



Clinical trial results:

A 52-week (plus extension until commercialization), single-arm study to evaluate psoriasis severity and its psychosocial impact using the Simplified Psoriasis Index (SPI) at 16 weeks, as well as long-term safety, tolerability and efficacy of secukinumab administered subcutaneously in participants suffering from moderate to severe psoriasis

Summary

| | |
|--------------------------|------------------|
| EudraCT number | 2014-003666-25 |
| Trial protocol | FR |
| Global end of trial date | 09 February 2017 |

Results information

| | |
|--------------------------------|------------------|
| Result version number | v1 (current) |
| This version publication date | 24 February 2018 |
| First version publication date | 24 February 2018 |

Trial information

Trial identification

| | |
|-----------------------|--------------|
| Sponsor protocol code | CAIN457AFR01 |
|-----------------------|--------------|

Additional study identifiers

| | |
|------------------------------------|-------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT02595970 |
| WHO universal trial number (UTN) | - |

Notes:

Sponsors

| | |
|------------------------------|---------------------------------------------------------------------------------------|
| Sponsor organisation name | Novartis Pharmaceuticals |
| Sponsor organisation address | CH-4056, Basel, Switzerland, |
| Public contact | Study Director, Novartis Pharmaceuticals, 41 61 324 1111, Novartis.email@novartis.com |
| Scientific contact | Study Director, Novartis Pharmaceuticals, 41 61 324 1111, Novartis.email@novartis.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 | 07 November 2017 |
| Is this the analysis of the primary completion data? | No |
| Global end of trial reached? | Yes |
| Global end of trial date | 09 February 2017 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

The primary objective was to evaluate the benefit of secukinumab on the severity of psoriasis based on the SPI. This index comprises 3 components: severity (s), psychosocial (p) and intervention (i) evaluated by both the physician (proSPI) and the patient (self-administered: saSPI). Only the severity components were evaluated for the primary objective (both proSPI (s) and saSPI (s)). Changes at Week 16 compared to Baseline in patients suffering from moderate to severe plaque psoriasis were analyzed.

Protection of trial subjects:

This study was in compliance with the ethical principles derived from the Declaration of Helsinki and the International Conference on Harmonization (ICH) Good Clinical Practice (GCP) guidelines. All the local regulatory requirements pertinent to safety of trial subjects were also followed during the conduct of the trial.

Background therapy: -

Evidence for comparator: -

| | |
|-----------------------------------------------------------|-------------|
| Actual start date of recruitment | 20 May 2015 |
| 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: 120 |
| Worldwide total number of subjects | 120 |
| EEA total number of subjects | 120 |

Notes:

Subjects enrolled per age group

| | |
|-------------------------------------------|-----|
| In utero | 0 |
| Preterm newborn - gestational age < 37 wk | 0 |
| Newborns (0-27 days) | 0 |
| Infants and toddlers (28 days-23 months) | 0 |
| Children (2-11 years) | 0 |
| Adolescents (12-17 years) | 0 |
| Adults (18-64 years) | 111 |
| From 65 to 84 years | 9 |

| | |
|-------------------|---|
| 85 years and over | 0 |
|-------------------|---|

Subject disposition

Recruitment

Recruitment details:

Study centers: This study involved 17 active centers who enrolled (or recruited) patients in France
First patient enrolled: 20-May-2015
Last patient completed: 09-Feb-2017

Pre-assignment

Screening details:

No significant events in the study (for example, wash out, run-in) that occur after participant enrollment, but prior to assignment of participants to the treatment arm

Period 1

| | |
|------------------------------|--------------------------------|
| Period 1 title | Overall Study (overall period) |
| Is this the baseline period? | Yes |
| Allocation method | Non-randomised - controlled |
| Blinding used | Not blinded |

Blinding implementation details:

This was an open label single-arm study; therefore treatment blinding was not necessary.

Arms

| | |
|-----------|------------------------|
| Arm title | Single Arm secukinumab |
|-----------|------------------------|

Arm description:

Weekly injections of 300mg of secukinumab during the first month (induction period), followed by monthly injections thereafter to week 48. During this extension period, patients continued to receive monthly injections until End of Extension visit.

| | |
|----------------------------------------|------------------------------------------------------------------------------------------|
| Arm type | Experimental |
| Investigational medicinal product name | This was an open label single-arm study; therefore treatment blinding was not necessary. |
| Investigational medicinal product code | AIN457A |
| Other name | |
| Pharmaceutical forms | Suspension for injection in pre-filled syringe |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Secukinumab is administered subcutaneously at a dosage of 300 mg per week during the induction phase (first month) and thereafter at a dosage of 300 mg per month.

| Number of subjects in period 1 | Single Arm secukinumab |
|--------------------------------|------------------------|
| Started | 120 |
| Completed | 100 |
| Not completed | 20 |
| Consent withdrawn by subject | 2 |
| Physician decision | 2 |
| Adverse event, non-fatal | 5 |
| Protocol deviation | 4 |
| Lack of efficacy | 7 |

Baseline characteristics

Reporting groups

| | |
|-----------------------|------------------------|
| Reporting group title | Single Arm secukinumab |
|-----------------------|------------------------|

Reporting group description:

Weekly injections of 300mg of secukinumab during the first month (induction period), followed by monthly injections thereafter to week 48. During this extension period, patients continued to receive monthly injections until End of Extension visit.

| Reporting group values | Single Arm secukinumab | Total | |
|-------------------------------------------------------|---------------------------|-------|--|
| Number of subjects | 120 | 120 | |
| Age categorical Units: Subjects | | | |
| In utero | 0 | 0 | |
| Preterm newborn infants (gestational age < 37 wks) | 0 | 0 | |
| Newborns (0-27 days) | 0 | 0 | |
| Infants and toddlers (28 days-23 months) | 0 | 0 | |
| Children (2-11 years) | 0 | 0 | |
| Adolescents (12-17 years) | 0 | 0 | |
| Adults (18-64 years) | 111 | 111 | |
| From 65-84 years | 9 | 9 | |
| 85 years and over | 0 | 0 | |
| Age Continuous Units: years | | | |
| arithmetic mean | 45.9 | | |
| standard deviation | ± 17.17 | - | |
| Gender, Male/Female Units: Subjects | | | |
| Female | 37 | 37 | |
| Male | 83 | 83 | |
| Race (NIH/OMB) Units: Subjects | | | |
| American Indian or Alaska Native | 1 | 1 | |
| Asian | 1 | 1 | |
| Native Hawaiian or Other Pacific Islander | 1 | 1 | |
| Black or African American | 1 | 1 | |
| White | 116 | 116 | |
| More than one race | 0 | 0 | |
| Unknown or Not Reported | 0 | 0 | |
| proSPI (s) Units: n/a | | | |
| arithmetic mean | 24.9 | | |
| standard deviation | ± 10.71 | - | |
| saSPI (s) Units: n/a | | | |
| arithmetic mean | 45.9 | | |
| standard deviation | ± 17.7 | - | |

End points

End points reporting groups

| | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|
| Reporting group title | Single Arm secukinumab |
| Reporting group description: Weekly injections of 300mg of secukinumab during the first month (induction period), followed by monthly injections thereafter to week 48. During this extension period, patients continued to receive monthly injections until End of Extension visit. | |

Primary: Severity component(s) of the Simplified Psoriasis Index (SPI)

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|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------|
| End point title | Severity component(s) of the Simplified Psoriasis Index (SPI) ^[1] |
| End point description: The primary efficacy outcome of this study evaluates the benefit of secukinumab on the severity of psoriasis based on the SPI. This index comprises 3 components: severity (SPIs), psychosocial (SPIp) and intervention (SPIi) and were evaluated by both health care professional (professional, proSPI) and the patient (self-administered: saSPI). Only the severity components were evaluated for the primary objective: proSPI (s) and saSPI (s). Changes at Week 16 compared to Baseline in patients suffering from moderate to severe plaque psoriasis were analyzed for the purpose of this study. | |
| End point type | Primary |
| End point timeframe: from baseline to 16 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 statistical analyses were planned for this single arm study | |

| End point values | Single Arm secukinumab | | | |
|--------------------------------------|------------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 119 | | | |
| Units: score SPI(s) (range: 0 to 50) | | | | |
| arithmetic mean (standard deviation) | | | | |
| W0 | 24.89 (± 10.747) | | | |
| W16 | 2.34 (± 6.144) | | | |

Statistical analyses

No statistical analyses for this end point

Primary: Changes of saSPI (s) at Week 16 compared to Baseline

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|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------|
| End point title | Changes of saSPI (s) at Week 16 compared to Baseline ^[2] |
| End point description: The primary efficacy objective of the study was to evaluate the benefit of secukinumab on the severity of psoriasis based on the SPI. This index comprises 3 components: severity (SPIs), psychosocial (SPIp) and intervention (SPIi) and were evaluated by both health care professional (professional, proSPI) and the patient (self-administered: saSPI). Only the severity components were evaluated for the primary objective: proSPI (s) and saSPI (s). Changes at Week 16 compared to Baseline in patients suffering from moderate to severe plaque psoriasis were analyzed. proSPI (s) score range is 0 to 50. Higher score means worse condition | |

| | |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
| End point type | Primary |
| End point timeframe: | |
| from baseline to 16 weeks | |
| Notes: | |
| [2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point. | |
| Justification: No statistical analyses were planned for this single arm study | |

| | | | | |
|--------------------------------------|------------------------|--|--|--|
| End point values | Single Arm secukinumab | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 118 | | | |
| Units: proSPI (s) score | | | | |
| arithmetic mean (standard deviation) | | | | |
| W0 | 23.54 (± 10.412) | | | |
| W16 | 1.99 (± 4.508) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: PASI (Psoriasis Area Severity Index) score

| | |
|----------------------------------------------------------|--------------------------------------------|
| End point title | PASI (Psoriasis Area Severity Index) score |
| End point description: | |
| PASI score range: 0 (no disease) to 72 (maximal disease) | |
| End point type | Secondary |
| End point timeframe: | |
| week 0, 16, 52 | |

| | | | | |
|--------------------------------------|------------------------|--|--|--|
| End point values | Single Arm secukinumab | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 109 | | | |
| Units: PASI score | | | | |
| arithmetic mean (standard deviation) | | | | |
| W0 | 23.09 (± 10.541) | | | |
| W16 | 2.23 (± 3.927) | | | |
| W52 | 3.16 (± 5.427) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Correlation between PASI and proSPI (s)

| | |
|------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------|
| End point title | Correlation between PASI and proSPI (s) |
| End point description: Psoriasis Area Severity Index vs Professional Version of Simplified Psoriasis Index (proSPI) score | |
| End point type | Secondary |
| End point timeframe: week 0, 16, 52 | |

| | | | | |
|----------------------------------|---------------------------|--|--|--|
| End point values | Single Arm secukinumab | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 118 | | | |
| Units: Correlation coefficient | | | | |
| number (confidence interval 95%) | | | | |
| WO | 0.691 (0.58 to 0.78) | | | |
| W16 | 0.814 (0.74 to 0.87) | | | |
| W52 | 0.927 (0.89 to 0.95) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: proSPI (s, p and i) over time

| | |
|---------------------------------------------------------------------------------------|-------------------------------|
| End point title | proSPI (s, p and i) over time |
| End point description: Professional Version of Simplified Psoriasis Index (proSPI) | |
| End point type | Secondary |
| End point timeframe: weeks 0, 16, 52 | |

| | | | | |
|--------------------------------------|---------------------------|--|--|--|
| End point values | Single Arm secukinumab | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 119 | | | |
| Units: proSPI score | | | | |
| arithmetic mean (standard deviation) | | | | |
| proSPI (s) - W0 | 24.89 (± 10.747) | | | |
| proSPI (s) - W16 | 1.83 (± 4.427) | | | |
| proSPI (s) - W52 | 2.93 (± 6.557) | | | |
| proSPI (p) - W0 | 7.80 (± 1.885) | | | |
| proSPI (p) - W16 | 1.34 (± 2.201) | | | |

| | | | | |
|------------------|----------------|--|--|--|
| proSPI (p) - W52 | 1.59 (± 2.341) | | | |
| proSPI (i) - W0 | 4.26 (± 1.924) | | | |
| proSPI (i) - W16 | 4.78 (± 1.633) | | | |
| proSPI (i) - W52 | 4.67 (± 1.613) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: saSPI (s, p and i) over time

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|--------------------------------------------------------------------------------|------------------------------|
| End point title | saSPI (s, p and i) over time |
| End point description: Self-administered Simplified Psoriasis Index (saSPI) | |
| End point type | Secondary |
| End point timeframe: weeks 0, 16, 52 | |

| End point values | Single Arm secukinumab | | | |
|--------------------------------------|---------------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 118 | | | |
| Units: saSPI score | | | | |
| arithmetic mean (standard deviation) | | | | |
| saSPI(s) - W0 | 23.54 (± 10.412) | | | |
| saSPI(s) - W16 | 1.80 (± 4.319) | | | |
| saSPI(s) - W52 | 2.15 (± 4.229) | | | |
| saSPI(p) - W0 | 8.18 (± 1.855) | | | |
| saSPI(p) - W16 | 1.54 (± 2.299) | | | |
| saSPI(p) - W52 | 1.47 (± 2.126) | | | |
| saSPI(i) - W0 | 4.34 (± 1.940) | | | |
| saSPI(i) - W16 | 4.39 (± 2.221) | | | |
| saSPI(i) - W52 | 4.33 (± 2.276) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: DLQI (Dermatology Life Quality Index) over time

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|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|
| End point title | DLQI (Dermatology Life Quality Index) over time |
| End point description: DLQI score has a maximum of 30 and a minimum of 0. The higher the score, the more quality of life is impaired MEANING OF DLQI SCORES 0 – 1 no effect on patient's life 2 – 5 small effect on patient's life 6 – 10 moderate effect on patient's life 11 – 20 very large effect on patient's life 21 – 30 extremely large effect on patient's life | |

| | |
|----------------------|-----------|
| End point type | Secondary |
| End point timeframe: | |
| weeks 0, 16, 52 | |

| | | | | |
|--------------------------------------|---------------------------|--|--|--|
| End point values | Single Arm secukinumab | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 119 | | | |
| Units: DLQI score (range : 0 - 30) | | | | |
| arithmetic mean (standard deviation) | | | | |
| WO | 13.6 (± 7.33) | | | |
| W16 | 2.1 (± 3.67) | | | |
| W52 | 1.9 (± 3.37) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: self-administered PASI (SA-PASI)

| | |
|------------------------------------------------------------------|----------------------------------|
| End point title | self-administered PASI (SA-PASI) |
| End point description: self-administered PASI (SA-PASI) score | |
| End point type | Secondary |
| End point timeframe: weeks 0, 16, 52 | |

| | | | | |
|--------------------------------------|---------------------------|--|--|--|
| End point values | Single Arm secukinumab | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 118 | | | |
| Units: saPASI score (range: 0 to 72) | | | | |
| arithmetic mean (standard deviation) | | | | |
| WO | 25.8 (± 13.55) | | | |
| W16 | 2.6 (± 6.66) | | | |
| W52 | 3.3 (± 7.10) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Psoriasis Symptom Diary (PSD) score

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|-----------------|-------------------------------------|
| End point title | Psoriasis Symptom Diary (PSD) score |
|-----------------|-------------------------------------|

End point description:

assessment of pain, itching and scaling using the Psoriasis Symptom Diary questionnaire over time PSD scores range from 0 to 10, with higher scores indicating a worse condition

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

End point timeframe:

weeks 0, 16, 52

| End point values | Single Arm secukinumab | | | |
|--------------------------------------------|---------------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 119 | | | |
| Units: PSD scores | | | | |
| arithmetic mean (standard deviation) | | | | |
| Intensity of pain recorded in PSD- W0 | 5.2 (± 3.18) | | | |
| Intensity of pain recorded in PSD - W16 | 0.9 (± 2.00) | | | |
| Intensity of pain recorded in PSD - W52 | 0.9 (± 1.78) | | | |
| Intensity of itching recorded in PSD - W0 | 6.7 (± 2.85) | | | |
| Intensity of itching recorded in PSD - W16 | 1.3 (± 2.21) | | | |
| Intensity of itching recorded in PSD - W52 | 1.4 (± 2.11) | | | |
| Intensity of scaling recorded in PSD - W0 | 6.5 (± 2.70) | | | |
| Intensity of scaling recorded in PSD - W16 | 1.0 (± 1.96) | | | |
| Intensity of scaling recorded in PSD - W52 | 1.3 (± 2.00) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Correlation between proSPI (for each component: s, p and i) and DLQI

| | |
|-----------------|----------------------------------------------------------------------|
| End point title | Correlation between proSPI (for each component: s, p and i) and DLQI |
|-----------------|----------------------------------------------------------------------|

End point description:

Correlation between proSPI (for each component: s, p and i) and DLQI is summarized in table below

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

End point timeframe:

weeks 0, 16, 52

| End point values | Single Arm secukinumab | | | |
|----------------------------------|---------------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 118 | | | |
| Units: correlation coefficient | | | | |
| number (confidence interval 95%) | | | | |
| proSPI (s) and DLQI - W0 | 0.224 (0.05 to 0.39) | | | |
| proSPI (s) and DLQI - W16 | 0.418 (0.25 to 0.56) | | | |
| proSPI (s) and DLQI - W52 | 0.514 (0.34 to 0.65) | | | |
| proSPI (p) and DLQI - W0 | 0.492 (0.34 to 0.62) | | | |
| proSPI (p) and DLQI - W16 | 0.671 (0.55 to 0.76) | | | |
| proSPI (p) and DLQI - W52 | 0.757 (0.65 to 0.83) | | | |
| proSPI (i) and DLQI - W0 | 0.102 (-0.08 to 0.28) | | | |
| proSPI (i) and DLQI - W16 | 0.016 (-0.17 to 0.20) | | | |
| proSPI (i) and DLQI - W52 | 0.131 (-0.08 to 0.33) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Correlation between proSPI (for components p and i) and PASI

| | |
|-----------------|--------------------------------------------------------------|
| End point title | Correlation between proSPI (for components p and i) and PASI |
|-----------------|--------------------------------------------------------------|

End point description:

Correlation between proSPI (p, i) and PASI score by visit (Full Analysis Set (observed)) is summarized in table below

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

End point timeframe:

Over time (from Week 0 to Week 52)

| End point values | Single Arm secukinumab | | | |
|----------------------------------|---------------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 118 | | | |
| Units: correlation coefficient | | | | |
| number (confidence interval 95%) | | | | |
| proSPI (p) and PASI - W0 | 0.173 (-0.01 to 0.34) | | | |
| proSPI (p) and PASI - W16 | 0.678 (0.56 to 0.77) | | | |
| proSPI (p) and PASI - W52 | 0.749 (0.64 to 0.83) | | | |
| proSPI (i) and PASI - W0 | 0.014 (-0.17 to 0.19) | | | |

| | | | | |
|---------------------------|-----------------------|--|--|--|
| proSPI (i) and PASI - W16 | 0.105 (-0.08 to 0.29) | | | |
| proSPI (i) and PASI - W52 | 0.172 (-0.04 to 0.36) | | | |

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse events are collected from First Patient First Visit (FPFV) until Last Patient Last Visit (LPLV). All adverse events reported in this record are from date of First Patient First Treatment until Last Patient Last Visit

Adverse event reporting additional description:

Consistent with EudraCT disclosure specifications, Novartis has reported under the Serious adverse events field "number of deaths resulting from adverse events" all those deaths, resulting from serious adverse events that are deemed to be causally related to treatment by the investigator.

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

Dictionary used

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

| | |
|--------------------|------|
| Dictionary version | 19.1 |
|--------------------|------|

Reporting groups

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|-----------------------|--------------|
| Reporting group title | AIN457 300mg |
|-----------------------|--------------|

Reporting group description:

AIN457 300mg

| Serious adverse events | AIN457 300mg | | |
|---------------------------------------------------------------------|-------------------|--|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 13 / 120 (10.83%) | | |
| number of deaths (all causes) | 2 | | |
| number of deaths resulting from adverse events | 0 | | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Breast cancer | | | |
| subjects affected / exposed | 1 / 120 (0.83%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Mycosis fungoides | | | |
| subjects affected / exposed | 1 / 120 (0.83%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 1 | | |
| Injury, poisoning and procedural complications | | | |
| Head injury | | | |
| subjects affected / exposed | 1 / 120 (0.83%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 1 | | |

| | | | |
|------------------------------------------------------|-----------------|--|--|
| Meniscus injury | | | |
| subjects affected / exposed | 1 / 120 (0.83%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Tendon rupture | | | |
| subjects affected / exposed | 1 / 120 (0.83%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Cardiac disorders | | | |
| Coronary artery occlusion | | | |
| subjects affected / exposed | 1 / 120 (0.83%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Nervous system disorders | | | |
| Cerebral ischaemia | | | |
| subjects affected / exposed | 1 / 120 (0.83%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Cerebrovascular accident | | | |
| subjects affected / exposed | 1 / 120 (0.83%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| General disorders and administration site conditions | | | |
| Face oedema | | | |
| subjects affected / exposed | 1 / 120 (0.83%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Eye disorders | | | |
| Punctate keratitis | | | |
| subjects affected / exposed | 1 / 120 (0.83%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Gastrointestinal disorders | | | |
| Stomatitis | | | |

| | | | |
|-------------------------------------------------|-----------------|--|--|
| subjects affected / exposed | 1 / 120 (0.83%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Strangulated umbilical hernia | | | |
| subjects affected / exposed | 1 / 120 (0.83%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Pneumothorax | | | |
| subjects affected / exposed | 1 / 120 (0.83%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Sleep apnoea syndrome | | | |
| subjects affected / exposed | 1 / 120 (0.83%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Skin and subcutaneous tissue disorders | | | |
| Ecchymosis | | | |
| subjects affected / exposed | 1 / 120 (0.83%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Musculoskeletal and connective tissue disorders | | | |
| Sjogren's syndrome | | | |
| subjects affected / exposed | 1 / 120 (0.83%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Metabolism and nutrition disorders | | | |
| Diabetes mellitus | | | |
| subjects affected / exposed | 1 / 120 (0.83%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Hypoglycaemia | | | |

| | | | |
|-------------------------------------------------|-----------------|--|--|
| subjects affected / exposed | 1 / 120 (0.83%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |

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

| | | | |
|-------------------------------------------------------|-------------------|--|--|
| Non-serious adverse events | AIN457 300mg | | |
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 86 / 120 (71.67%) | | |
| Vascular disorders | | | |
| Hypertension | | | |
| subjects affected / exposed | 9 / 120 (7.50%) | | |
| occurrences (all) | 10 | | |
| Nervous system disorders | | | |
| Headache | | | |
| subjects affected / exposed | 9 / 120 (7.50%) | | |
| occurrences (all) | 13 | | |
| General disorders and administration site conditions | | | |
| Asthenia | | | |
| subjects affected / exposed | 10 / 120 (8.33%) | | |
| occurrences (all) | 10 | | |
| Gastrointestinal disorders | | | |
| Diarrhoea | | | |
| subjects affected / exposed | 12 / 120 (10.00%) | | |
| occurrences (all) | 21 | | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Cough | | | |
| subjects affected / exposed | 7 / 120 (5.83%) | | |
| occurrences (all) | 8 | | |
| Skin and subcutaneous tissue disorders | | | |
| Psoriasis | | | |
| subjects affected / exposed | 11 / 120 (9.17%) | | |
| occurrences (all) | 12 | | |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |

| | | | |
|---------------------------------------------------------------------------------------------|-------------------------|--|--|
| subjects affected / exposed occurrences (all) | 7 / 120 (5.83%) 8 | | |
| Back pain subjects affected / exposed occurrences (all) | 13 / 120 (10.83%) 15 | | |
| Infections and infestations | | | |
| Bronchitis subjects affected / exposed occurrences (all) | 11 / 120 (9.17%) 12 | | |
| Influenza subjects affected / exposed occurrences (all) | 10 / 120 (8.33%) 10 | | |
| Nasopharyngitis subjects affected / exposed occurrences (all) | 13 / 120 (10.83%) 13 | | |
| Rhinitis subjects affected / exposed occurrences (all) | 11 / 120 (9.17%) 13 | | |
| Viral upper respiratory tract infection subjects affected / exposed occurrences (all) | 8 / 120 (6.67%) 8 | | |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported