



## Clinical trial results:

### ESTUDIO PARA EVALUAR LA EFICACIA Y SEGURIDAD DE LA LENALIDOMIDA EN EL TRATAMIENTO DEL LUPUS ERITEMATOSO CUTÁNEO.

### STUDY TO EVALUATE THE EFFECTIVENESS AND SAFETY OF LENALIDOMIDE IN THE TREATMENT OF CUTANEOUS LUPUS ERYTHEMATOSUS.

#### Summary

|                          |                 |
|--------------------------|-----------------|
| EudraCT number           | 2009-016508-21  |
| Trial protocol           | ES              |
| Global end of trial date | 31 October 2010 |

#### Results information

|                                |                  |
|--------------------------------|------------------|
| Result version number          | v1 (current)     |
| This version publication date  | 07 November 2021 |
| First version publication date | 07 November 2021 |

#### Trial information

##### Trial identification

|                       |         |
|-----------------------|---------|
| Sponsor protocol code | ORDI-02 |
|-----------------------|---------|

##### Additional study identifiers

|                                    |             |
|------------------------------------|-------------|
| ISRCTN number                      | -           |
| ClinicalTrials.gov id (NCT number) | NCT01408199 |
| WHO universal trial number (UTN)   | -           |

Notes:

#### Sponsors

|                              |   |
|------------------------------|---|
| Sponsor organisation name    | VHIR  |
| Sponsor organisation address | Passeig Vall Hebron 119-129, Barcelona, Spain, 08035        |
| Public contact               | Joaquin Lopez-Soriano, VHIR, joaquin.lopez.soriano@vhir.org |
| Scientific contact           | Josefina Cortés, VHIR, fina.cortes@vhir.org                 |

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:

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**Results analysis stage**

|  |                 |
|--|-----------------|
| Analysis stage                                       | Final           |
| Date of interim/final analysis                       | 31 October 2010 |
| Is this the analysis of the primary completion data? | No              |
| Global end of trial reached?                         | Yes             |
| Global end of trial date                             | 31 October 2010 |
| Was the trial ended prematurely?                     | No              |

Notes:

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**General information about the trial**

Main objective of the trial:

To evaluate the efficacy and safety of lenalidomide in patients with refractory Cutaneous lupus erythematosus

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Protection of trial subjects:

For all patients, there was no known hypersensitivity to thalidomide. Women were excluded from the study if pregnant, lactating or not using adequate contraception

Background therapy: -

Evidence for comparator: -

|   |                 |
|---|-----------------|
| Actual start date of recruitment                          | 05 January 2009 |
| Long term follow-up planned                               | No              |
| Independent data monitoring committee (IDMC) involvement? | No              |

Notes:

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**Population of trial subjects**

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**Subjects enrolled per country**

|                                      |           |
|--------------------------------------|-----------|
| Country: Number of subjects enrolled | Spain: 15 |
| Worldwide total number of subjects   | 15        |
| EEA total number of subjects         | 15        |

Notes:

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**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)                      | 15 |
| From 65 to 84 years                       | 0  |
| 85 years and over                         | 0  |

## Subject disposition

### Recruitment

Recruitment details: -

### Pre-assignment

Screening details:

All patients were female and of Caucasian origin, with refractory cutaneous lupus disease, histological proven CLE with or without associated systemic lupus erythematosus (SLE) disease diagnosed according to the American College of Rheumatology (ACR) SLE classification criteria; presence of at least a grade II erythema; stable prednisone

### Period 1

|                              |                                |
|------------------------------|--------------------------------|
| Period 1 title               | Overall trial (overall period) |
| Is this the baseline period? | Yes                            |
| Allocation method            | Not applicable                 |
| Blinding used                | Not blinded                    |

### Arms

|  |              |
|--|--------------|
| Arm title                              | Lenalidomide |
| Arm description: -                     |              |
| Arm type                               | Experimental |
| Investigational medicinal product name | Lenalidomide |
| Investigational medicinal product code |              |
| Other name                             |              |
| Pharmaceutical forms                   | Tablet       |
| Routes of administration               | Oral use     |

Dosage and administration details:

Lenalidomide was started at 5 mg/day for 4 weeks. At that time, if no clinical improvement was observed, using the criteria specified before, dose was increased to 10 mg/day. Otherwise, lenalidomide was sustained at 5 mg/day in case of partial response or decreased progressively monthly until its withdrawal if complete response was achieved.

| Number of subjects in period 1 | Lenalidomide |
|--------------------------------|--------------|
| Started                        | 15           |
| Completed                      | 15           |

## Baseline characteristics

## End points

### End points reporting groups

|                                |              |
|--------------------------------|--------------|
| Reporting group title          | Lenalidomide |
| Reporting group description: - |              |

### Primary: Patients achieving complete response

|                 |   |
|-----------------|---|
| End point title | Patients achieving complete response <sup>[1]</sup> |
|-----------------|---|

End point description:

The efficacy primary endpoint was the proportion of patients achieving complete response. Clinical response was evaluated by the validated Cutaneous Lupus Erythematosus Disease Area and Severity Index (CLASI). Response was defined as follows: complete response (CR) as a complete resolution of the inflammatory rash (CLASI activity score = 0); partial response (PR) by at least a 50% improvement in the CLASI score by week 12 when compared to baseline, and no response when no improvement or worsening in the CLASI score was observed at the same time period

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

End point timeframe:

12 weeks

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 statistics is given since no comparison with any group is done (single arm)

| End point values            | Lenalidomide    |  |  |  |
|-----------------------------|-----------------|--|--|--|
| Subject group type          | Reporting group |  |  |  |
| Number of subjects analysed | 15              |  |  |  |
| Units: percent              |                 |  |  |  |
| number (not applicable)     | 12              |  |  |  |

### Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

12 weeks

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

### Dictionary used

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

|                    |      |
|--------------------|------|
| Dictionary version | 14.1 |
|--------------------|------|

### Reporting groups

|                       |                      |
|-----------------------|----------------------|
| Reporting group title | Total adverse events |
|-----------------------|----------------------|

Reporting group description: -

| <b>Serious adverse events</b>                     | Total adverse events |  |  |
|---|----------------------|--|--|
| Total subjects affected by serious adverse events |                      |  |  |
| subjects affected / exposed                       | 0 / 15 (0.00%)       |  |  |
| number of deaths (all causes)                     | 0                    |  |  |
| number of deaths resulting from adverse events    | 0                    |  |  |

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

| <b>Non-serious adverse events</b>                     | Total adverse events |  |  |
|---|----------------------|--|--|
| Total subjects affected by non-serious adverse events |                      |  |  |
| subjects affected / exposed                           | 2 / 15 (13.33%)      |  |  |
| General disorders and administration site conditions  |                      |  |  |
| Fatigue   |                      |  |  |
| subjects affected / exposed                           | 1 / 15 (6.67%)       |  |  |
| occurrences (all)                                     | 1                    |  |  |
| Insomnia  |                      |  |  |
| subjects affected / exposed                           | 1 / 15 (6.67%)       |  |  |
| occurrences (all)                                     | 1                    |  |  |
| Blood and lymphatic system disorders                  |                      |  |  |
| Neutropenia   |                      |  |  |
| subjects affected / exposed                           | 1 / 15 (6.67%)       |  |  |
| occurrences (all)                                     | 1                    |  |  |
| Gastrointestinal disorders                            |                      |  |  |

|  |                     |  |  |
|--|---------------------|--|--|
| Vomiting<br>subjects affected / exposed<br>occurrences (all)   | 1 / 15 (6.67%)<br>1 |  |  |
| Diarrhoea<br>subjects affected / exposed<br>occurrences (all)  | 1 / 15 (6.67%)<br>1 |  |  |
| Metabolism and nutrition disorders<br>Weight decreased<br>subjects affected / exposed<br>occurrences (all) | 1 / 15 (6.67%)<br>1 |  |  |

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

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| The main limitation is the absence of a randomized group control and the insufficient small sample size to draw conclusions at the histological subtype level since the majority of included patients had DLE. Further larger trials are required |
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Notes:

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### Online references

<http://www.ncbi.nlm.nih.gov/pubmed/23217273>