



## Clinical trial results:

### An Open-label, Active-Controlled, Safety and Efficacy Study of Oral Baricitinib in Patients from 2 Years to Less Than 18 Years Old with Active Juvenile Idiopathic Arthritis-Associated Uveitis or Chronic Anterior Antinuclear Antibody Positive Uveitis

#### Summary

|                          |                |
|--------------------------|----------------|
| EudraCT number           | 2019-000119-10 |
| Trial protocol           | GB FR DE IT    |
| Global end of trial date |                |

#### Results information

|                                |                |
|--------------------------------|----------------|
| Result version number          | v1 (current)   |
| This version publication date  | 02 August 2024 |
| First version publication date | 02 August 2024 |

#### Trial information

##### Trial identification

|                       |             |
|-----------------------|-------------|
| Sponsor protocol code | I4V-MC-JAHW |
|-----------------------|-------------|

##### Additional study identifiers

|                                    |                     |
|------------------------------------|---------------------|
| ISRCTN number                      | -                   |
| ClinicalTrials.gov id (NCT number) | NCT04088409         |
| WHO universal trial number (UTN)   | -                   |
| Other trial identifiers            | Trial Number: 16277 |

Notes:

##### Sponsors

|                              |   |
|------------------------------|---|
| Sponsor organisation name    | Eli Lilly and Company   |
| Sponsor organisation address | Lilly Corporate Center, Indianapolis, IN, United States, 46285            |
| Public contact               | Available Mon - Fri 9 AM - 5 PM EST, Eli Lilly and Company, 1 877CTLilly, |
| Scientific contact           | Available Mon - Fri 9 AM - 5 PM EST, Eli Lilly and Company, 1 8772854559, |

Notes:

##### Paediatric regulatory details

|  |                     |
|--|---------------------|
| Is trial part of an agreed paediatric investigation plan (PIP)       | Yes                 |
| EMA paediatric investigation plan number(s)                          | EMA-001220-PIP01-11 |
| 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                                       | Interim      |
| Date of interim/final analysis                       | 17 July 2023 |
| Is this the analysis of the primary completion data? | Yes          |
| Primary completion date                              | 17 July 2023 |
| Global end of trial reached?                         | No           |

Notes:

## General information about the trial

Main objective of the trial:

The reason for this study is to see if the study drug baricitinib given orally is safe and effective in participants with active juvenile idiopathic arthritis (JIA)-associated uveitis or chronic anterior antinuclear antibody-positive uveitis from 2 years to less than 18 years old.

Protection of trial subjects:

This study was conducted in accordance with International Conference on Harmonization (ICH) Good Clinical Practice, and the principles of the Declaration of Helsinki, in addition to following the laws and regulations of the country or countries in which a study is conducted.

Background therapy: -

Evidence for comparator: -

|   |                 |
|---|-----------------|
| Actual start date of recruitment                          | 16 October 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 | France: 4          |
| Country: Number of subjects enrolled | Germany: 2         |
| Country: Number of subjects enrolled | Italy: 5           |
| Country: Number of subjects enrolled | Spain: 3           |
| Country: Number of subjects enrolled | United Kingdom: 15 |
| Worldwide total number of subjects   | 29                 |
| EEA total number of subjects         | 14                 |

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)                     | 16 |
| Adolescents (12-17 years)                 | 13 |
| Adults (18-64 years)                      | 0  |

|                     |   |
|---------------------|---|
| From 65 to 84 years | 0 |
| 85 years and over   | 0 |

## Subject disposition

### Recruitment

Recruitment details:

Overall, 30 participants were enrolled in the study. One participant (in baricitinib arm) withdrew from the study before administration of the study drug. This study is conducted in 2 parts. Part A (24 weeks) and Part B (260 weeks). Participants assigned to baricitinib and completed the Part A as a responder continued receiving (contd..)

### Pre-assignment

Screening details:

(contd..) baricitinib until the end of study or discontinuation from the study.

### Period 1

|                              |                         |
|------------------------------|-------------------------|
| Period 1 title               | Part A                  |
| Is this the baseline period? | Yes                     |
| Allocation method            | Randomised - controlled |
| Blinding used                | Not blinded             |

### Arms

|                              |             |
|------------------------------|-------------|
| Are arms mutually exclusive? | Yes         |
| <b>Arm title</b>             | Baricitinib |

Arm description:

Participants  $\geq 9$  to  $< 18$  years of age were administered 4 milligrams (mg) baricitinib once daily (QD). Participants  $< 9$  years of age were administered 2 mg baricitinib QD. Participants  $< 6$  years of age received an oral suspension. Participants  $\geq 6$  to  $< 12$  years of age had the option of receiving an oral suspension. Participants  $> 12$  years of age were supplied tablets.

|  |                                |
|--|--------------------------------|
| Arm type                               | Experimental                   |
| Investigational medicinal product name | Baricitinib                    |
| Investigational medicinal product code |                                |
| Other name                             | LY3009104                      |
| Pharmaceutical forms                   | Tablet, Oral drops, suspension |
| Routes of administration               | Oral use                       |

Dosage and administration details:

Administered orally

|                  |            |
|------------------|------------|
| <b>Arm title</b> | Adalimumab |
|------------------|------------|

Arm description:

Participants received adalimumab administered subcutaneously (SC) once every 2 weeks. The dose was based on body weight: 20 mg every 2 weeks for participants weighing  $< 30$  kilograms (kg), or 40 mg every 2 weeks for participants weighing  $\geq 30$  kg.

|  |                   |
|--|-------------------|
| Arm type                               | Active comparator |
| Investigational medicinal product name | Adalimumab        |
| Investigational medicinal product code |                   |
| Other name                             |                   |
| Pharmaceutical forms                   | Injection         |
| Routes of administration               | Subcutaneous use  |

Dosage and administration details:

Administered SC

| Number of subjects in period 1                | Baricitinib | Adalimumab |
|---|-------------|------------|
| Started                                       | 24          | 5          |
| Received At Least 1 Dose of Study Drug        | 24          | 5          |
| Completed                                     | 10          | 0          |
| Not completed                                 | 14          | 5          |
| Consent withdrawn by subject                  | 1           | 1          |
| Adverse event, non-fatal                      | 1           | -          |
| Did Not Meet Randomization Criteria           | 2           | -          |
| Lost to follow-up                             | 1           | -          |
| Per Protocol, Participants Discontinued Study | -           | 4          |
| Lack of efficacy                              | 9           | -          |

## Period 2

|                              |                             |
|------------------------------|-----------------------------|
| Period 2 title               | Part B                      |
| Is this the baseline period? | No                          |
| Allocation method            | Non-randomised - controlled |
| Blinding used                | Not blinded                 |

## Arms

|           |             |
|-----------|-------------|
| Arm title | Baricitinib |
|-----------|-------------|

### Arm description:

Participants  $\geq 9$  to  $< 18$  years of age were administered 4 milligrams (mg) baricitinib once daily (QD).

Participants  $< 9$  years of age were administered 2 mg baricitinib QD.

Participants  $< 6$  years of age received an oral suspension. Participants  $\geq 6$  to  $< 12$  years of age had the option of receiving an oral suspension. Participants  $> 12$  years of age were supplied tablets.

|  |                         |
|--|-------------------------|
| Arm type                               | Experimental            |
| Investigational medicinal product name | Baricitinib             |
| Investigational medicinal product code |                         |
| Other name                             | LY3009104               |
| Pharmaceutical forms                   | Oral suspension, Tablet |
| Routes of administration               | Oral use                |

### Dosage and administration details:

Administered orally

| Number of subjects in period 2 | Baricitinib |
|--------------------------------|-------------|
| Started                        | 10          |
| Completed                      | 0           |
| Not completed                  | 10          |
| Ongoing Treatment              | 10          |



## Baseline characteristics

### Reporting groups

|                       |             |
|-----------------------|-------------|
| Reporting group title | Baricitinib |
|-----------------------|-------------|

Reporting group description:

Participants  $\geq 9$  to  $< 18$  years of age were administered 4 milligrams (mg) baricitinib once daily (QD).

Participants  $< 9$  years of age were administered 2 mg baricitinib QD.

Participants  $< 6$  years of age received an oral suspension. Participants  $\geq 6$  to  $< 12$  years of age had the option of receiving an oral suspension. Participants  $> 12$  years of age were supplied tablets.

|                       |            |
|-----------------------|------------|
| Reporting group title | Adalimumab |
|-----------------------|------------|

Reporting group description:

Participants received adalimumab administered subcutaneously (SC) once every 2 weeks. The dose was based on body weight: 20 mg every 2 weeks for participants weighing  $< 30$  kilograms (kg), or 40 mg

every 2 weeks for participants weighing  $\geq 30$  kg.

| Reporting group values | Baricitinib | Adalimumab | Total |
|------------------------|-------------|------------|-------|
| Number of subjects     | 24          | 5          | 29    |
| Age categorical        |             |            |       |
| Units: Subjects        |             |            |       |

|   |            |            |    |
|---|------------|------------|----|
| Age continuous                            |            |            |    |
| Units: years                              |            |            |    |
| arithmetic mean                           | 11.60      | 6.60       |    |
| standard deviation                        | $\pm 3.53$ | $\pm 2.51$ | -  |
| Gender categorical                        |            |            |    |
| Units: Subjects                           |            |            |    |
| Female                                    | 14         | 5          | 19 |
| Male                                      | 10         | 0          | 10 |
| Ethnicity (NIH/OMB)                       |            |            |    |
| Units: Subjects                           |            |            |    |
| Hispanic or Latino                        | 2          | 0          | 2  |
| Not Hispanic or Latino                    | 12         | 4          | 16 |
| Unknown or Not Reported                   | 10         | 1          | 11 |
| Race (NIH/OMB)                            |            |            |    |
| Units: Subjects                           |            |            |    |
| American Indian or Alaska Native          | 0          | 0          | 0  |
| Asian                                     | 0          | 0          | 0  |
| Native Hawaiian or Other Pacific Islander | 0          | 0          | 0  |
| Black or African American                 | 0          | 1          | 1  |
| White                                     | 20         | 4          | 24 |
| More than one race                        | 0          | 0          | 0  |
| Unknown or Not Reported                   | 4          | 0          | 4  |
| Region of Enrollment                      |            |            |    |
| Units: Subjects                           |            |            |    |
| France                                    | 4          | 0          | 4  |
| Germany                                   | 1          | 1          | 2  |
| Italy                                     | 3          | 2          | 5  |
| Spain                                     | 3          | 0          | 3  |
| United Kingdom                            | 13         | 2          | 15 |

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## Subject analysis sets

|                            |              |
|----------------------------|--------------|
| Subject analysis set title | Baricitinib  |
| Subject analysis set type  | Per protocol |

Subject analysis set description:

Participants  $\geq 9$  to  $< 18$  years of age were administered 4 mg baricitinib QD. Participants  $< 9$  years of age were administered 2 mg baricitinib QD.

Participants  $< 6$  years of age received an oral suspension. Participants  $\geq 6$  to  $< 12$  years of age had the option of receiving an oral suspension. Participants  $> 12$  years of age were supplied tablets.

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|                               |             |  |  |
|-------------------------------|-------------|--|--|
| <b>Reporting group values</b> | Baricitinib |  |  |
| Number of subjects            | 24          |  |  |
| Age categorical               |             |  |  |
| Units: Subjects               |             |  |  |

|   |            |  |  |
|---|------------|--|--|
| Age continuous                            |            |  |  |
| Units: years                              |            |  |  |
| arithmetic mean                           | 11.60      |  |  |
| standard deviation                        | $\pm 3.53$ |  |  |
| Gender categorical                        |            |  |  |
| Units: Subjects                           |            |  |  |
| Female                                    | 14         |  |  |
| Male                                      | 10         |  |  |
| Ethnicity (NIH/OMB)                       |            |  |  |
| Units: Subjects                           |            |  |  |
| Hispanic or Latino                        | 2          |  |  |
| Not Hispanic or Latino                    | 12         |  |  |
| Unknown or Not Reported                   | 10         |  |  |
| Race (NIH/OMB)                            |            |  |  |
| Units: Subjects                           |            |  |  |
| American Indian or Alaska Native          | 0          |  |  |
| Asian                                     | 0          |  |  |
| Native Hawaiian or Other Pacific Islander | 0          |  |  |
| Black or African American                 | 0          |  |  |
| White                                     | 20         |  |  |
| More than one race                        | 0          |  |  |
| Unknown or Not Reported                   | 4          |  |  |
| Region of Enrollment                      |            |  |  |
| Units: Subjects                           |            |  |  |
| France                                    | 4          |  |  |
| Germany                                   | 1          |  |  |
| Italy                                     | 3          |  |  |
| Spain                                     | 3          |  |  |
| United Kingdom                            | 13         |  |  |

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## End points

### End points reporting groups

|  |              |
|--|--------------|
| Reporting group title  | Baricitinib  |
| Reporting group description:<br>Participants $\geq 9$ to $< 18$ years of age were administered 4 milligrams (mg) baricitinib once daily (QD).<br>Participants $< 9$ years of age were administered 2 mg baricitinib QD.<br>Participants $< 6$ years of age received an oral suspension. Participants $\geq 6$ to $< 12$ years of age had the option of receiving an oral suspension. Participants $> 12$ years of age were supplied tablets. |              |
| Reporting group title  | Adalimumab   |
| Reporting group description:<br>Participants received adalimumab administered subcutaneously (SC) once every 2 weeks. The dose was based on body weight: 20 mg every 2 weeks for participants weighing $< 30$ kilograms (kg), or 40 mg every 2 weeks for participants weighing $\geq 30$ kg.   |              |
| Reporting group title  | Baricitinib  |
| Reporting group description:<br>Participants $\geq 9$ to $< 18$ years of age were administered 4 milligrams (mg) baricitinib once daily (QD).<br>Participants $< 9$ years of age were administered 2 mg baricitinib QD.<br>Participants $< 6$ years of age received an oral suspension. Participants $\geq 6$ to $< 12$ years of age had the option of receiving an oral suspension. Participants $> 12$ years of age were supplied tablets. |              |
| Subject analysis set title   | Baricitinib  |
| Subject analysis set type  | Per protocol |
| Subject analysis set description:<br>Participants $\geq 9$ to $< 18$ years of age were administered 4 mg baricitinib QD. Participants $< 9$ years of age were administered 2 mg baricitinib QD.<br>Participants $< 6$ years of age received an oral suspension. Participants $\geq 6$ to $< 12$ years of age had the option of receiving an oral suspension. Participants $> 12$ years of age were supplied tablets.                         |              |

### Primary: Part A: Percentage of Responders for Baricitinib at Week 24

|   |   |
|---|---|
| End point title   | Part A: Percentage of Responders for Baricitinib at Week 24 <sup>[1][2]</sup> |
| End point description:<br>Response was defined according to the Standardization of Uveitis Nomenclature (SUN) criteria as a 2-step decrease in the level of inflammation (anterior chamber cells) or decrease to zero through week 24, in the eye most severely affected at baseline.<br>Analysis population description: All participants who received at least one dose of baricitinib in Part A. |   |
| End point type  | Primary   |
| End point timeframe:<br>Week 24   |   |

#### 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 inferential statistics was planned for this end point.

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Descriptive statistics was added in baseline period reporting arms. The complete results will be disclosed after the study is completed.

| End point values                  | Baricitinib     |  |  |  |
|-----------------------------------|-----------------|--|--|--|
| Subject group type                | Reporting group |  |  |  |
| Number of subjects analysed       | 24              |  |  |  |
| Units: Percentage of participants |                 |  |  |  |
| number (not applicable)           | 33.3            |  |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Change from Baseline in SUN Grade of Cells in the Anterior Chamber in the Most Severely Affected Eye

|                 |   |
|-----------------|---|
| End point title | Change from Baseline in SUN Grade of Cells in the Anterior Chamber in the Most Severely Affected Eye <sup>[3]</sup> |
|-----------------|---|

End point description:

Outcome data will be provided after the study is completed.

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Baseline, Week 24

Notes:

[3] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Descriptive statistics was added in baseline period reporting arms. The complete results will be disclosed after the study is completed.

|                             |                  |  |  |  |
|-----------------------------|------------------|--|--|--|
| <b>End point values</b>     | Baricitinib      |  |  |  |
| Subject group type          | Reporting group  |  |  |  |
| Number of subjects analysed | 0 <sup>[4]</sup> |  |  |  |
| Units: Score on a Scale     |                  |  |  |  |
| number (not applicable)     |                  |  |  |  |

Notes:

[4] - Outcome data will be provided after the study is completed.

## Statistical analyses

No statistical analyses for this end point

### Secondary: Change from Baseline in SUN Grade of Cells in the Anterior Chamber in the Less Severely Affected Eye (If Applicable)

|                 |   |
|-----------------|---|
| End point title | Change from Baseline in SUN Grade of Cells in the Anterior Chamber in the Less Severely Affected Eye (If Applicable) <sup>[5]</sup> |
|-----------------|---|

End point description:

Outcome data will be provided after the study is completed.

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Baseline, Week 24

Notes:

[5] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Descriptive statistics was added in baseline period reporting arms. The complete results will be disclosed after the study is completed.

| End point values            | Baricitinib      |  |  |  |
|-----------------------------|------------------|--|--|--|
| Subject group type          | Reporting group  |  |  |  |
| Number of subjects analysed | 0 <sup>[6]</sup> |  |  |  |
| Units: score on a Scale     |                  |  |  |  |
| number (not applicable)     |                  |  |  |  |

Notes:

[6] - Outcome data will be provided after the study is completed.

## Statistical analyses

No statistical analyses for this end point

### Secondary: Percentage of Responders in Participants with Bilateral Uveitis Disease at Baseline

|                 |  |
|-----------------|--|
| End point title | Percentage of Responders in Participants with Bilateral Uveitis Disease at Baseline <sup>[7]</sup> |
|-----------------|--|

End point description:

Outcome data will be provided after the study is completed.

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Week 24

Notes:

[7] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Descriptive statistics was added in baseline period reporting arms. The complete results will be disclosed after the study is completed.

| End point values                  | Baricitinib      |  |  |  |
|-----------------------------------|------------------|--|--|--|
| Subject group type                | Reporting group  |  |  |  |
| Number of subjects analysed       | 0 <sup>[8]</sup> |  |  |  |
| Units: Percentage of Participants |                  |  |  |  |
| number (not applicable)           |                  |  |  |  |

Notes:

[8] - Outcome data will be provided after the study is completed.

## Statistical analyses

No statistical analyses for this end point

### Secondary: Change from Baseline in Visual Acuity Measured by Age-AppropriateLogarithm of the Minimum Angle of Resolution (LogMAR) Test

|                 |  |
|-----------------|--|
| End point title | Change from Baseline in Visual Acuity Measured by Age-AppropriateLogarithm of the Minimum Angle of Resolution (LogMAR) Test <sup>[9]</sup> |
|-----------------|--|

End point description:

Outcome data will be provided after the study is completed.

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Baseline, Week 24

Notes:

[9] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: Descriptive statistics was added in baseline period reporting arms. The complete results will be disclosed after the study is completed.

| End point values            | Baricitinib       |  |  |  |
|-----------------------------|-------------------|--|--|--|
| Subject group type          | Reporting group   |  |  |  |
| Number of subjects analysed | 0 <sup>[10]</sup> |  |  |  |
| Units: Score on a Scale     |                   |  |  |  |
| number (not applicable)     |                   |  |  |  |

Notes:

[10] - Outcome data will be provided after the study is completed.

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change from Baseline in Vitreous Haze

|   |   |
|---|---|
| End point title   | Change from Baseline in Vitreous Haze <sup>[11]</sup> |
| End point description:                                      |   |
| Outcome data will be provided after the study is completed. |   |
| End point type  | Secondary   |
| End point timeframe:  |   |
| Baseline, Week 24   |   |

Notes:

[11] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: Descriptive statistics was added in baseline period reporting arms. The complete results will be disclosed after the study is completed.

| End point values            | Baricitinib       |  |  |  |
|-----------------------------|-------------------|--|--|--|
| Subject group type          | Reporting group   |  |  |  |
| Number of subjects analysed | 0 <sup>[12]</sup> |  |  |  |
| Units: Score on a Scale     |                   |  |  |  |
| number (not applicable)     |                   |  |  |  |

Notes:

[12] - Outcome data will be provided after the study is completed.

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change from Baseline in Grade of Flare in the Anterior Chamber

|   |  |
|---|--|
| End point title   | Change from Baseline in Grade of Flare in the Anterior Chamber <sup>[13]</sup> |
| End point description:                                      |  |
| Outcome data will be provided after the study is completed. |  |
| End point type  | Secondary  |
| End point timeframe:  |  |
| Baseline, Week 24   |  |

Notes:

[13] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Descriptive statistics was added in baseline period reporting arms. The complete results will be disclosed after the study is completed.

| End point values            | Baricitinib       |  |  |  |
|-----------------------------|-------------------|--|--|--|
| Subject group type          | Reporting group   |  |  |  |
| Number of subjects analysed | 0 <sup>[14]</sup> |  |  |  |
| Units: Score on a Scale     |                   |  |  |  |
| number (not applicable)     |                   |  |  |  |

Notes:

[14] - Outcome data will be provided after the study is completed.

## Statistical analyses

No statistical analyses for this end point

## Secondary: Percentage of Participants with Inactive Anterior Uveitis (usingSUN Definition)

|                 |   |
|-----------------|---|
| End point title | Percentage of Participants with Inactive Anterior Uveitis (usingSUN Definition) <sup>[15]</sup> |
|-----------------|---|

End point description:

Outcome data will be provided after the study is completed.

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Week 24

Notes:

[15] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Descriptive statistics was added in baseline period reporting arms. The complete results will be disclosed after the study is completed.

| End point values                  | Baricitinib       |  |  |  |
|-----------------------------------|-------------------|--|--|--|
| Subject group type                | Reporting group   |  |  |  |
| Number of subjects analysed       | 0 <sup>[16]</sup> |  |  |  |
| Units: Percentage of Participants |                   |  |  |  |
| number (not applicable)           |                   |  |  |  |

Notes:

[16] - Outcome data will be provided after the study is completed.

## Statistical analyses

No statistical analyses for this end point

## Secondary: Time to Inactive Anterior Uveitis Disease (Using SUNDefinition)

|                 |  |
|-----------------|--|
| End point title | Time to Inactive Anterior Uveitis Disease (Using |
|-----------------|--|

End point description:

Outcome data will be provided after the study is completed.

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Baseline, Week 24

Notes:

[17] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Descriptive statistics was added in baseline period reporting arms. The complete results will be disclosed after the study is completed.

| End point values            | Baricitinib       |  |  |  |
|-----------------------------|-------------------|--|--|--|
| Subject group type          | Reporting group   |  |  |  |
| Number of subjects analysed | 0 <sup>[18]</sup> |  |  |  |
| Units: Weeks                |                   |  |  |  |
| number (not applicable)     |                   |  |  |  |

Notes:

[18] - Outcome data will be provided after the study is completed.

## Statistical analyses

No statistical analyses for this end point

## Secondary: Percentage of Participants who are Able to Taper Concomitant Topical Corticosteroids to <2 Drops Per Day

|                 |  |
|-----------------|--|
| End point title | Percentage of Participants who are Able to Taper Concomitant Topical Corticosteroids to <2 Drops Per Day <sup>[19]</sup> |
|-----------------|--|

End point description:

Outcome data will be provided after the study is completed.

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Week 24

Notes:

[19] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Descriptive statistics was added in baseline period reporting arms. The complete results will be disclosed after the study is completed.

| End point values                  | Baricitinib       |  |  |  |
|-----------------------------------|-------------------|--|--|--|
| Subject group type                | Reporting group   |  |  |  |
| Number of subjects analysed       | 0 <sup>[20]</sup> |  |  |  |
| Units: Percentage of Participants |                   |  |  |  |
| number (not applicable)           |                   |  |  |  |

Notes:

[20] - Outcome data will be provided after the study is completed.

## Statistical analyses

No statistical analyses for this end point

## Secondary: Pediatric American College of Rheumatology (PediACR30) Response Rate (For Participants with JIA-U)

|                 |  |
|-----------------|--|
| End point title | Pediatric American College of Rheumatology (PediACR30) Response Rate (For Participants with JIA-U) <sup>[21]</sup> |
|-----------------|--|

End point description:

Outcome data will be provided after the study is completed.

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Week 24

Notes:

[21] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Descriptive statistics was added in baseline period reporting arms. The complete results will be disclosed after the study is completed.

| End point values                  | Baricitinib       |  |  |  |
|-----------------------------------|-------------------|--|--|--|
| Subject group type                | Reporting group   |  |  |  |
| Number of subjects analysed       | 0 <sup>[22]</sup> |  |  |  |
| Units: Percentage of Participants |                   |  |  |  |
| number (not applicable)           |                   |  |  |  |

Notes:

[22] - Outcome data will be provided after the study is completed.

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change from Baseline in Overall Uveitis-Related Disability

|                 |  |
|-----------------|--|
| End point title | Change from Baseline in Overall Uveitis-Related Disability <sup>[23]</sup> |
|-----------------|--|

End point description:

Outcome data will be provided after the study is completed.

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Baseline, Week 24

Notes:

[23] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Descriptive statistics was added in baseline period reporting arms. The complete results will be disclosed after the study is completed.

| End point values            | Baricitinib       |  |  |  |
|-----------------------------|-------------------|--|--|--|
| Subject group type          | Reporting group   |  |  |  |
| Number of subjects analysed | 0 <sup>[24]</sup> |  |  |  |
| Units: Score on a Scale     |                   |  |  |  |
| number (not applicable)     |                   |  |  |  |

Notes:

[24] - Outcome data will be provided after the study is completed.

## Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Baseline To Up To 55 Weeks

Adverse event reporting additional description:

I4V-MC-JAHW

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

### Dictionary used

|                 |        |
|-----------------|--------|
| Dictionary name | MedDRA |
|-----------------|--------|

|                    |      |
|--------------------|------|
| Dictionary version | 26.1 |
|--------------------|------|

### Reporting groups

|                       |            |
|-----------------------|------------|
| Reporting group title | Adalimumab |
|-----------------------|------------|

Reporting group description: -

|                       |             |
|-----------------------|-------------|
| Reporting group title | Baricitinib |
|-----------------------|-------------|

Reporting group description: -

| Serious adverse events                            | Adalimumab     | Baricitinib    |  |
|---|----------------|----------------|--|
| Total subjects affected by serious adverse events |                |                |  |
| subjects affected / exposed                       | 1 / 5 (20.00%) | 2 / 24 (8.33%) |  |
| number of deaths (all causes)                     | 0              | 0              |  |
| number of deaths resulting from adverse events    |                |                |  |
| Injury, poisoning and procedural complications    |                |                |  |
| intentional overdose                              |                |                |  |
| alternative dictionary used: MedDRA 26.1          |                |                |  |
| subjects affected / exposed                       | 0 / 5 (0.00%)  | 1 / 24 (4.17%) |  |
| occurrences causally related to treatment / all   | 0 / 0          | 0 / 1          |  |
| deaths causally related to treatment / all        | 0 / 0          | 0 / 0          |  |
| Eye disorders                                     |                |                |  |
| uveitis   |                |                |  |
| alternative dictionary used: MedDRA 26.1          |                |                |  |
| subjects affected / exposed                       | 0 / 5 (0.00%)  | 1 / 24 (4.17%) |  |
| occurrences causally related to treatment / all   | 0 / 0          | 0 / 1          |  |
| deaths causally related to treatment / all        | 0 / 0          | 0 / 0          |  |
| Musculoskeletal and connective tissue disorders   |                |                |  |
| juvenile idiopathic arthritis                     |                |                |  |
| alternative dictionary used: MedDRA 26.1          |                |                |  |



|   |                |                |  |
|---|----------------|----------------|--|
| subjects affected / exposed                     | 1 / 5 (20.00%) | 0 / 24 (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 %

| <b>Non-serious adverse events</b>   | Adalimumab          | Baricitinib         |  |
|---|---------------------|---------------------|--|
| Total subjects affected by non-serious adverse events   |                     |                     |  |
| subjects affected / exposed   | 4 / 5 (80.00%)      | 16 / 24 (66.67%)    |  |
| Investigations  |                     |                     |  |
| alanine aminotransferase increased<br>alternative dictionary used:<br>MedDRA 26.1<br>subjects affected / exposed<br>occurrences (all)   | 1 / 5 (20.00%)<br>1 | 0 / 24 (0.00%)<br>0 |  |
| blood triglycerides increased<br>alternative dictionary used:<br>MedDRA 26.1<br>subjects affected / exposed<br>occurrences (all)        | 1 / 5 (20.00%)<br>1 | 1 / 24 (4.17%)<br>1 |  |
| blood bilirubin increased<br>alternative dictionary used:<br>MedDRA 26.1<br>subjects affected / exposed<br>occurrences (all)            | 1 / 5 (20.00%)<br>1 | 0 / 24 (0.00%)<br>0 |  |
| aspartate aminotransferase increased<br>alternative dictionary used:<br>MedDRA 26.1<br>subjects affected / exposed<br>occurrences (all) | 1 / 5 (20.00%)<br>1 | 0 / 24 (0.00%)<br>0 |  |
| bilirubin conjugated increased<br>alternative dictionary used:<br>MedDRA 26.1<br>subjects affected / exposed<br>occurrences (all)       | 1 / 5 (20.00%)<br>1 | 0 / 24 (0.00%)<br>0 |  |
| mean platelet volume decreased<br>alternative dictionary used:<br>MedDRA 26.1<br>subjects affected / exposed<br>occurrences (all)       | 1 / 5 (20.00%)<br>1 | 0 / 24 (0.00%)<br>0 |  |

|  |   |  |  |
|--|---|--|--|
| neutrophil count decreased<br>alternative dictionary used:<br>MedDRA 26.1<br>subjects affected / exposed<br>occurrences (all)  | 1 / 5 (20.00%)<br>1   | 0 / 24 (0.00%)<br>0  |  |
| Injury, poisoning and procedural complications<br>injection related reaction<br>alternative dictionary used:<br>MedDRA 26.1<br>subjects affected / exposed<br>occurrences (all)  | 1 / 5 (20.00%)<br>1   | 0 / 24 (0.00%)<br>0  |  |
| Nervous system disorders<br>headache<br>alternative dictionary used:<br>MedDRA 26.1<br>subjects affected / exposed<br>occurrences (all)  | 0 / 5 (0.00%)<br>0  | 3 / 24 (12.50%)<br>3   |  |
| General disorders and administration site conditions<br>adverse drug reaction<br>alternative dictionary used:<br>MedDRA 26.1<br>subjects affected / exposed<br>occurrences (all)<br><br>illness<br>alternative dictionary used:<br>MedDRA 26.1<br>subjects affected / exposed<br>occurrences (all)<br><br>pyrexia<br>alternative dictionary used:<br>MedDRA 26.1<br>subjects affected / exposed<br>occurrences (all) | 1 / 5 (20.00%)<br>1<br><br>1 / 5 (20.00%)<br>1<br><br>1 / 5 (20.00%)<br>1 | 0 / 24 (0.00%)<br>0<br><br>0 / 24 (0.00%)<br>0<br><br>3 / 24 (12.50%)<br>3 |  |
| Blood and lymphatic system disorders<br>iron deficiency anaemia<br>alternative dictionary used:<br>MedDRA 26.1<br>subjects affected / exposed<br>occurrences (all)   | 1 / 5 (20.00%)<br>1   | 0 / 24 (0.00%)<br>0  |  |
| Eye disorders<br>macular oedema<br>alternative dictionary used:<br>MedDRA 26.1   |   |  |  |

|   |                     |                      |  |
|---|---------------------|----------------------|--|
| subjects affected / exposed<br>occurrences (all)  | 1 / 5 (20.00%)<br>1 | 0 / 24 (0.00%)<br>0  |  |
| Gastrointestinal disorders<br>abdominal pain upper<br>alternative dictionary used:<br>MedDRA 26.1<br>subjects affected / exposed<br>occurrences (all)                           | 1 / 5 (20.00%)<br>1 | 3 / 24 (12.50%)<br>3 |  |
| nausea<br>alternative dictionary used:<br>MedDRA 26.1<br>subjects affected / exposed<br>occurrences (all)   | 0 / 5 (0.00%)<br>0  | 4 / 24 (16.67%)<br>4 |  |
| vomiting<br>alternative dictionary used:<br>MedDRA 26.1<br>subjects affected / exposed<br>occurrences (all)   | 0 / 5 (0.00%)<br>0  | 3 / 24 (12.50%)<br>3 |  |
| Respiratory, thoracic and mediastinal disorders<br>cough<br>alternative dictionary used:<br>MedDRA 26.1<br>subjects affected / exposed<br>occurrences (all)                     | 0 / 5 (0.00%)<br>0  | 2 / 24 (8.33%)<br>2  |  |
| oropharyngeal pain<br>alternative dictionary used:<br>MedDRA 26.1<br>subjects affected / exposed<br>occurrences (all)   | 0 / 5 (0.00%)<br>0  | 4 / 24 (16.67%)<br>4 |  |
| Skin and subcutaneous tissue disorders<br>acne<br>alternative dictionary used:<br>MedDRA 26.1<br>subjects affected / exposed<br>occurrences (all)                               | 0 / 5 (0.00%)<br>0  | 2 / 24 (8.33%)<br>2  |  |
| Musculoskeletal and connective tissue disorders<br>bone development abnormal<br>alternative dictionary used:<br>MedDRA 26.1<br>subjects affected / exposed<br>occurrences (all) | 1 / 5 (20.00%)<br>1 | 0 / 24 (0.00%)<br>0  |  |
| Infections and infestations   |                     |                      |  |

|   |                |                |  |
|---|----------------|----------------|--|
| covid-19                                    |                |                |  |
| alternative dictionary used:<br>MedDRA 26.1 |                |                |  |
| subjects affected / exposed                 | 1 / 5 (20.00%) | 1 / 24 (4.17%) |  |
| occurrences (all)                           | 1              | 1              |  |
| nasopharyngitis                             |                |                |  |
| alternative dictionary used:<br>MedDRA 26.1 |                |                |  |
| subjects affected / exposed                 | 1 / 5 (20.00%) | 2 / 24 (8.33%) |  |
| occurrences (all)                           | 1              | 2              |  |
| otitis media                                |                |                |  |
| alternative dictionary used:<br>MedDRA 26.1 |                |                |  |
| subjects affected / exposed                 | 1 / 5 (20.00%) | 0 / 24 (0.00%) |  |
| occurrences (all)                           | 1              | 0              |  |
| urinary tract infection                     |                |                |  |
| alternative dictionary used:<br>MedDRA 26.1 |                |                |  |
| subjects affected / exposed                 | 1 / 5 (20.00%) | 1 / 24 (4.17%) |  |
| occurrences (all)                           | 1              | 1              |  |

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date             | Amendment  |
|------------------|--|
| 05 April 2019    | - Clarified statements in Schedule of Activities section, Inclusion and Exclusion Criteria; - Updated information related to Study Assessments and Procedures. |
| 31 May 2019      | -Specified number of participants enrolled; -Updated sample size determination secondary analyses table to make the information more specific.                 |
| 14 August 2020   | -Updated study figure for the overall design; - Updated terms in the Schedule of Activities section.   |
| 07 November 2020 | -Updated study figure for the overall design; - Updated terms in the Schedule of Activities section.   |
| 14 June 2023     | -Updated cohorts and study figure for more clarity; - Editorial changes made throughout the protocol to improve the clarity.                                   |

Notes:

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported