



## Clinical trial results:

### A Multicenter, Randomized, Double-Blind, Placebo-Controlled Phase 3 Trial to Evaluate Efficacy and Safety of Lenabasum in Dermatomyositis Summary

|                          |                         |
|--------------------------|-------------------------|
| EudraCT number           | 2018-003273-10          |
| Trial protocol           | GB DE HU CZ BG SE ES IT |
| Global end of trial date | 05 October 2021         |

#### Results information

|                                |              |
|--------------------------------|--------------|
| Result version number          | v1 (current) |
| This version publication date  | 30 July 2022 |
| First version publication date | 30 July 2022 |

#### Trial information

##### Trial identification

|                       |               |
|-----------------------|---------------|
| Sponsor protocol code | JBT101-DM-002 |
|-----------------------|---------------|

##### Additional study identifiers

|                                    |             |
|------------------------------------|-------------|
| ISRCTN number                      | -           |
| ClinicalTrials.gov id (NCT number) | NCT03813160 |
| WHO universal trial number (UTN)   | -           |

Notes:

#### Sponsors

|                              |                                                                                           |
|------------------------------|-------------------------------------------------------------------------------------------|
| Sponsor organisation name    | Corbus Pharmaceuticals, Inc.                                                              |
| Sponsor organisation address | 500 River Ridge Drive, Second Floor, Norwood, Massachusetts, United States, 02062         |
| Public contact               | Brian Walsh, Corbus Pharmaceuticals, Inc.,<br>brian.walsh@corbuspharma.com                |
| Scientific contact           | Rachael Brake, Corbus Pharmaceuticals, Inc.,<br>rachael.brakeBrian.Walsh@corbuspharma.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                       | 18 March 2022   |
| Is this the analysis of the primary completion data? | Yes             |
| Primary completion date                              | 05 October 2021 |
| Global end of trial reached?                         | Yes             |
| Global end of trial date                             | 05 October 2021 |
| Was the trial ended prematurely?                     | No              |

Notes:

## General information about the trial

Main objective of the trial:

To evaluate the efficacy of lenabasum compared to placebo in subjects with dermatomyositis (DM) as measured by Total Improvement Score (TIS).

To evaluate the safety and tolerability of lenabasum in subjects with DM.

To evaluate the pharmacokinetics (PK) of lenabasum and investigate its metabolites in subjects with DM.

To evaluate the effect of lenabasum compared to placebo on blood biomarkers of inflammation in subjects with DM.

To evaluate the effect of lenabasum compared to placebo in skin biopsies in involved skin in subjects with DM (optional at selected sites).

To evaluate the effect of lenabasum compared to placebo in involved skin as evaluated by skin photography in subjects with DM (optional at selected sites).

To evaluate the long-term efficacy and safety of lenabasum in subjects who completed the study treatment phase and continued to receive treatment in an optional open-label extension (OLE).

Protection of trial subjects:

Oversight of subject safety was provided by an independent unblinded Data Monitoring Committee (DMC), which advised the Sponsor and the investigators. The independent DMC reviewed the accumulated safety and operational data about every 6 months through the last subject/last visit or more frequently, if necessary. The DMC reviewed interim/cumulative data for evidence of study-related AEs and factors external to the study such as scientific or therapeutic developments that could impact subject safety. The DMC also reviewed progress of the study and efficacy outcomes. The DMC made recommendations to the Sponsor about any of the items it reviewed.

Background therapy:

Subjects were allowed to continue their standard-of-care treatment (stable dose of immunosuppressive medication) while participating in the study, in order to reduce the risk of disease flare precipitated by having to discontinue medication to meet entry criteria. To avoid confounding efficacy and safety evaluations, changes in ongoing treatments and introduction of new therapies were kept to a minimum.

Evidence for comparator:

Placebo was a powder-in-capsule containing microcrystalline cellulose and magnesium stearate (no active ingredient).

|                                                           |                  |
|-----------------------------------------------------------|------------------|
| Actual start date of recruitment                          | 30 December 2018 |
| 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 | Poland: 7 |
| Country: Number of subjects enrolled | Spain: 8  |

|                                      |                       |
|--------------------------------------|-----------------------|
| Country: Number of subjects enrolled | Sweden: 2             |
| Country: Number of subjects enrolled | United Kingdom: 3     |
| Country: Number of subjects enrolled | Bulgaria: 7           |
| Country: Number of subjects enrolled | Czechia: 6            |
| Country: Number of subjects enrolled | Germany: 4            |
| Country: Number of subjects enrolled | Hungary: 7            |
| Country: Number of subjects enrolled | Italy: 7              |
| Country: Number of subjects enrolled | Canada: 1             |
| Country: Number of subjects enrolled | Japan: 26             |
| Country: Number of subjects enrolled | Korea, Republic of: 8 |
| Country: Number of subjects enrolled | United States: 92     |
| Worldwide total number of subjects   | 178                   |
| EEA total number of subjects         | 48                    |

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)                      | 153 |
| From 65 to 84 years                       | 25  |
| 85 years and over                         | 0   |

## Subject disposition

### Recruitment

Recruitment details:

A total of 178 subjects were randomized to receive lenabasum 5 mg BID, lenabasum 20 mg BID or placebo at multiple study sites in the United States, Bulgaria, Canada, Czech Republic, Germany, Hungary, Italy, Japan, Poland, Republic of Korea, Spain, Sweden, and United Kingdom. Subjects were randomized between 17 Dec 2018 and 26 Apr 2021.

### Pre-assignment

Screening details:

Of the 178 randomized subjects, 23 subjects were screen failures. The most common reasons for screen failure were failure to satisfy inclusion/exclusion criteria (15) and other (8). Three (1.7%) subjects discontinued prior to dosing, and 175 (98.3%) subjects were included in the modified intent-to-treat (mITT) population.

### Period 1

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

Blinding implementation details:

Lenabasum and placebo capsules had a similar physical appearance and were packaged, labeled, and handled so that subjects and study staff were not able to distinguish between the two. Identical assessments and procedures were followed during the study for subjects assigned to lenabasum or placebo.

### Arms

|                              |                 |
|------------------------------|-----------------|
| Are arms mutually exclusive? | Yes             |
| <b>Arm title</b>             | Lenabasum 20 mg |

Arm description:

Lenabasum 20mg was given orally, twice daily as a hard capsule.

|                                        |                    |
|----------------------------------------|--------------------|
| Arm type                               | Experimental       |
| Investigational medicinal product name | Lenabasum 20mg BID |
| Investigational medicinal product code |                    |
| Other name                             |                    |
| Pharmaceutical forms                   | Capsule, hard      |
| Routes of administration               | Oral use           |

Dosage and administration details:

Lenabasum 20mg was given twice daily as a hard capsule for 52 weeks.

|                  |               |
|------------------|---------------|
| <b>Arm title</b> | Lenabasum 5mg |
|------------------|---------------|

Arm description:

Lenabasum 5mg was given orally, twice daily as a hard capsule.

|                                        |                   |
|----------------------------------------|-------------------|
| Arm type                               | Experimental      |
| Investigational medicinal product name | Lenabasum 5mg BID |
| Investigational medicinal product code |                   |
| Other name                             |                   |
| Pharmaceutical forms                   | Capsule, hard     |
| Routes of administration               | Oral use          |

Dosage and administration details:

Lenabasum 5mg was given twice daily as a hard capsule for 52 weeks.

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

**Arm description:**

Placebo was given as a powder-in-capsule containing microcrystalline cellulose and magnesium stearate.

|                                        |               |
|----------------------------------------|---------------|
| Arm type                               | Placebo       |
| Investigational medicinal product name | Placebo       |
| Investigational medicinal product code |               |
| Other name                             |               |
| Pharmaceutical forms                   | Capsule, hard |
| Routes of administration               | Oral use      |

**Dosage and administration details:**

Placebo was given as a hard capsule twice daily for 52 weeks.

| <b>Number of subjects in period 1</b> | Lenabasum 20 mg | Lenabasum 5mg | Placebo |
|---------------------------------------|-----------------|---------------|---------|
| Started                               | 71              | 35            | 72      |
| Completed                             | 35              | 22            | 38      |
| Not completed                         | 36              | 13            | 34      |
| Physician decision                    | 1               | -             | -       |
| Consent withdrawn by subject          | 6               | 1             | 1       |
| unknown                               | 1               | -             | -       |
| Study terminated by Sponsor           | -               | -             | 25      |
| Adverse event, non-fatal              | 2               | 1             | 4       |
| Not specified                         | -               | -             | 1       |
| Non-compliance with the study         | -               | -             | 1       |
| Lost to follow-up                     | -               | 1             | 1       |
| Study terminated by Sponsor.          | 26              | -             | -       |
| Study terminated by the Sponsor       | -               | 10            | -       |
| Lack of efficacy                      | -               | -             | 1       |

**Period 2**

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

**Arms**

|                                                             |                   |
|-------------------------------------------------------------|-------------------|
| <b>Arm title</b>                                            | Lenabasum 20mg    |
| Arm description:                                            |                   |
| Lenabasum 20mg given orally, twice daily as a hard capsule. |                   |
| Arm type                                                    | Active comparator |

|                                        |                    |
|----------------------------------------|--------------------|
| Investigational medicinal product name | Lenabasum 20mg BID |
| Investigational medicinal product code |                    |
| Other name                             |                    |
| Pharmaceutical forms                   | Capsule, hard      |
| Routes of administration               | Oral use           |

Dosage and administration details:

Lenabasum 20mg BID was given orally as a hard-gelatin capsule in the open-label extension period (Part B).

| <b>Number of subjects in period 2<sup>[1]</sup></b> | Lenabasum 20mg |
|-----------------------------------------------------|----------------|
| Started                                             | 49             |
| Completed                                           | 9              |
| Not completed                                       | 40             |
| Sponsor terminated the study                        | 27             |
| Adverse event, non-fatal                            | 1              |
| Not specified                                       | 1              |
| Lost to follow-up                                   | 1              |
| Missing                                             | 10             |

Notes:

[1] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.

Justification: Out of 95 subjects who completed Part A of the study, 81 subjects entered the open-label extension phase of the study (Part B).

## Baseline characteristics

### Reporting groups

|                                                                                                                                        |                 |
|----------------------------------------------------------------------------------------------------------------------------------------|-----------------|
| Reporting group title                                                                                                                  | Lenabasum 20 mg |
| Reporting group description:<br>Lenabasum 20mg was given orally, twice daily as a hard capsule.                                        |                 |
| Reporting group title                                                                                                                  | Lenabasum 5mg   |
| Reporting group description:<br>Lenabasum 5mg was given orally, twice daily as a hard capsule.                                         |                 |
| Reporting group title                                                                                                                  | Placebo         |
| Reporting group description:<br>Placebo was given as a powder-in-capsule containing microcrystalline cellulose and magnesium stearate. |                 |

| Reporting group values                             | Lenabasum 20 mg | Lenabasum 5mg | Placebo |
|----------------------------------------------------|-----------------|---------------|---------|
| Number of subjects                                 | 71              | 35            | 72      |
| Age categorical                                    |                 |               |         |
| < 65 Years                                         |                 |               |         |
| Units: Subjects                                    |                 |               |         |
| In utero                                           | 0               | 0             | 0       |
| Preterm newborn infants (gestational age < 37 wks) | 0               | 0             | 0       |
| Newborns (0-27 days)                               | 0               | 0             | 0       |
| Infants and toddlers (28 days-23 months)           | 0               | 0             | 0       |
| Children (2-11 years)                              | 0               | 0             | 0       |
| Adolescents (12-17 years)                          | 0               | 0             | 0       |
| Adults (18-64 years)                               | 59              | 30            | 63      |
| From 65-84 years                                   | 12              | 5             | 9       |
| 85 years and over                                  | 0               | 0             | 0       |
| Age continuous                                     |                 |               |         |
| Units: years                                       |                 |               |         |
| arithmetic mean                                    | 52.7            | 51.5          | 51.5    |
| standard deviation                                 | ± 12.76         | ± 11.34       | ± 12.19 |
| Gender categorical                                 |                 |               |         |
| Female                                             |                 |               |         |
| Male                                               |                 |               |         |
| Units: Subjects                                    |                 |               |         |
| Female                                             | 56              | 30            | 59      |
| Male                                               | 15              | 5             | 13      |
| Race                                               |                 |               |         |
| Units: Subjects                                    |                 |               |         |
| American Indian or Alaska Native                   | 0               | 0             | 3       |
| Asian                                              | 15              | 7             | 13      |
| Black or African American                          | 3               | 0             | 0       |
| White                                              | 53              | 26            | 56      |
| Other                                              | 0               | 2             | 0       |

| Reporting group values | Total |  |  |
|------------------------|-------|--|--|
| Number of subjects     | 178   |  |  |

|                                                       |     |  |  |
|-------------------------------------------------------|-----|--|--|
| Age categorical                                       |     |  |  |
| < 65 Years                                            |     |  |  |
| Units: Subjects                                       |     |  |  |
| In utero                                              | 0   |  |  |
| Preterm newborn infants<br>(gestational age < 37 wks) | 0   |  |  |
| Newborns (0-27 days)                                  | 0   |  |  |
| Infants and toddlers (28 days-23<br>months)           | 0   |  |  |
| Children (2-11 years)                                 | 0   |  |  |
| Adolescents (12-17 years)                             | 0   |  |  |
| Adults (18-64 years)                                  | 152 |  |  |
| From 65-84 years                                      | 26  |  |  |
| 85 years and over                                     | 0   |  |  |
| Age continuous                                        |     |  |  |
| Units: years                                          |     |  |  |
| arithmetic mean                                       |     |  |  |
| standard deviation                                    | -   |  |  |
| Gender categorical                                    |     |  |  |
| Female                                                |     |  |  |
| Male                                                  |     |  |  |
| Units: Subjects                                       |     |  |  |
| Female                                                | 145 |  |  |
| Male                                                  | 33  |  |  |
| Race                                                  |     |  |  |
| Units: Subjects                                       |     |  |  |
| American Indian or Alaska Native                      | 3   |  |  |
| Asian                                                 | 35  |  |  |
| Black or African American                             | 3   |  |  |
| White                                                 | 135 |  |  |
| Other                                                 | 2   |  |  |

## End points

### End points reporting groups

|                                                                                                                                        |                 |
|----------------------------------------------------------------------------------------------------------------------------------------|-----------------|
| Reporting group title                                                                                                                  | Lenabasum 20 mg |
| Reporting group description:<br>Lenabasum 20mg was given orally, twice daily as a hard capsule.                                        |                 |
| Reporting group title                                                                                                                  | Lenabasum 5mg   |
| Reporting group description:<br>Lenabasum 5mg was given orally, twice daily as a hard capsule.                                         |                 |
| Reporting group title                                                                                                                  | Placebo         |
| Reporting group description:<br>Placebo was given as a powder-in-capsule containing microcrystalline cellulose and magnesium stearate. |                 |
| Reporting group title                                                                                                                  | Lenabasum 20mg  |
| Reporting group description:<br>Lenabasum 20mg given orally, twice daily as a hard capsule.                                            |                 |

### Primary: Total Improvement Score

|                                                                                                               |                         |
|---------------------------------------------------------------------------------------------------------------|-------------------------|
| End point title                                                                                               | Total Improvement Score |
| End point description:<br>Modified Intent-to-Treat Population                                                 |                         |
| End point type                                                                                                | Primary                 |
| End point timeframe:<br>Total Improvement Score (TIS) for lenabasum 20 mg BID compared to placebo at Week 28. |                         |

| End point values                    | Lenabasum 20 mg | Lenabasum 5mg   | Placebo         |  |
|-------------------------------------|-----------------|-----------------|-----------------|--|
| Subject group type                  | Reporting group | Reporting group | Reporting group |  |
| Number of subjects analysed         | 69              | 28              | 71              |  |
| Units: LS Mean (SE)                 |                 |                 |                 |  |
| least squares mean (standard error) | 26.8 (± 2.85)   | 22.7 (± 3.81)   | 23.7 (± 2.79)   |  |

### Statistical analyses

|                                                                                                                                                                                                                                                                                                                                                                |                                    |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|
| Statistical analysis title                                                                                                                                                                                                                                                                                                                                     | Lenabasum 20 mg BID versus placebo |
| Statistical analysis description:<br>The analysis of the primary endpoint was performed using an mixed model for repeated measures (MMRM) using data after missing data or visits due to COVID-19 using LOCF. The primary efficacy endpoint analysis compared TIS (by the 2016 ACR/EULAR Myositis Response Criteria) of lenabasum 20 mg to placebo at Week 28. |                                    |
| Comparison groups                                                                                                                                                                                                                                                                                                                                              | Lenabasum 20 mg v Placebo          |

|                                         |                                |
|-----------------------------------------|--------------------------------|
| Number of subjects included in analysis | 140                            |
| Analysis specification                  | Pre-specified                  |
| Analysis type                           | superiority                    |
| P-value                                 | = 0.3311 <sup>[1]</sup>        |
| Method                                  | Mixed models analysis          |
| Parameter estimate                      | Mean difference (final values) |
| Point estimate                          | 3.2                            |
| Confidence interval                     |                                |
| level                                   | 95 %                           |
| sides                                   | 2-sided                        |
| lower limit                             | -3.3                           |
| upper limit                             | 9.6                            |

Notes:

[1] - Based on MMRM with region, Sex, Baseline MMT-8 score, Baseline immunosuppressive use, visit, treatment and Baseline immunosuppressive use by-visit and treatment-by-visit interaction as fixed effects. Covariance structure type = un.

|                                                                                          |                                  |
|------------------------------------------------------------------------------------------|----------------------------------|
| <b>Statistical analysis title</b>                                                        | Lenabasum 5mg BID versus Placebo |
| Statistical analysis description:                                                        |                                  |
| Secondary analyses compared lenabasum 5 mg BID and all lenabasum vs. placebo at Week 28. |                                  |
| Comparison groups                                                                        | Lenabasum 5mg v Placebo          |
| Number of subjects included in analysis                                                  | 99                               |
| Analysis specification                                                                   | Pre-specified                    |
| Analysis type                                                                            | superiority <sup>[2]</sup>       |
| P-value                                                                                  | = 0.8161                         |
| Method                                                                                   | Mixed models analysis            |
| Parameter estimate                                                                       | Mean difference (final values)   |
| Point estimate                                                                           | -0.9                             |
| Confidence interval                                                                      |                                  |
| level                                                                                    | 95 %                             |
| sides                                                                                    | 2-sided                          |
| lower limit                                                                              | -8.9                             |
| upper limit                                                                              | 7                                |

Notes:

[2] - Based on MMRM with region, Sex, Baseline MMT-8 score, Baseline immunosuppressive use, visit, treatment and Baseline immunosuppressive use by-visit and treatment-by-visit interaction as fixed effects. Covariance structure type = un.

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Assessment of Treatment emergent adverse events from Day 1 through Week 52.

Adverse event reporting additional description:

Part A: The Safety Follow-up Visit was to occur 4±1 weeks after the last visit (Visit 10/ET) and was to be completed by subjects who did not rollover into Part B.

Part B: The Safety Follow-up Visit was to occur 4 ± 1 weeks after the last visit (Visit B8 or Visit C8 if OLE was extended).

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

### Dictionary used

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

|                    |      |
|--------------------|------|
| Dictionary version | 23.1 |
|--------------------|------|

### Reporting groups

|                       |                             |
|-----------------------|-----------------------------|
| Reporting group title | Lenabasum 20 mg BID, Part A |
|-----------------------|-----------------------------|

Reporting group description:

Adverse events in Part A.

|                       |                            |
|-----------------------|----------------------------|
| Reporting group title | Lenabasum 5 mg BID, Part A |
|-----------------------|----------------------------|

Reporting group description:

Adverse events in Part A.

|                       |                 |
|-----------------------|-----------------|
| Reporting group title | Placebo, Part A |
|-----------------------|-----------------|

Reporting group description:

Adverse events in Part A.

|                       |                             |
|-----------------------|-----------------------------|
| Reporting group title | Lenabasum 20 mg BID, Part B |
|-----------------------|-----------------------------|

Reporting group description:

Adverse events in Part B.

| Serious adverse events                                              | Lenabasum 20 mg BID, Part A | Lenabasum 5 mg BID, Part A | Placebo, Part A |
|---------------------------------------------------------------------|-----------------------------|----------------------------|-----------------|
| Total subjects affected by serious adverse events                   |                             |                            |                 |
| subjects affected / exposed                                         | 8 / 69 (11.59%)             | 3 / 35 (8.57%)             | 3 / 71 (4.23%)  |
| number of deaths (all causes)                                       | 0                           | 0                          | 0               |
| number of deaths resulting from adverse events                      | 0                           | 0                          | 0               |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) |                             |                            |                 |
| Epstein-Barr virus associated lymphoma                              |                             |                            |                 |
| subjects affected / exposed                                         | 1 / 69 (1.45%)              | 0 / 35 (0.00%)             | 0 / 71 (0.00%)  |
| occurrences causally related to treatment / all                     | 1 / 1                       | 0 / 0                      | 0 / 0           |
| deaths causally related to treatment / all                          | 0 / 0                       | 0 / 0                      | 0 / 0           |
| Malignant melanoma                                                  |                             |                            |                 |

|                                                 |                |                |                |
|-------------------------------------------------|----------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 35 (0.00%) | 1 / 71 (1.41%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Papillary thyroid cancer                        |                |                |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 1 / 35 (2.86%) | 0 / 71 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 1          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Injury, poisoning and procedural complications  |                |                |                |
| Gastrointestinal procedural complication        |                |                |                |
| subjects affected / exposed                     | 1 / 69 (1.45%) | 0 / 35 (0.00%) | 0 / 71 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Vascular disorders                              |                |                |                |
| Aortic thrombosis                               |                |                |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 35 (0.00%) | 1 / 71 (1.41%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Deep vein thrombosis                            |                |                |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 1 / 35 (2.86%) | 0 / 71 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 1          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Cardiac disorders                               |                |                |                |
| Atrial fibrillation                             |                |                |                |
| subjects affected / exposed                     | 1 / 69 (1.45%) | 0 / 35 (0.00%) | 0 / 71 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Accelerated idioventricular rhythm              |                |                |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 35 (0.00%) | 1 / 71 (1.41%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Coronary artery dissection                      |                |                |                |

|                                                      |                |                |                |
|------------------------------------------------------|----------------|----------------|----------------|
| subjects affected / exposed                          | 0 / 69 (0.00%) | 1 / 35 (2.86%) | 0 / 71 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0          | 0 / 1          | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          | 0 / 0          |
| Nervous system disorders                             |                |                |                |
| Vertebral artery dissection                          |                |                |                |
| subjects affected / exposed                          | 0 / 69 (0.00%) | 0 / 35 (0.00%) | 1 / 71 (1.41%) |
| occurrences causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          | 0 / 0          |
| Headache                                             |                |                |                |
| subjects affected / exposed                          | 0 / 69 (0.00%) | 0 / 35 (0.00%) | 1 / 71 (1.41%) |
| occurrences causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          | 0 / 0          |
| General disorders and administration site conditions |                |                |                |
| Influenza like illness                               |                |                |                |
| subjects affected / exposed                          | 0 / 69 (0.00%) | 0 / 35 (0.00%) | 1 / 71 (1.41%) |
| occurrences causally related to treatment / all      | 0 / 0          | 0 / 0          | 1 / 1          |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          | 0 / 0          |
| Ear and labyrinth disorders                          |                |                |                |
| Tinnitus                                             |                |                |                |
| subjects affected / exposed                          | 0 / 69 (0.00%) | 0 / 35 (0.00%) | 1 / 71 (1.41%) |
| occurrences causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          | 0 / 0          |
| Respiratory, thoracic and mediastinal disorders      |                |                |                |
| Pneumonia aspiration                                 |                |                |                |
| subjects affected / exposed                          | 1 / 69 (1.45%) | 0 / 35 (0.00%) | 0 / 71 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 1          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          | 0 / 0          |
| Skin and subcutaneous tissue disorders               |                |                |                |
| Dermatomyositis                                      |                |                |                |
| subjects affected / exposed                          | 1 / 69 (1.45%) | 1 / 35 (2.86%) | 0 / 71 (0.00%) |
| occurrences causally related to treatment / all      | 1 / 1          | 1 / 1          | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          | 0 / 0          |
| Musculoskeletal and connective tissue disorders      |                |                |                |

|                                                 |                |                |                |
|-------------------------------------------------|----------------|----------------|----------------|
| Spinal stenosis                                 |                |                |                |
| subjects affected / exposed                     | 1 / 69 (1.45%) | 0 / 35 (0.00%) | 0 / 71 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Infections and infestations                     |                |                |                |
| Appendicitis perforated                         |                |                |                |
| subjects affected / exposed                     | 1 / 69 (1.45%) | 0 / 35 (0.00%) | 0 / 71 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Gastroenteritis viral                           |                |                |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 1 / 35 (2.86%) | 0 / 71 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 1          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Pneumonia respiratory syncytial viral           |                |                |                |
| subjects affected / exposed                     | 1 / 69 (1.45%) | 0 / 35 (0.00%) | 0 / 71 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| COVID-19                                        |                |                |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 35 (0.00%) | 0 / 71 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |
| Cellulitis                                      |                |                |                |
| subjects affected / exposed                     | 1 / 69 (1.45%) | 0 / 35 (0.00%) | 0 / 71 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0          |

|                                                                     |                                |  |  |
|---------------------------------------------------------------------|--------------------------------|--|--|
| <b>Serious adverse events</b>                                       | Lenabasum 20 mg<br>BID, Part B |  |  |
| Total subjects affected by serious adverse events                   |                                |  |  |
| subjects affected / exposed                                         | 3 / 49 (6.12%)                 |  |  |
| number of deaths (all causes)                                       | 0                              |  |  |
| number of deaths resulting from adverse events                      | 0                              |  |  |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) |                                |  |  |
| Epstein-Barr virus associated lymphoma                              |                                |  |  |

|                                                 |                |  |  |
|-------------------------------------------------|----------------|--|--|
| subjects affected / exposed                     | 0 / 49 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| Malignant melanoma                              |                |  |  |
| subjects affected / exposed                     | 0 / 49 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| Papillary thyroid cancer                        |                |  |  |
| subjects affected / exposed                     | 0 / 49 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| Injury, poisoning and procedural complications  |                |  |  |
| Gastrointestinal procedural complication        |                |  |  |
| subjects affected / exposed                     | 0 / 49 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| Vascular disorders                              |                |  |  |
| Aortic thrombosis                               |                |  |  |
| subjects affected / exposed                     | 0 / 49 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| Deep vein thrombosis                            |                |  |  |
| subjects affected / exposed                     | 0 / 49 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| Cardiac disorders                               |                |  |  |
| Atrial fibrillation                             |                |  |  |
| subjects affected / exposed                     | 0 / 49 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| Accelerated idioventricular rhythm              |                |  |  |

|                                                      |                |  |  |
|------------------------------------------------------|----------------|--|--|
| subjects affected / exposed                          | 0 / 49 (0.00%) |  |  |
| occurrences causally related to treatment / all      | 0 / 0          |  |  |
| deaths causally related to treatment / all           | 0 / 0          |  |  |
| Coronary artery dissection                           |                |  |  |
| subjects affected / exposed                          | 0 / 49 (0.00%) |  |  |
| occurrences causally related to treatment / all      | 0 / 0          |  |  |
| deaths causally related to treatment / all           | 0 / 0          |  |  |
| Nervous system disorders                             |                |  |  |
| Vertebral artery dissection                          |                |  |  |
| subjects affected / exposed                          | 0 / 49 (0.00%) |  |  |
| occurrences causally related to treatment / all      | 0 / 0          |  |  |
| deaths causally related to treatment / all           | 0 / 0          |  |  |
| Headache                                             |                |  |  |
| subjects affected / exposed                          | 0 / 49 (0.00%) |  |  |
| occurrences causally related to treatment / all      | 0 / 0          |  |  |
| deaths causally related to treatment / all           | 0 / 0          |  |  |
| General disorders and administration site conditions |                |  |  |
| Influenza like illness                               |                |  |  |
| subjects affected / exposed                          | 0 / 49 (0.00%) |  |  |
| occurrences causally related to treatment / all      | 0 / 0          |  |  |
| deaths causally related to treatment / all           | 0 / 0          |  |  |
| Ear and labyrinth disorders                          |                |  |  |
| Tinnitus                                             |                |  |  |
| subjects affected / exposed                          | 0 / 49 (0.00%) |  |  |
| occurrences causally related to treatment / all      | 0 / 0          |  |  |
| deaths causally related to treatment / all           | 0 / 0          |  |  |
| Respiratory, thoracic and mediastinal disorders      |                |  |  |
| Pneumonia aspiration                                 |                |  |  |
| subjects affected / exposed                          | 0 / 49 (0.00%) |  |  |
| occurrences causally related to treatment / all      | 0 / 0          |  |  |
| deaths causally related to treatment / all           | 0 / 0          |  |  |
| Skin and subcutaneous tissue disorders               |                |  |  |
| Dermatomyositis                                      |                |  |  |

|                                                 |                |  |  |
|-------------------------------------------------|----------------|--|--|
| subjects affected / exposed                     | 0 / 49 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| Musculoskeletal and connective tissue disorders |                |  |  |
| Spinal stenosis                                 |                |  |  |
| subjects affected / exposed                     | 0 / 49 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| Infections and infestations                     |                |  |  |
| Appendicitis perforated                         |                |  |  |
| subjects affected / exposed                     | 0 / 49 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| Gastroenteritis viral                           |                |  |  |
| subjects affected / exposed                     | 0 / 49 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| Pneumonia respiratory syncytial viral           |                |  |  |
| subjects affected / exposed                     | 0 / 49 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| COVID-19                                        |                |  |  |
| subjects affected / exposed                     | 2 / 49 (4.08%) |  |  |
| occurrences causally related to treatment / all | 0 / 2          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |
| Cellulitis                                      |                |  |  |
| subjects affected / exposed                     | 0 / 49 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0          |  |  |
| deaths causally related to treatment / all      | 0 / 0          |  |  |

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

| <b>Non-serious adverse events</b>                                                                                                                                                                                                                                                                                                                      | Lenabasum 20 mg<br>BID, Part A                                                                       | Lenabasum 5 mg<br>BID, Part A                                                                        | Placebo, Part A                                                                                      |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------|
| Total subjects affected by non-serious<br>adverse events<br>subjects affected / exposed                                                                                                                                                                                                                                                                | 60 / 69 (86.96%)                                                                                     | 30 / 35 (85.71%)                                                                                     | 62 / 71 (87.32%)                                                                                     |
| Investigations<br>Blood pressure increased<br>subjects affected / exposed<br>occurrences (all)                                                                                                                                                                                                                                                         | 0 / 69 (0.00%)<br>0                                                                                  | 2 / 35 (5.71%)<br>2                                                                                  | 1 / 71 (1.41%)<br>1                                                                                  |
| Nervous system disorders<br>Dizziness<br>subjects affected / exposed<br>occurrences (all)<br><br>Headache<br>subjects affected / exposed<br>occurrences (all)<br><br>Somnolence<br>subjects affected / exposed<br>occurrences (all)                                                                                                                    | 9 / 69 (13.04%)<br>10<br><br>7 / 69 (10.14%)<br>8<br><br>2 / 69 (2.90%)<br>2                         | 2 / 35 (5.71%)<br>2<br><br>5 / 35 (14.29%)<br>6<br><br>2 / 35 (5.71%)<br>2                           | 3 / 71 (4.23%)<br>3<br><br>10 / 71 (14.08%)<br>10<br><br>0 / 71 (0.00%)<br>0                         |
| General disorders and administration<br>site conditions<br>Fatigue<br>subjects affected / exposed<br>occurrences (all)<br><br>Adverse drug reaction<br>subjects affected / exposed<br>occurrences (all)<br><br>Chills<br>subjects affected / exposed<br>occurrences (all)<br><br>Oedema peripheral<br>subjects affected / exposed<br>occurrences (all) | 6 / 69 (8.70%)<br>6<br><br>2 / 69 (2.90%)<br>2<br><br>0 / 69 (0.00%)<br>0<br><br>2 / 69 (2.90%)<br>3 | 1 / 35 (2.86%)<br>1<br><br>2 / 35 (5.71%)<br>2<br><br>2 / 35 (5.71%)<br>2<br><br>2 / 35 (5.71%)<br>2 | 2 / 71 (2.82%)<br>2<br><br>3 / 71 (4.23%)<br>4<br><br>0 / 71 (0.00%)<br>0<br><br>1 / 71 (1.41%)<br>1 |
| Gastrointestinal disorders<br>Diarrhoea<br>subjects affected / exposed<br>occurrences (all)<br><br>Dry mouth                                                                                                                                                                                                                                           | 10 / 69 (14.49%)<br>12                                                                               | 4 / 35 (11.43%)<br>7                                                                                 | 6 / 71 (8.45%)<br>7                                                                                  |

|                                                                                                                   |                        |                        |                        |
|-------------------------------------------------------------------------------------------------------------------|------------------------|------------------------|------------------------|
| subjects affected / exposed<br>occurrences (all)                                                                  | 5 / 69 (7.25%)<br>5    | 2 / 35 (5.71%)<br>2    | 2 / 71 (2.82%)<br>2    |
| Nausea<br>subjects affected / exposed<br>occurrences (all)                                                        | 8 / 69 (11.59%)<br>10  | 4 / 35 (11.43%)<br>5   | 3 / 71 (4.23%)<br>3    |
| Abdominal pain upper<br>subjects affected / exposed<br>occurrences (all)                                          | 1 / 69 (1.45%)<br>1    | 3 / 35 (8.57%)<br>3    | 0 / 71 (0.00%)<br>0    |
| Constipation<br>subjects affected / exposed<br>occurrences (all)                                                  | 1 / 69 (1.45%)<br>1    | 2 / 35 (5.71%)<br>2    | 1 / 71 (1.41%)<br>1    |
| Skin and subcutaneous tissue disorders<br>Rash<br>subjects affected / exposed<br>occurrences (all)                | 0 / 69 (0.00%)<br>0    | 2 / 35 (5.71%)<br>2    | 0 / 71 (0.00%)<br>0    |
| Dermatomyositis<br>subjects affected / exposed<br>occurrences (all)                                               | 19 / 69 (27.54%)<br>27 | 11 / 35 (31.43%)<br>17 | 29 / 71 (40.85%)<br>45 |
| Psychiatric disorders<br>Insomnia<br>subjects affected / exposed<br>occurrences (all)                             | 0 / 69 (0.00%)<br>0    | 2 / 35 (5.71%)<br>2    | 4 / 71 (5.63%)<br>4    |
| Endocrine disorders<br>Hypothyroidism<br>subjects affected / exposed<br>occurrences (all)                         | 0 / 69 (0.00%)<br>0    | 2 / 35 (5.71%)<br>2    | 0 / 71 (0.00%)<br>0    |
| Musculoskeletal and connective tissue disorders<br>Arthralgia<br>subjects affected / exposed<br>occurrences (all) | 7 / 69 (10.14%)<br>8   | 0 / 35 (0.00%)<br>0    | 2 / 71 (2.82%)<br>4    |
| Back pain<br>subjects affected / exposed<br>occurrences (all)                                                     | 2 / 69 (2.90%)<br>2    | 0 / 35 (0.00%)<br>0    | 4 / 71 (5.63%)<br>4    |
| Pain in extremity<br>subjects affected / exposed<br>occurrences (all)                                             | 2 / 69 (2.90%)<br>3    | 2 / 35 (5.71%)<br>2    | 4 / 71 (5.63%)<br>4    |

|                                                                             |                     |                     |                     |
|-----------------------------------------------------------------------------|---------------------|---------------------|---------------------|
| Neck pain<br>subjects affected / exposed<br>occurrences (all)               | 1 / 69 (1.45%)<br>1 | 2 / 35 (5.71%)<br>2 | 0 / 71 (0.00%)<br>0 |
| Infections and infestations                                                 |                     |                     |                     |
| Bronchitis<br>subjects affected / exposed<br>occurrences (all)              | 4 / 69 (5.80%)<br>4 | 1 / 35 (2.86%)<br>1 | 3 / 71 (4.23%)<br>5 |
| Nasopharyngitis<br>subjects affected / exposed<br>occurrences (all)         | 5 / 69 (7.25%)<br>5 | 3 / 35 (8.57%)<br>3 | 2 / 71 (2.82%)<br>2 |
| Urinary tract infection<br>subjects affected / exposed<br>occurrences (all) | 4 / 69 (5.80%)<br>5 | 2 / 35 (5.71%)<br>2 | 3 / 71 (4.23%)<br>4 |
| Metabolism and nutrition disorders                                          |                     |                     |                     |
| Decreased appetite<br>subjects affected / exposed<br>occurrences (all)      | 4 / 69 (5.80%)<br>4 | 0 / 35 (0.00%)<br>0 | 0 / 71 (0.00%)<br>0 |

|                                                                                         |                                |  |  |
|-----------------------------------------------------------------------------------------|--------------------------------|--|--|
| <b>Non-serious adverse events</b>                                                       | Lenabasum 20 mg<br>BID, Part B |  |  |
| Total subjects affected by non-serious<br>adverse events<br>subjects affected / exposed | 37 / 49 (75.51%)               |  |  |
| Investigations                                                                          |                                |  |  |
| Blood pressure increased<br>subjects affected / exposed<br>occurrences (all)            | 0 / 49 (0.00%)<br>0            |  |  |
| Nervous system disorders                                                                |                                |  |  |
| Dizziness<br>subjects affected / exposed<br>occurrences (all)                           | 2 / 49 (4.08%)<br>2            |  |  |
| Headache<br>subjects affected / exposed<br>occurrences (all)                            | 10 / 49 (20.41%)<br>10         |  |  |
| Somnolence<br>subjects affected / exposed<br>occurrences (all)                          | 3 / 49 (6.12%)<br>3            |  |  |
| General disorders and administration<br>site conditions                                 |                                |  |  |

|                                                                           |                        |  |  |
|---------------------------------------------------------------------------|------------------------|--|--|
| Fatigue<br>subjects affected / exposed<br>occurrences (all)               | 2 / 49 (4.08%)<br>2    |  |  |
| Adverse drug reaction<br>subjects affected / exposed<br>occurrences (all) | 2 / 49 (4.08%)<br>2    |  |  |
| Chills<br>subjects affected / exposed<br>occurrences (all)                | 0 / 49 (0.00%)<br>0    |  |  |
| Oedema peripheral<br>subjects affected / exposed<br>occurrences (all)     | 0 / 49 (0.00%)<br>0    |  |  |
| Gastrointestinal disorders                                                |                        |  |  |
| Diarrhoea<br>subjects affected / exposed<br>occurrences (all)             | 7 / 49 (14.29%)<br>8   |  |  |
| Dry mouth<br>subjects affected / exposed<br>occurrences (all)             | 3 / 49 (6.12%)<br>3    |  |  |
| Nausea<br>subjects affected / exposed<br>occurrences (all)                | 2 / 49 (4.08%)<br>2    |  |  |
| Abdominal pain upper<br>subjects affected / exposed<br>occurrences (all)  | 0 / 49 (0.00%)<br>0    |  |  |
| Constipation<br>subjects affected / exposed<br>occurrences (all)          | 0 / 49 (0.00%)<br>0    |  |  |
| Skin and subcutaneous tissue disorders                                    |                        |  |  |
| Rash<br>subjects affected / exposed<br>occurrences (all)                  | 4 / 49 (8.16%)<br>4    |  |  |
| Dermatomyositis<br>subjects affected / exposed<br>occurrences (all)       | 35 / 49 (71.43%)<br>42 |  |  |
| Psychiatric disorders                                                     |                        |  |  |

|                                                                                                                                                                                                                                                                                                                                          |                                                                                                       |  |  |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------|--|--|
| Insomnia<br>subjects affected / exposed<br>occurrences (all)                                                                                                                                                                                                                                                                             | 1 / 49 (2.04%)<br>1                                                                                   |  |  |
| Endocrine disorders<br>Hypothyroidism<br>subjects affected / exposed<br>occurrences (all)                                                                                                                                                                                                                                                | 1 / 49 (2.04%)<br>1                                                                                   |  |  |
| Musculoskeletal and connective tissue disorders<br>Arthralgia<br>subjects affected / exposed<br>occurrences (all)<br><br>Back pain<br>subjects affected / exposed<br>occurrences (all)<br><br>Pain in extremity<br>subjects affected / exposed<br>occurrences (all)<br><br>Neck pain<br>subjects affected / exposed<br>occurrences (all) | 7 / 49 (14.29%)<br>9<br><br>3 / 49 (6.12%)<br>3<br><br>4 / 49 (8.16%)<br>5<br><br>1 / 49 (2.04%)<br>1 |  |  |
| Infections and infestations<br>Bronchitis<br>subjects affected / exposed<br>occurrences (all)<br><br>Nasopharyngitis<br>subjects affected / exposed<br>occurrences (all)<br><br>Urinary tract infection<br>subjects affected / exposed<br>occurrences (all)                                                                              | 1 / 49 (2.04%)<br>1<br><br>2 / 49 (4.08%)<br>2<br><br>1 / 49 (2.04%)<br>2                             |  |  |
| Metabolism and nutrition disorders<br>Decreased appetite<br>subjects affected / exposed<br>occurrences (all)                                                                                                                                                                                                                             | 1 / 49 (2.04%)<br>1                                                                                   |  |  |

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date             | Amendment                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 03 October 2018  | Version 1.1                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| 17 October 2018  | Version 1.2                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| 05 December 2019 | Version 2.0:<br>Secondary efficacy endpoint was revised to include each component of the TIS (MDGA, PtGA, HAQ, muscle enzymes, and EMGA) at the request of Regulatory Authorities.<br>Evaluation of long-term efficacy and safety as an additional objective in an optional open-label extension (OLE) was added. Subjects received lenabasum 20 mg BID. A schedule of assessments was provided for one year with the potential for the OLE to be extended beyond 1 year. Due to a continued favorable safety profile and efficacy signals for lenabasum, an optional OLE was added for further evaluation of long-term safety and efficacy.<br>Added key inclusion criteria including DM diagnosis by Bohan and Peter or ACR/EULAR criteria at the request of Regulatory Authorities. No major changes were made to eligibility criteria other than providing additional clarity to address questions from sites/ IRB/EC/Regulatory Authorities. |
| 13 January 2021  | Version 2.2                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |

Notes:

### Interruptions (globally)

Were there any global interruptions to the trial? Yes

| Date          | Interruption                                                                                                                                                                                                                                    | Restart date |
|---------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|
| 26 April 2021 | Sponsor made the decision to terminate the double-blind study once all subjects had completed at least Visit 6 allowing for analysis of the amended primary endpoint. Sponsor made the decision to discontinue development of lenabasum for DM. | -            |

Notes:

### Limitations and caveats

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

None reported.

Notes: