|---|
| 07 October 2019 | <p>The following is a summary of the major changes implemented with Protocol Amendment 2 (substantial), dated 07 Oct 2019:</p> <ul style="list-style-type: none">• The vesatolimod dose was reduced from 8 mg to 6 mg and study monitoring plan following the first dose of vesatolimod and subsequent doses was updated to include a 24-hour on-site admission period following the first dose and an 8-hour observation period following subsequent doses to monitor for CRS.• The study was simplified by removing the GALT substudy, eliminating 2 treatment arms (and reducing the number of participants), and eliminating the sentinel dosing cohort (based on safety data from another study).• The size of intensive PK substudy was reduced from 18 to 15 participants.• The number of participants was changed to 57 (38 in the CCMM + vesatolimod group and 19 in the placebo group).• The randomization stratification by sentinel and non-sentinel cohorts was removed.• Stratification based on the potential for superior viral control (based on HLA genotype) was added. |
| 24 September 2020 | <p>The following is a summary of the major changes implemented with Protocol Amendment 4 (substantial), dated 24 Sep 2020:</p> <ul style="list-style-type: none">• Text was added to introduce the conduct of the study during the COVID-19 pandemic, including the benefit-risk assessment of ChAdOx1. HTI, MVA.HTI, and vesatolimod, and the measures taken during the COVID-19 pandemic, such as SARS CoV 2 PCR, serological tests, and remote visits in relation to vesatolimod/placebo administration and certain non-IMP dosing visits.• Safety data of the relevant clinical studies on the study vaccines were updated based on the latest DSUR, dated on 08 Apr 2020. |

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported