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Trial record **2 of 2** for: CAIN457A2209

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# Double Blind, Placebo Controlled Study to Assess Efficacy of AIN457 in Moderate to Severe Ankylosing Spondylitis

**This study has been completed.**

**Sponsor:**
Novartis Pharmaceuticals

**Information provided by (Responsible Party):**
Novartis ( Novartis Pharmaceuticals )

**ClinicalTrials.gov Identifier:**
NCT00809159

First received: December 16, 2008
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History of Changes

Full Text View | Tabular View | Study Results | Disclaimer | How to Read a Study Record

Results First Received: January 29, 2015

| | |
|---|---|
| **Study Type:** | Interventional |
| **Study Design:** | Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study;<br>Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator) |
| **Condition:** | Ankylosing Spondylitis |
| **Interventions:** | Biological: AIN457<br>Drug: Placebo |

## Participant Flow

Hide Participant Flow

### Recruitment Details

| **Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations** |
|---|
| Part 1 of the study, patients received 2 infusions spaced three weeks apart of 10 mg/kg AIN457 or placebo, and in Part 2 of the study, patients received 2 infusions spaced three weeks apart of 0.1 mg/kg, 1.0 mg/kg or 10 mg/kg AIN457, respectively. |

### Pre-Assignment Details

| **Significant events and approaches for the overall study following participant enrollment, but prior to group assignment** |
|---|
| Part 1 participants were randomized 4:1 to receive AIN457A or placebo. Part 2, the randomization ratio was to be 2:2:1 for the three dose groups, 0.1 mg/kg, 1 mg/kg and 10 mg/kg. More subjects were randomized to the 0.1 and 1mg/kg dose groups as compared to the 10 mg/kg group, as 24 subjects were already randomized to the 10 mg/kg group in Part 1. |

### Reporting Groups

| | **Description** |
|---|---|
| **Part 1 - AIN457A 10 mg/kg** | AIN457A 10.0 mg/kg was administered intravenously as a single dose. |
| **Part 1 - Placebo** | Placebo to AIN457A was administered intravenously as a single dose |
| **Parts 1 and 2 - AIN457A 10 mg/kg** | AIN457A 10 mg/kg was administered intravenously as 2 doses 21 days apart, i.e. the first dose on day 1 and the second dose on day 22. |
| **Part 1 and 2 - AIN457 1.0 mg/kg** | AIN457A 1.0 mg/kg was administered intravenously as 2 doses 21 days apart, i.e. the first dose on day 1 and the second dose on day 22 |

| | |
|---|---|
| **Part 1 and 2 - AIN457 0.1 mg/kg** | AIN457A 0.1 mg/kg was administered intravenously as 2 doses 21 days apart, i.e. the first dose on day 1 and the second dose on day 22 |
| **Part 1 and 2 - Placebo** | Placebo to AIN457A was administered intravenously as a single dose |

**Participant Flow for 2 periods**

**Period 1: Part 1**

| | Part 1 - AIN457A 10 mg/kg | Part 1 - Placebo | Parts 1 and 2 - AIN457A 10 mg/kg | Part 1 and 2 - AIN457 1.0 mg/kg | Part 1 and 2 - AIN457 0.1 mg/kg | Part 1 and 2 - Placebo |
|---|---|---|---|---|---|---|
| **STARTED** | 24 | 6 | 0 | 0 | 0 | 0 |
| **PK Analysis Set** | 24 | 6 | 0 | 0 | 0 | 0 |
| **PD Analysis Set** | 23 | 6 | 0 | 0 | 0 | 0 |
| **COMPLETED** | 16 | 3 | 0 | 0 | 0 | 0 |
| **NOT COMPLETED** | 8 | 3 | 0 | 0 | 0 | 0 |
| **Adverse Event** | 1 | 1 | 0 | 0 | 0 | 0 |
| **Lost to Follow-up** | 1 | 0 | 0 | 0 | 0 | 0 |
| **Withdrawal by Subject** | 3 | 1 | 0 | 0 | 0 | 0 |
| **Unsatisfactory therapeutic effect** | 3 | 1 | 0 | 0 | 0 | 0 |

**Period 2: Part 1 and 2**

| | Part 1 - AIN457A 10 mg/kg | Part 1 - Placebo | Parts 1 and 2 - AIN457A 10 mg/kg | Part 1 and 2 - AIN457 1.0 mg/kg | Part 1 and 2 - AIN457 0.1 mg/kg | Part 1 and 2 - Placebo |
|---|---|---|---|---|---|---|
| **STARTED** | 0 | 0 | 30 | 12 | 12 | 6 |
| **PK Analysis Set** | 0 | 0 | 30 | 12 | 12 | 6 |
| **PD Analysis Set** | 0 | 0 | 28 | 12 | 12 | 6 |
| **COMPLETED** | 0 | 0 | 20 | 7 | 6 | 3 |
| **NOT COMPLETED** | 0 | 0 | 10 | 5 | 6 | 3 |
| **Unsatisfactory therapeutic effect** | 0 | 0 | 4 | 3 | 5 | 1 |
| **Administrative problems** | 0 | 0 | 0 | 1 | 0 | 0 |
| **Adverse Event** | 0 | 0 | 1 | 0 | 1 | 1 |
| **Lost to Follow-up** | 0 | 0 | 1 | 1 | 0 | 0 |
| **Withdrawal by Subject** | 0 | 0 | 4 | 0 | 0 | 1 |

## Baseline Characteristics

Hide Baseline Characteristics

**Population Description**

| **Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.** |
|---|
| No text entered. |

**Reporting Groups**

| | **Description** |
|---|---|
| **Parts 1 and 2 - AIN457A 10 mg/kg** | AIN457A 10 mg/kg was administered intravenously as 2 doses 21 days apart, i.e. the first dose on day 1 and the second dose on day 22. |
| **Part 1 and 2 - AIN457 1.0 mg/kg** | AIN457A 1.0 mg/kg was administered intravenously as 2 doses 21 days apart, i.e. the first dose on day 1 and the second dose on day 22 |
| **Part 1 and 2 - AIN457 0.1 mg/kg** | AIN457A 0.1 mg/kg was administered intravenously as 2 doses 21 days apart, i.e. the first dose on day 1 and the second dose on day 22 |
| **Part 1 and 2 - Placebo** | Placebo to AIN457A was administered intravenously as a single dose |
| **Total** | Total of all reporting groups |

**Baseline Measures**

| | **Parts 1 and 2 - AIN457A 10 mg/kg** | **Part 1 and 2 - AIN457 1.0 mg/kg** | **Part 1 and 2 - AIN457 0.1 mg/kg** | **Part 1 and 2 - Placebo** | **Total** |
|---|---|---|---|---|---|
| **Number of Participants [units: participants]** | **30** | **12** | **12** | **6** | **60** |
| **Age [units: Years] Mean (Standard Deviation)** | **40.7 (9.69)** | **47.2 (10.50)** | **42.8 (9.17)** | **45.0 (9.96)** | **42.8 (9.88)** |
| **Gender [units: Participants]** | | | | | |
| **Female** | **11** | **6** | **4** | **1** | **22** |
| **Male** | **19** | **6** | **8** | **5** | **38** |

## Outcome Measures

Hide All Outcome Measures

1. Primary: Percentage of Participants Who Achieved ASAS20 Response [ Time Frame: 6 Weeks ]

| | |
|---|---|
| **Measure Type** | Primary |
| **Measure Title** | Percentage of Participants Who Achieved ASAS20 Response |
| **Measure Description** | Clinical response to treatment was assessed according to ASAS20 criteria. ASAS20 responder had improvement of 20% or more and absolute improvement of at least 1 units (on a scale of 0 [least] to 10 [worst]) from Baseline in at least 3 of the following 4 domains, with absence of deterioration (worsening of at least 20% an absolute Worsening of at least 1 unit) in the potential remaining domain: Patient's Global Assessment of Disease Activity; Total Back Pain visual analog scale (VAS); Function (Bath Ankylosing Spondylitis Functional Index (BASFI)); and Inflammation (mean of 2 morning stiffness-related Bath Ankylosing Spondylitis Disease Activity Index [BASDAI] scores |
| **Time Frame** | 6 Weeks |
| **Safety Issue** | No |

**Population Description**

| **Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.** |
|---|
| |

Pharmacodynamic Analysis set: All patients with a least one evaluable post-treatment PD measurement and no major protocol deviations with impact on PD data were included. One subjects was excluded from the PD set in the AIN457 10mg/kg Part 1 due to protocol deviation

**Reporting Groups**

| | Description |
|---|---|
| **Part 1 - AIN457A 10 mg/kg** | AIN457A 10.0 mg/kg was administered intravenously as a single dose. |
| **Part 1 - Placebo** | Placebo to AIN457A was administered intravenously as a single dose |

**Measured Values**

| | Part 1 - AIN457A 10 mg/kg | Part 1 - Placebo |
|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **23** | **6** |
| **Percentage of Participants Who Achieved ASAS20 Response [units: Percentage]** | **59.2** | **24.5** |

**No statistical analysis provided for Percentage of Participants Who Achieved ASAS20 Response**

2. Primary: Change in Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) Score From Baseline to 6 Weeks After First Infusion in Part 2 [ Time Frame: 6 Weeks ]

| | |
|---|---|
| **Measure Type** | Primary |
| **Measure Title** | Change in Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) Score From Baseline to 6 Weeks After First Infusion in Part 2 |
| **Measure Description** | ASAS20 as described in Primary Outcome. ASAS40 responder had improvement of 40% or more and absolute improvement of at least 2 units (on a scale of 0 [least] to 10 [worst]) from Baseline in at least 3 of the following 4 domains, with no deterioration in the potential remaining domain: Patient's Global Assessment of Disease Activity; Total Back Pain visual analog scale (VAS); Function (Bath Ankylosing Spondylitis Functional Index (BASFI)); and Inflammation (mean of 2 morning stiffness-related Bath Ankylosing Spondylitis Disease Activity Index [BASDAI] scores). ASAS 5/6 responder had improvement of 20% or more) from Baseline in at least 5 of the following 6 domains: Patient's Global Assessment of Disease Activity; Total Back Pain visual analog scale (VAS); Function (BASFI); and Inflammation (mean of 2 morning stiffness-related Bath Ankylosing Spondylitis Disease Activity Index [BASDAI] scores); Spinal Mobility (BASFI); Acute phase reactant (CRP) |
| **Time Frame** | 6 Weeks |
| **Safety Issue** | No |

**Population Description**

| |
|---|
| **Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.** |
| Pharmacodynamic Analysis set: All patients with a least one evaluable post-treatment PD measurement and no major protocol deviations with impact on PD data were included. One subjects was excluded from the PD set in the AIN457 10mg/kg Part 2 due to the absence of available post-baseline PD measurements |

**Reporting Groups**

| | Description |
|---|---|
| **Parts 1 and 2 - AIN457A 10 mg/kg** | AIN457A 10 mg/kg was administered intravenously as 2 doses 21 days apart, i.e. the first dose on day 1 and the second dose on day 22. |
| **Part 1 and 2 - AIN457 1.0 mg/kg** | AIN457A 1.0 mg/kg was administered intravenously as 2 doses 21 days apart, i.e. the first dose on day 1 and the second dose on day 22 |
| **Part 1 and 2 - AIN457 0.1 mg/kg** | AIN457A 0.1 mg/kg was administered intravenously as 2 doses 21 days apart, i.e. the first dose on day 1 and the second dose on day 22 |
| **Part 1 and 2 - Placebo** | Placebo to AIN457A was administered intravenously as a single dose |

**Measured Values**

| | Parts 1 and 2 - AIN457A 10 mg/kg | Part 1 and 2 - AIN457 1.0 mg/kg | Part 1 and 2 - AIN457 0.1 mg/kg | Part 1 and 2 - Placebo |
|---|---|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **26** | **11** | **11** | **3** |
| **Change in Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) Score From Baseline to 6 Weeks After First Infusion in Part 2 [units: Units on a scale] Least Squares Mean (95% Confidence Interval)** | **-1.87 (-2.691 to -1.051)** | **-2.0151 (-3.275 to -0.755)** | **-1.2002 (-2.514 to 0.113)** | **-1.0577 (-2.893 to 0.777)** |

**No statistical analysis provided for Change in Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) Score From Baseline to 6 Weeks After First Infusion in Part 2**

3. Secondary: Number of Participants Who Achieved ASAS20, ASAS40, and ASAS 5/6 Over Time in Part 1 [ Time Frame: Day8,15,29,week 6, 8, 10, 12, 16, 20, 24, 28 ]

| | |
|---|---|
| **Measure Type** | Secondary |
| **Measure Title** | Number of Participants Who Achieved ASAS20, ASAS40, and ASAS 5/6 Over Time in Part 1 |
| **Measure Description** | ASAS20 responder had improvement of 40% or more and absolute improvement of at least 2 units (scale of 0 [least] to 10 [worst]) from Baseline in at least 3 of the following 4 domains, with no deterioration in the potential remaining domain: Patient's Global Assessment of Disease Activity; Total Back Pain visual analog scale (VAS); Function (Bath Ankylosing Spondylitis Functional Index (BASFI)); and Inflammation (mean of 2 morning stiffness-related Bath Ankylosing Spondylitis Disease Activity Index [BASDAI] scores). ASAS 5/6 responder had improvement of 20% or more) from Baseline in at least 5 of the following 6 domains: Patient's Global Assessment of Disease Activity; Total Back Pain visual analog scale (VAS); Function (Bath Ankylosing Spondylitis Functional Index (BASFI)); and Inflammation (mean of 2 morning stiffness-related Bath Ankylosing Spondylitis Disease Activity Index [BASDAI] scores); Spinal Mobility (BASFI); Acute phase reactant (CRP) |
| **Time Frame** | Day8,15,29,week 6, 8, 10, 12, 16, 20, 24, 28 |
| **Safety Issue** | No |

**Population Description**

| **Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.** |
|---|
| Pharmacodynamic Analysis set: All patients with a least one evaluable post-treatment PD measurement and no major protocol deviations with impact on PD data were included. One subjects was excluded from the PD set in the AIN457 10mg/kg Part 1 due to protocol deviation |

**Reporting Groups**

| | **Description** |
|---|---|
| **Part 1 - AIN457A 10 mg/kg** | AIN457A 10.0 mg/kg was administered intravenously as a single dose. |
| **Part 1 - Placebo** | Placebo to AIN457A was administered intravenously as a single dose |

**Measured Values**

| | Part 1 - AIN457A 10 mg/kg | Part 1 - Placebo |
|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **23** | **6** |
| **Number of Participants Who Achieved ASAS20, ASAS40, and ASAS 5/6 Over Time in Part 1 [units: Participants]** | | |

| | | |
|---|---|---|
| **ASAS20 at Day 8** | **9** | **2** |
| **ASAS20 at Day 15** | **9** | **1** |
| **ASAS20 at Day 29** | **11** | **0** |
| **ASAS40 at Day 8** | **4** | **0** |
| **ASAS40 at Day 15** | **4** | **0** |
| **ASAS40 at Day 29** | **8** | **0** |
| **ASAS 5/6 at Day 8** | **5** | **1** |
| **ASAS 5/6 at Day 15** | **5** | **0** |
| **ASAS 5/6 at Day 29** | **8** | **0** |
| **ASAS20 at week 6** | **14** | **1** |
| **ASAS20 at week 8** | **8** | **1** |
| **ASAS20 at week 10** | **9** | **0** |
| **ASAS20 at week 12** | **9** | **1** |
| **ASAS20 at week 16** | **8** | **1** |
| **ASAS20 at week 20** | **6** | **1** |
| **ASAS20 at week 24** | **7** | **0** |
| **ASAS20 at week 28** | **7** | **1** |
| **ASAS40 at week 6** | **7** | **1** |
| **ASAS40 at week 8** | **5** | **0** |
| **ASAS40 at week 10** | **5** | **0** |
| **ASAS40 at week 12** | **3** | **0** |
| **ASAS40 at week 16** | **3** | **1** |
| **ASAS40 at week 20** | **2** | **1** |
| **ASAS40 at week 24** | **3** | **0** |
| **ASAS40 at week 28** | **2** | **0** |
| **ASAS 5/6 at week 6** | **8** | **0** |
| **ASAS 5/6 at week 8** | **7** | **0** |
| **ASAS 5/6 at week 10** | **6** | **0** |
| **ASAS 5/6 at week 12** | **3** | **0** |
| **ASAS 5/6 at week 16** | **4** | **0** |
| **ASAS 5/6 at week 20** | **2** | **1** |
| **ASAS 5/6 at week 24** | **3** | **0** |
| **ASAS 5/6 at week 28** | **1** | **0** |

**No statistical analysis provided for Number of Participants Who Achieved ASAS20, ASAS40, and ASAS 5/6 Over Time in Part 1**

4. Secondary: Number of Participants Who Achieved ASAS20, ASAS40, and ASAS 5/6 in Part 1 and 2 Combined [ Time Frame: Day 8,15,29,week 6, 8, 10, 12, 16, 20, 24, 28 ]

| | |
|---|---|
| **Measure Type** | Secondary |
| **Measure Title** | Number of Participants Who Achieved ASAS20, ASAS40, and ASAS 5/6 in Part 1 and 2 Combined |
| **Measure Description** | a Bayesian model was fitted to the ASAS20 , ASAS40 and ASAS 5/6 response rates on active and placebo treatments. |

| | |
|---|---|
| | A Bayesian analysis had been chosen to allow the direct incorporation into the analysis of information about placebo response rates from historical data |
| **Time Frame** | Day 8,15,29,week 6, 8, 10, 12, 16, 20, 24, 28 |
| **Safety Issue** | No |

**Population Description**

| **Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.** |
|---|
| Pharmacodynamic Analysis set: All patients with a least one evaluable post-treatment PD measurement and no major protocol deviations with impact on PD data were included. One subjects was excluded from the PD set in the AIN457 10mg/kg Part 2 due to the absence of available post-baseline PD measurements |

**Reporting Groups**

| | **Description** |
|---|---|
| **Parts 1 and 2 - AIN457A 10 mg/kg** | AIN457A 10 mg/kg was administered intravenously as 2 doses 21 days apart, i.e. the first dose on day 1 and the second dose on day 22. |
| **Part 1 and 2 - AIN457 1.0 mg/kg** | AIN457A 1.0 mg/kg was administered intravenously as 2 doses 21 days apart, i.e. the first dose on day 1 and the second dose on day 22 |
| **Part 1 and 2 - AIN457 0.1 mg/kg** | AIN457A 0.1 mg/kg was administered intravenously as 2 doses 21 days apart, i.e. the first dose on day 1 and the second dose on day 22 |
| **Part 1 and 2 - Placebo** | Placebo to AIN457A was administered intravenously as a single dose |

**Measured Values**

| | **Parts 1 and 2 - AIN457A 10 mg/kg** | **Part 1 and 2 - AIN457 1.0 mg/kg** | **Part 1 and 2 - AIN457 0.1 mg/kg** | **Part 1 and 2 - Placebo** |
|---|---|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **28** | **12** | **12** | **6** |
| **Number of Participants Who Achieved ASAS20, ASAS40, and ASAS 5/6 in Part 1 and 2 Combined [units: Participants]** | | | | |
| **ASAS20 at day 8 (n=28,12,12,6)** | **12** | **3** | **6** | **2** |
| **ASAS20 at day 15 (n=28,12,12,5)** | **11** | **7** | **4** | **1** |
| **ASAS20 at day 29 (n=28,12,11,6)** | **14** | **6** | **4** | **0** |
| **ASAS40 at day 8 (n=28,12,12,6)** | **6** | **2** | **2** | **0** |
| **ASAS40 at day 15 (n=28,12,12,5)** | **5** | **3** | **3** | **0** |
| **ASAS40 at day 29 (28,12,11,6)** | **10** | **3** | **1** | **0** |
| **ASAS 5/6 at day 8 (28,12,12,6)** | **6** | **3** | **5** | **1** |
| **ASAS 5/6 at day 15 (n=28,12,12,5)** | **5** | **5** | **2** | **0** |
| **ASAS 5/6 at day 29 (n=28,12,11,6)** | **9** | **5** | **3** | **0** |
| **ASAS20 at week 6 (n=27,11,11,6)** | **16** | **4** | **3** | **1** |
| **ASAS20 at week 8 (n=28,11,11,6)** | **10** | **4** | **3** | **1** |
| **ASAS20 at week 10 (n=27,11,10,6)** | **11** | **5** | **2** | **0** |
| **ASAS20 at week 12 (n=27,12,11,6)** | **12** | **3** | **4** | **1** |
| **ASAS20 at week 16 (n=28,12,11,6)** | **9** | **5** | **3** | **1** |
| **ASAS20 at week 20 (n=28,12,11,6)** | **6** | **4** | **2** | **1** |
| **ASAS20 at week 24 (n=28,12,11,6)** | **7** | **2** | **1** | **0** |
| **ASAS20 at week 28 (n=28,11,11,6)** | **8** | **2** | **2** | **1** |

| | | | | |
|---|---|---|---|---|
| **ASAS40 at week 6 (n=27,11,11,6)** | **8** | **2** | **3** | **1** |
| **ASAS40 at week 8 (n=28,11,11,6)** | **5** | **2** | **2** | **0** |
| **ASAS40 at week 10 (28,11,11,6)** | **5** | **2** | **1** | **0** |
| **ASAS40 at week 12 (n=27,12,11,6)** | **3** | **2** | **3** | **0** |
| **ASAS40 at week 16 (n=28,12,11,6)** | **3** | **3** | **2** | **1** |
| **ASAS40 at week 20 (n=28,12,11,6)** | **2** | **1** | **2** | **1** |
| **ASAS40 at week 24 (n=28,12,11,6)** | **3** | **1** | **1** | **0** |
| **ASAS40 at week 28 (n=28,11,11,6)** | **3** | **0** | **1** | **0** |
| **ASAS 5/6 at week 6 (n=28,11,11,6)** | **9** | **3** | **2** | **0** |
| **ASAS 5/6 at week 8 (n=28,11,11,6)** | **7** | **4** | **1** | **0** |
| **ASAS 5/6 at week 10 (n=27,11,10,6)** | **6** | **4** | **1** | **0** |
| **ASAS 5/6 at week 12 (n=28,12,11,6)** | **5** | **2** | **1** | **0** |
| **ASAS 5/6 at week 16 (n=28,12,11,6)** | **5** | **5** | **2** | **0** |
| **ASAS 5/6 at week 20 (n=28,12,11,6)** | **2** | **3** | **1** | **1** |
| **ASAS 5/6 at week 24 (n=28,12,11,6)** | **3** | **2** | **1** | **0** |
| **ASAS 5/6 at week 28 (n=28,11,10,6)** | **2** | **0** | **1** | **0** |

**No statistical analysis provided for Number of Participants Who Achieved ASAS20, ASAS40, and ASAS 5/6 in Part 1 and 2 Combined**

5. Secondary: Magnetic Resonance Imaging (MRI) Inflammatory Scores at Baseline, Week 6 in Part 1 [ Time Frame: Baseline, week 6, week 28 ]

| | |
|---|---|
| **Measure Type** | Secondary |
| **Measure Title** | Magnetic Resonance Imaging (MRI) Inflammatory Scores at Baseline, Week 6 in Part 1 |
| **Measure Description** | The study used MRI with fat-saturating techniques such as short tau inversion recovery (STIR) to look for the presence of bone marrow edema. The Berlin modification of ASspiMRI-a (ASspiMRI-a) scoring technique assesses inflammation in each of the 23 disc vertebral units (DVU), capturing edema and erosion. Scores for each DVU range from 0-3 (0=normal; 1=minor bone marrow edema (less than25% of DVU; 3=severe bone marrow edema (more that 50% of DVU). The composite score ranges from 0 to 69, with higher scores indicating more severe inflammation |
| **Time Frame** | Baseline, week 6, week 28 |
| **Safety Issue** | No |

**Population Description**

| **Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.** |
|---|
| Pharmacodynamic Analysis set: All patients with a least one evaluable post-treatment PD measurement and no major protocol deviations with impact on PD data were included. One subjects was excluded from the PD set in the AIN457 10mg/kg Part 1 due to protocol deviation |

**Reporting Groups**

| | **Description** |
|---|---|
| **Part 1 - AIN457A 10 mg/kg** | AIN457A 10.0 mg/kg was administered intravenously as a single dose. |
| **Part 1 - Placebo** | Placebo to AIN457A was administered intravenously as a single dose |

**Measured Values**

| | **Part 1 - AIN457A 10 mg/kg** | **Part 1 - Placebo** |
|---|---|---|
| | | |

| | | |
|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **22** | **5** |
| **Magnetic Resonance Imaging (MRI) Inflammatory Scores at Baseline, Week 6 in Part 1 [units: Score] Mean (Standard Deviation)** | | |
| **Baseline (n=22,5)** | **9.2 (8.87)** | **20.6 (20.18)** |
| **Week 6 (n=22,3)** | **6.6 (6.56)** | **21.0 (24.56)** |
| **Week 28 (n=16,5)** | **5.7 (6.20)** | **19.0 (19.33)** |

**No statistical analysis provided for Magnetic Resonance Imaging (MRI) Inflammatory Scores at Baseline, Week 6 in Part 1**

6. Secondary: Pharmacokinetics (PK) of AIN457: Time to Reach the Maximum Concentration After Drug Administration (Tmax) in Part 1 [ Time Frame: Week 28 ]

| | |
|---|---|
| **Measure Type** | Secondary |
| **Measure Title** | Pharmacokinetics (PK) of AIN457: Time to Reach the Maximum Concentration After Drug Administration (Tmax) in Part 1 |
| **Measure Description** | Serum samples were collected pre-dose 2, 3, 4 and 24 hours after initiation of the infusions (Days 1 and 22), Weeks 1, 2, 4, 6, 8, 12, 16, 20, 24 and end of study/Week 28. |
| **Time Frame** | Week 28 |
| **Safety Issue** | No |

**Population Description**

| **Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.** |
|---|
| Pharmacokinetic Analysis set: All patients with quantifiable PK measurements and no major protocol deviations with impact on PK data. Due to several discontinuations, the full set of PK parameters could not be obtained in all treated patients. Patients who received only one infusion and/or had a too short PK sampling period were excluded. |

**Reporting Groups**

| | **Description** |
|---|---|
| **Part 1 - AIN457A 10 mg/kg** | AIN457A 10.0 mg/kg was administered intravenously as a single dose. |

**Measured Values**

| | **Part 1 - AIN457A 10 mg/kg** |
|---|---|
| **Number of Participants Analyzed [units: participants]** | **23** |
| **Pharmacokinetics (PK) of AIN457: Time to Reach the Maximum Concentration After Drug Administration (Tmax) in Part 1 [units: Days] Median (Full Range)** | **21.07 (0.083 to 21.9)** |

**No statistical analysis provided for Pharmacokinetics (PK) of AIN457: Time to Reach the Maximum Concentration After Drug Administration (Tmax) in Part 1**

7. Secondary: Pharmacokinetics (PK) of AIN457: Time to Reach the Maximum Concentration After Drug Administration (Tmax) in Part 1 and 2 [ Time Frame: Week 28 ]

| | |
|---|---|
| **Measure Type** | Secondary |
| **Measure Title** | Pharmacokinetics (PK) of AIN457: Time to Reach the Maximum Concentration After Drug Administration (Tmax) in Part 1 and 2 |
| **Measure Description** | Serum samples were collected pre-dose 2, 3, 4 and 24 hours after initiation of the infusions (Days 1 and 22), Weeks 1, 2, 4, 6, 8, 12, 16, 20, 24 and end of study/Week 28. |
| **Time Frame** | Week 28 |
| **Safety Issue** | No |

**Population Description**

| |
|---|
| **Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.** |
| Pharmacokinetic Analysis set: All patients with quantifiable PK measurements and no major protocol deviations with impact on PK data. Due to several discontinuations, the full set of PK parameters could not be obtained in all treated patients. Patients who received only one infusion and/or had a too short PK sampling period were excluded. |

**Reporting Groups**

| | **Description** |
|---|---|
| **Parts 1 and 2 - AIN457A 10 mg/kg** | AIN457A 10 mg/kg was administered intravenously as 2 doses 21 days apart, i.e. the first dose on day 1 and the second dose on day 22. |
| **Part 1 and 2 - AIN457 1.0 mg/kg** | AIN457A 1.0 mg/kg was administered intravenously as 2 doses 21 days apart, i.e. the first dose on day 1 and the second dose on day 22 |
| **Part 1 and 2 - AIN457 0.1 mg/kg** | AIN457A 0.1 mg/kg was administered intravenously as 2 doses 21 days apart, i.e. the first dose on day 1 and the second dose on day 22 |

**Measured Values**

| | **Parts 1 and 2 - AIN457A 10 mg/kg** | **Part 1 and 2 - AIN457 1.0 mg/kg** | **Part 1 and 2 - AIN457 0.1 mg/kg** |
|---|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **28** | **12** | **12** |
| **Pharmacokinetics (PK) of AIN457: Time to Reach the Maximum Concentration After Drug Administration (Tmax) in Part 1 and 2 [units: Days] Median (Full Range)** | **21.08 (0.083 to 22.2)** | **21.08 (0.125 to 23.0)** | **21.12 (19.1 to 22.1)** |

**No statistical analysis provided for Pharmacokinetics (PK) of AIN457: Time to Reach the Maximum Concentration After Drug Administration (Tmax) in Part 1 and 2**

8. Secondary: PK of AIN457: Observed Maximum Serum Concentration Following Drug Administration (Cmax) in Part 1 [ Time Frame: Week 28 ]

| | |
|---|---|
| **Measure Type** | Secondary |
| **Measure Title** | PK of AIN457: Observed Maximum Serum Concentration Following Drug Administration (Cmax) in Part 1 |
| **Measure Description** | Serum samples were collected pre-dose 2, 3, 4 and 24 hours after initiation of the infusions (Days 1 and 22), Weeks 1, 2, 4, 6, 8, 12, 16, 20, 24 and end of study/Week 28 |
| **Time Frame** | Week 28 |
| **Safety Issue** | No |

**Population Description**

| |
|---|
| **Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.** |

| |
|---|
| Pharmacokinetic Analysis set: All patients with quantifiable PK measurements and no major protocol deviations with impact on PK data. Due to several discontinuations, the full set of PK parameters could not be obtained in all treated patients. Patients who received only one infusion and/or had a too short PK sampling period were excluded |

**Reporting Groups**

| | Description |
|---|---|
| **Part 1 - AIN457A 10 mg/kg** | AIN457A 10.0 mg/kg was administered intravenously as a single dose. |

**Measured Values**

| | Part 1 - AIN457A 10 mg/kg |
|---|---|
| **Number of Participants Analyzed [units: participants]** | **23** |
| **PK of AIN457: Observed Maximum Serum Concentration Following Drug Administration (Cmax) in Part 1 [units: ug/mL] Mean (Standard Deviation)** | **357.7 (87.74)** |

**No statistical analysis provided for PK of AIN457: Observed Maximum Serum Concentration Following Drug Administration (Cmax) in Part 1**

9. Secondary: PK of AIN457: Observed Maximum Serum Concentration Following Drug Administration (Cmax) in Part 1 and 2 [ Time Frame: Week 28 ]

| | |
|---|---|
| **Measure Type** | Secondary |
| **Measure Title** | PK of AIN457: Observed Maximum Serum Concentration Following Drug Administration (Cmax) in Part 1 and 2 |
| **Measure Description** | Serum samples were collected pre-dose 2, 3, 4 and 24 hours after initiation of the infusions (Days 1 and 22), Weeks 1, 2, 4, 6, 8, 12, 16, 20, 24 and end of study/Week 28 |
| **Time Frame** | Week 28 |
| **Safety Issue** | No |

**Population Description**

| |
|---|
| **Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.** |
| Pharmacokinetic Analysis set: All patients with quantifiable PK measurements and no major protocol deviations with impact on PK data. Due to several discontinuations, the full set of PK parameters could not be obtained in all treated patients. Patients who received only one infusion and/or had a too short PK sampling period were excluded |

**Reporting Groups**

| | Description |
|---|---|
| **Parts 1 and 2 - AIN457A 10 mg/kg** | AIN457A 10 mg/kg was administered intravenously as 2 doses 21 days apart, i.e. the first dose on day 1 and the second dose on day 22. |
| **Part 1 and 2 - AIN457 1.0 mg/kg** | AIN457A 1.0 mg/kg was administered intravenously as 2 doses 21 days apart, i.e. the first dose on day 1 and the second dose on day 22 |
| **Part 1 and 2 - AIN457 0.1 mg/kg** | AIN457A 0.1 mg/kg was administered intravenously as 2 doses 21 days apart, i.e. the first dose on day 1 and the second dose on day 22 |

**Measured Values**

| | Parts 1 and 2 - AIN457A 10 mg/kg | Part 1 and 2 - AIN457 1.0 mg/kg | Part 1 and 2 - AIN457 0.1 mg/kg |
|---|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **28** | **12** | **12** |
| **PK of AIN457: Observed Maximum Serum Concentration Following** | | | |

| | | | |
|---|---|---|---|
| **Drug Administration (Cmax) in Part 1 and 2 [units: ug/mL] Mean (Standard Deviation)** | **363.9 (82.30)** | **33.13 (9.828)** | **5.509 (5.418)** |

**No statistical analysis provided for PK of AIN457: Observed Maximum Serum Concentration Following Drug Administration (Cmax) in Part 1 and 2**

10. Secondary: PK of AIN457: Area Under the Serum Concentration-time Cure From Time Zero to the Time of Last Quantifiable Concentration (AUClast), Area Under the Serum Concentration-time Curve From Time Zero to (AUCinf) in Part 1 [ Time Frame: Week 28 ]

| | |
|---|---|
| **Measure Type** | Secondary |
| **Measure Title** | PK of AIN457: Area Under the Serum Concentration-time Cure From Time Zero to the Time of Last Quantifiable Concentration (AUClast), Area Under the Serum Concentration-time Curve From Time Zero to (AUCinf) in Part 1 |
| **Measure Description** | Serum samples were collected pre-dose 2, 3, 4 and 24 hours after initiation of the infusions (Days 1 and 22), Weeks 1, 2, 4, 6, 8, 12, 16, 20, 24 and end of study/Week 28 |
| **Time Frame** | Week 28 |
| **Safety Issue** | No |

**Population Description**

| **Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.** |
|---|
| Pharmacokinetic Analysis set: All patients with quantifiable PK measurements and no major protocol deviations with impact on PK data. Due to several discontinuations, the full set of PK parameters could not be obtained in all treated patients. Patients who received only one infusion and/or had a too short PK sampling period were excluded |

**Reporting Groups**

| | **Description** |
|---|---|
| **Part 1 - AIN457A 10 mg/kg** | AIN457A 10.0 mg/kg was administered intravenously as a single dose. |

**Measured Values**

| | **Part 1 - AIN457A 10 mg/kg** |
|---|---|
| **Number of Participants Analyzed [units: participants]** | **20** |
| **PK of AIN457: Area Under the Serum Concentration-time Cure From Time Zero to the Time of Last Quantifiable Concentration (AUClast), Area Under the Serum Concentration-time Curve From Time Zero to (AUCinf) in Part 1 [units: day*ug/mL] Mean (Standard Deviation)** | |
| **AUCinf** | **10510 (3036)** |
| **AUClast** | **10310 (2869)** |

**No statistical analysis provided for PK of AIN457: Area Under the Serum Concentration-time Cure From Time Zero to the Time of Last Quantifiable Concentration (AUClast), Area Under the Serum Concentration-time Curve From Time Zero to (AUCinf) in Part 1**

11. Secondary: PK of AIN457: Area Under the Serum Concentration-time Cure From Time Zero to the Time of Last Quantifiable Concentration (AUClast), Area Under the Serum Concentration-time Curve From Time Zero to (AUCinf) in Part 1 and 2 [ Time Frame: Week 28 ]

| | |
|---|---|
| **Measure Type** | Secondary |

| | |
|---|---|
| **Measure Title** | PK of AIN457: Area Under the Serum Concentration-time Cure From Time Zero to the Time of Last Quantifiable Concentration (AUClast), Area Under the Serum Concentration-time Curve From Time Zero to (AUCinf) in Part 1 and 2 |
| **Measure Description** | Serum samples were collected pre-dose 2, 3, 4 and 24 hours after initiation of the infusions (Days 1 and 22), Weeks 1, 2, 4, 6, 8, 12, 16, 20, 24 and end of study/Week 28 |
| **Time Frame** | Week 28 |
| **Safety Issue** | No |

**Population Description**

| **Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.** |
|---|
| Pharmacokinetic Analysis set: All patients with quantifiable PK measurements and no major protocol deviations with impact on PK data. Due to several discontinuations, the full set of PK parameters could not be obtained in all treated patients. Patients who received only one infusion and/or had a too short PK sampling period were excluded |

**Reporting Groups**

| | **Description** |
|---|---|
| **Parts 1 and 2 - AIN457A 10 mg/kg** | AIN457A 10 mg/kg was administered intravenously as 2 doses 21 days apart, i.e. the first dose on day 1 and the second dose on day 22. |
| **Part 1 and 2 - AIN457 1.0 mg/kg** | AIN457A 1.0 mg/kg was administered intravenously as 2 doses 21 days apart, i.e. the first dose on day 1 and the second dose on day 22 |
| **Part 1 and 2 - AIN457 0.1 mg/kg** | AIN457A 0.1 mg/kg was administered intravenously as 2 doses 21 days apart, i.e. the first dose on day 1 and the second dose on day 22 |

**Measured Values**

| | **Parts 1 and 2 - AIN457A 10 mg/kg** | **Part 1 and 2 - AIN457 1.0 mg/kg** | **Part 1 and 2 - AIN457 0.1 mg/kg** |
|---|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **25** | **11** | **11** |
| **PK of AIN457: Area Under the Serum Concentration-time Cure From Time Zero to the Time of Last Quantifiable Concentration (AUClast), Area Under the Serum Concentration-time Curve From Time Zero to (AUCinf) in Part 1 and 2 [units: day*ug/mL] Mean (Standard Deviation)** | | | |
| **AUCinf** | **10880 (2983)** | **1025 (276.0)** | **198.0 (195.5)** |
| **AUClast** | **10630 (2818)** | **993.0 (279.5)** | **187.7 (190.7)** |

**No statistical analysis provided for PK of AIN457: Area Under the Serum Concentration-time Cure From Time Zero to the Time of Last Quantifiable Concentration (AUClast), Area Under the Serum Concentration-time Curve From Time Zero to (AUCinf) in Part 1 and 2**

12. Secondary: PK of AIN457: Systemic Clearance From Serum Following Intravenous Administration (CL) in Part 1 [ Time Frame: Week 28 ]

| | |
|---|---|
| **Measure Type** | Secondary |
| **Measure Title** | PK of AIN457: Systemic Clearance From Serum Following Intravenous Administration (CL) in Part 1 |
| **Measure Description** | Serum samples were collected pre-dose 2, 3, 4 and 24 hours after initiation of the infusions (Days 1 and 22), Weeks 1, 2, 4, 6, 8, 12, 16, 20, 24 and end of study/Week 28 |
| **Time Frame** | Week 28 |

| | |
|---|---|
| **Safety Issue** | No |

**Population Description**

| |
|---|
| **Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.** |
| Pharmacokinetic Analysis set: All patients with quantifiable PK measurements and no major protocol deviations with impact on PK data. Due to several discontinuations, the full set of PK parameters could not be obtained in all treated patients. Patients who received only one infusion and/or had a too short PK sampling period were excluded |

**Reporting Groups**

| | Description |
|---|---|
| **Part 1 - AIN457A 10 mg/kg** | AIN457A 10.0 mg/kg was administered intravenously as a single dose. |

**Measured Values**

| | Part 1 - AIN457A 10 mg/kg |
|---|---|
| **Number of Participants Analyzed [units: participants]** | **20** |
| **PK of AIN457: Systemic Clearance From Serum Following Intravenous Administration (CL) in Part 1 [units: Liters/day] Mean (Standard Deviation)** | **0.1594 (0.04998)** |

**No statistical analysis provided for PK of AIN457: Systemic Clearance From Serum Following Intravenous Administration (CL) in Part 1**

13. Secondary: PK of AIN457: Systemic Clearance From Serum Following Intravenous Administration (CL) in Part 1 and 2 [ Time Frame: Week 28 ]

| | |
|---|---|
| **Measure Type** | Secondary |
| **Measure Title** | PK of AIN457: Systemic Clearance From Serum Following Intravenous Administration (CL) in Part 1 and 2 |
| **Measure Description** | Serum samples were collected pre-dose 2, 3, 4 and 24 hours after initiation of the infusions (Days 1 and 22), Weeks 1, 2, 4, 6, 8, 12, 16, 20, 24 and end of study/Week 28 |
| **Time Frame** | Week 28 |
| **Safety Issue** | No |

**Population Description**

| |
|---|
| **Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.** |
| Pharmacokinetic Analysis set: All patients with quantifiable PK measurements and no major protocol deviations with impact on PK data. Due to several discontinuations, the full set of PK parameters could not be obtained in all treated patients. Patients who received only one infusion and/or had a too short PK sampling period were excluded |

**Reporting Groups**

| | Description |
|---|---|
| **Parts 1 and 2 - AIN457A 10 mg/kg** | AIN457A 10 mg/kg was administered intravenously as 2 doses 21 days apart, i.e. the first dose on day 1 and the second dose on day 22. |
| **Part 1 and 2 - AIN457 1.0 mg/kg** | AIN457A 1.0 mg/kg was administered intravenously as 2 doses 21 days apart, i.e. the first dose on day 1 and the second dose on day 22 |
| **Part 1 and 2 - AIN457 0.1 mg/kg** | AIN457A 0.1 mg/kg was administered intravenously as 2 doses 21 days apart, i.e. the first dose on day 1 and the second dose on day 22 |

**Measured Values**

| | Parts 1 and 2 - AIN457A 10 mg/kg | Part 1 and 2 - AIN457 1.0 mg/kg | Part 1 and 2 - AIN457 0.1 mg/kg |
|---|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **25** | **11** | **11** |
| **PK of AIN457: Systemic Clearance From Serum Following Intravenous Administration (CL) in Part 1 and 2 [units: Liters/day] Mean (Standard Deviation)** | **0.1571 (0.04734)** | **0.1718 (0.04942)** | **0.1182 (0.05474)** |

**No statistical analysis provided for PK of AIN457: Systemic Clearance From Serum Following Intravenous Administration (CL) in Part 1 and 2**

14. Secondary: PK of AIN457: Volume of Distribution During the Terminal Phase Following Intravenous Elimination (Vz) in Part 1 [ Time Frame: Week 28 ]

| | |
|---|---|
| **Measure Type** | Secondary |
| **Measure Title** | PK of AIN457: Volume of Distribution During the Terminal Phase Following Intravenous Elimination (Vz) in Part 1 |
| **Measure Description** | Serum samples were collected pre-dose 2, 3, 4 and 24 hours after initiation of the infusions (Days 1 and 22), Weeks 1, 2, 4, 6, 8, 12, 16, 20, 24 and end of study/Week 28 |
| **Time Frame** | Week 28 |
| **Safety Issue** | No |

**Population Description**

| **Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.** |
|---|
| Pharmacokinetic Analysis set: All patients with quantifiable PK measurements and no major protocol deviations with impact on PK data. Due to several discontinuations, the full set of PK parameters could not be obtained in all treated patients. Patients who received only one infusion and/or had a too short PK sampling period were excluded |

**Reporting Groups**

| | Description |
|---|---|
| **Part 1 - AIN457A 10 mg/kg** | AIN457A 10.0 mg/kg was administered intravenously as a single dose. |

**Measured Values**

| | Part 1 - AIN457A 10 mg/kg |
|---|---|
| **Number of Participants Analyzed [units: participants]** | **20** |
| **PK of AIN457: Volume of Distribution During the Terminal Phase Following Intravenous Elimination (Vz) in Part 1 [units: Liters] Mean (Standard Deviation)** | **6.121 (0.999)** |

**No statistical analysis provided for PK of AIN457: Volume of Distribution During the Terminal Phase Following Intravenous Elimination (Vz) in Part 1**

15. Secondary: PK of AIN457: Volume of Distribution During the Terminal Phase Following Intravenous Elimination (Vz) in Part 1 and 2 [ Time Frame: Week 28 ]

| | |
|---|---|
| **Measure Type** | Secondary |
| **Measure Title** | PK of AIN457: Volume of Distribution During the Terminal Phase Following Intravenous Elimination (Vz) in Part 1 and 2 |

| | |
|---|---|
| **Measure Description** | Serum samples were collected pre-dose 2, 3, 4 and 24 hours after initiation of the infusions (Days 1 and 22), Weeks 1, 2, 4, 6, 8, 12, 16, 20, 24 and end of study/Week 28 |
| **Time Frame** | Week 28 |
| **Safety Issue** | No |

**Population Description**

| |
|---|
| **Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.** |
| Pharmacokinetic Analysis set: All patients with quantifiable PK measurements and no major protocol deviations with impact on PK data. Due to several discontinuations, the full set of PK parameters could not be obtained in all treated patients. Patients who received only one infusion and/or had a too short PK sampling period were excluded |

**Reporting Groups**

| | **Description** |
|---|---|
| **Parts 1 and 2 - AIN457A 10 mg/kg** | AIN457A 10 mg/kg was administered intravenously as 2 doses 21 days apart, i.e. the first dose on day 1 and the second dose on day 22. |
| **Part 1 and 2 - AIN457 1.0 mg/kg** | AIN457A 1.0 mg/kg was administered intravenously as 2 doses 21 days apart, i.e. the first dose on day 1 and the second dose on day 22 |
| **Part 1 and 2 - AIN457 0.1 mg/kg** | AIN457A 0.1 mg/kg was administered intravenously as 2 doses 21 days apart, i.e. the first dose on day 1 and the second dose on day 22 |

**Measured Values**

| | **Parts 1 and 2 - AIN457A 10 mg/kg** | **Part 1 and 2 - AIN457 1.0 mg/kg** | **Part 1 and 2 - AIN457 0.1 mg/kg** |
|---|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **25** | **11** | **11** |
| **PK of AIN457: Volume of Distribution During the Terminal Phase Following Intravenous Elimination (Vz) in Part 1 and 2 [units: Liters] Mean (Standard Deviation)** | **6.055 (0.943)** | **6.481 (1.701)** | **5.827 (2.887)** |

**No statistical analysis provided for PK of AIN457: Volume of Distribution During the Terminal Phase Following Intravenous Elimination (Vz) in Part 1 and 2**

16. Secondary: PK of AIN457: Terminal Elimination Half-life (T1/2) in Part 1 [ Time Frame: Week 28 ]

| | |
|---|---|
| **Measure Type** | Secondary |
| **Measure Title** | PK of AIN457: Terminal Elimination Half-life (T1/2) in Part 1 |
| **Measure Description** | Serum samples were collected pre-dose 2, 3, 4 and 24 hours after initiation of the infusions (Days 1 and 22), Weeks 1, 2, 4, 6, 8, 12, 16, 20, 24 and end of study/Week 28 |
| **Time Frame** | Week 28 |
| **Safety Issue** | No |

**Population Description**

| |
|---|
| **Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.** |
| Pharmacokinetic Analysis set: All patients with quantifiable PK measurements and no major protocol deviations with impact on PK data. Due to several discontinuations, the full set of PK parameters could not be obtained in all treated patients. Patients who received only one infusion and/or had a too short PK sampling period were excluded |

**Reporting Groups**

| | Description |
|---|---|
| **Part 1 - AIN457A 10 mg/kg** | AIN457A 10.0 mg/kg was administered intravenously as a single dose. |

**Measured Values**

| | Part 1 - AIN457A 10 mg/kg |
|---|---|
| **Number of Participants Analyzed [units: participants]** | **20** |
| **PK of AIN457: Terminal Elimination Half-life (T1/2) in Part 1 [units: day] Mean (Standard Deviation)** | **27.95 (5.624)** |

**No statistical analysis provided for PK of AIN457: Terminal Elimination Half-life (T1/2) in Part 1**

17. Secondary: PK of AIN457: Terminal Elimination Half-life (T1/2) in Part 1 and 2 [ Time Frame: Week 28 ]

| | |
|---|---|
| **Measure Type** | Secondary |
| **Measure Title** | PK of AIN457: Terminal Elimination Half-life (T1/2) in Part 1 and 2 |
| **Measure Description** | Serum samples were collected pre-dose 2, 3, 4 and 24 hours after initiation of the infusions (Days 1 and 22), Weeks 1, 2, 4, 6, 8, 12, 16, 20, 24 and end of study/Week 28 |
| **Time Frame** | Week 28 |
| **Safety Issue** | No |

**Population Description**

| **Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.** |
|---|
| Pharmacokinetic Analysis set: All patients with quantifiable PK measurements and no major protocol deviations with impact on PK data. Due to several discontinuations, the full set of PK parameters could not be obtained in all treated patients. Patients who received only one infusion and/or had a too short PK sampling period were excluded |

**Reporting Groups**

| | Description |
|---|---|
| **Parts 1 and 2 - AIN457A 10 mg/kg** | AIN457A 10 mg/kg was administered intravenously as 2 doses 21 days apart, i.e. the first dose on day 1 and the second dose on day 22. |
| **Part 1 and 2 - AIN457 1.0 mg/kg** | AIN457A 1.0 mg/kg was administered intravenously as 2 doses 21 days apart, i.e. the first dose on day 1 and the second dose on day 22 |
| **Part 1 and 2 - AIN457 0.1 mg/kg** | AIN457A 0.1 mg/kg was administered intravenously as 2 doses 21 days apart, i.e. the first dose on day 1 and the second dose on day 22 |

**Measured Values**

| | Parts 1 and 2 - AIN457A 10 mg/kg | Part 1 and 2 - AIN457 1.0 mg/kg | Part 1 and 2 - AIN457 0.1 mg/kg |
|---|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **25** | **11** | **11** |
| **PK of AIN457: Terminal Elimination Half-life (T1/2) in Part 1 and 2 [units: day] Mean (Standard Deviation)** | **28.09 (5.994)** | **27.32 (7.234)** | **34.31 (6.656)** |

**No statistical analysis provided for PK of AIN457: Terminal Elimination Half-life (T1/2) in Part 1 and 2**

18. Secondary: Mean Change Bath Ankylosing Spondylitis Metrology Index (BASMI) Score in Part 1 and 2 [ Time Frame: Baseline, day 8,15,29, week 6,8,10,12,16,20,24,28 ]

| | |
|---|---|
| **Measure Type** | Secondary |
| **Measure Title** | Mean Change Bath Ankylosing Spondylitis Metrology Index (BASMI) Score in Part 1 and 2 |
| **Measure Description** | BASMI measures the range of motion based on five clinical measurements: 1) cervical rotation, 2) tragus to wall distance, 3) lumbar side flexion, 4) lumbar flexion (modified Schober's) and 5) intermalleolar distance. BASMI 0 = indicates mild disease involvement, 1 = moderate disease, and 2 = severe disease involvement. The results for cervical rotation and lumbar side flexion are the means of the left and right measurements. Scoring range 0-10. The higher the BASMI score, the more severe was the subject's limitation of movement |
| **Time Frame** | Baseline, day 8,15,29, week 6,8,10,12,16,20,24,28 |
| **Safety Issue** | No |

**Population Description**

| |
|---|
| **Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.** |
| Pharmacodynamic Analysis set: All patients with a least one evaluable post-treatment PD measurement and no major protocol deviations with impact on PD data were included. One subjects was excluded from the PD set in the AIN457 10mg/kg Part 2 due to the absence of available post-baseline PD measurements |

**Reporting Groups**

| | **Description** |
|---|---|
| **Parts 1 and 2 - AIN457A 10 mg/kg** | AIN457A 10 mg/kg was administered intravenously as 2 doses 21 days apart, i.e. the first dose on day 1 and the second dose on day 22 |
| **Part 1 and 2 - AIN457 1.0 mg/kg** | AIN457A 1.0 mg/kg was administered intravenously as 2 doses 21 days apart, i.e. the first dose on day 1 and the second dose on day 22 |
| **Part 1 and 2 - AIN457 0.1 mg/kg** | AIN457A 0.1 mg/kg was administered intravenously as 2 doses 21 days apart, i.e. the first dose on day 1 and the second dose on day 22 |
| **Part 1 and 2 - Placebo** | Placebo to AIN457A was administered intravenously as a single dose |

**Measured Values**

| | **Parts 1 and 2 - AIN457A 10 mg/kg** | **Part 1 and 2 - AIN457 1.0 mg/kg** | **Part 1 and 2 - AIN457 0.1 mg/kg** | **Part 1 and 2 - Placebo** |
|---|---|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **28** | **12** | **12** | **6** |
| **Mean Change Bath Ankylosing Spondylitis Metrology Index (BASMI) Score in Part 1 and 2 [units: Score] Mean (Standard Deviation)** | | | | |
| **Day 8 (n=28,12,12,5)** | **-0.121 (0.7969)** | **-0.117 (0.6293)** | **-0.233 (0.9335)** | **0.240 (0.2966)** |
| **Day 15 (n=28,12,12,5)** | **-0.200 (0.7364)** | **-0.383 (0.5937)** | **-0.350 (0.7775)** | **0.160 (0.8764)** |
| **Day 29 (n=28,12,11,6)** | **-0.157 (0.8404)** | **-0.417 (0.7259)** | **-0.382 (1.0713)** | **0.100 (0.2098)** |
| **Week 6 (n=27,11,11,3)** | **-0.281 (0.8138)** | **-0.436 (0.7256)** | **-0.291 (0.8961)** | **0.133 (0.6110)** |
| **Week 8 (n=26,11,11,3)** | **-0.238 (0.8100)** | **-0.518 (1.0925)** | **-0.509 (0.9523)** | **-0.133 (0.6110)** |

| | | | | |
|---|---|---|---|---|
| **Week 10 (n=25,11,10,3)** | **-0.376 (0.8686)** | **-0.200 (0.9077)** | **-0.400 (0.6325)** | **-0.067 (0.4163)** |
| **Week 12 (n=25,12,11,3)** | **-0.384 (0.8887)** | **-0.267 (0.7738)** | **-0.455 (0.9883)** | **-0.200 (0.6928)** |
| **Week 16 (n=24,10,8,3)** | **-0.200 (0.8299)** | **-0.400 (0.7424)** | **-0.550 (0.9304)** | **0.400 (0.8000)** |
| **Week 20 (n=21,9,6,3)** | **-0.143 (0.9168)** | **-0.356 (0.6064)** | **-0.633 (1.0912)** | **-0.200 (1.5875)** |
| **Week 24 (n=20,8,5,3)** | **-0.250 (0.7564)** | **0.200 (0.5657)** | **-0.800 (1.1045)** | **0.400 (0.7211)** |
| **Week 28 (n=28,11,11,5)** | **-0.036 (0.7345)** | **-0.182 (0.9527)** | **-0.230 (0.8145)** | **0.400 (0.4690)** |

**No statistical analysis provided for Mean Change Bath Ankylosing Spondylitis Metrology Index (BASMI) Score in Part 1 and 2**

19. Secondary: Change From Baseline in Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) in Part 1 and 2 [ Time Frame: Baseline, day 8,15,29,week 6,8,10,12,16,20,24,28 ]

| | |
|---|---|
| **Measure Type** | Secondary |
| **Measure Title** | Change From Baseline in Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) in Part 1 and 2 |
| **Measure Description** | The BASDAI consists of a 1 through 10 scale (1 being no problem and 10 being the worst problem), which was used to answer 6 questions pertaining to the 5 major symptoms of AS: Fatigue, Spinal pain, Joint pain / swelling, areas of localized tenderness (called enthesitis, or inflammation of insertion sites of tendons and ligaments), morning stiffness duration, and morning stiffness severity. The physician will globally assess the subject's current disease state using a visual analog scale (VAS) scale with 0 being very good and 100 being very bad. |
| **Time Frame** | Baseline, day 8,15,29,week 6,8,10,12,16,20,24,28 |
| **Safety Issue** | No |

**Population Description**

| |
|---|
| **Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.** |
| Pharmacodynamic Analysis set: All patients with a least one evaluable post-treatment PD measurement and no major protocol deviations with impact on PD data were included. One subjects was excluded from the PD set in the AIN457 10mg/kg Part 2 due to the absence of available post-baseline PD measurements |

**Reporting Groups**

| | **Description** |
|---|---|
| **Parts 1 and 2 - AIN457A 10 mg/kg** | AIN457A 10 mg/kg was administered intravenously as 2 doses 21 days apart, i.e. the first dose on day 1 and the second dose on day 22. |
| **Part 1 and 2 - AIN457 1.0 mg/Kg** | AIN457A 1.0 mg/kg was administered intravenously as 2 doses 21 days apart, i.e. the first dose on day 1 and the second dose on day 22 |
| **Part 1 and 2 - AIN457 0.1 mg/kg** | AIN457A 0.1 mg/kg was administered intravenously as 2 doses 21 days apart, i.e. the first dose on day 1 and the second dose on day 22 |
| **Part 1 and 2 - Placebo** | Placebo to AIN457A was administered intravenously as a single dose |

**Measured Values**

| | **Parts 1 and 2 - AIN457A 10 mg/kg** | **Part 1 and 2 - AIN457 1.0 mg/Kg** | **Part 1 and 2 - AIN457 0.1 mg/kg** | **Part 1 and 2 - Placebo** |
|---|---|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **28** | **12** | **12** | **6** |

| **Change From Baseline in Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) in Part 1 and 2 [units: Score] Least Squares Mean (95% Confidence Interval)** | | | | |
|---|---|---|---|---|
| **Day 8 (n=28,12,11,6)** | **-1.7011 (-2.533 to -0.870)** | **-1.2793 (-2.559 to 0.001)** | **-1.2920 (-2.635 to 0.051)** | **-1.0837 (-2.737 to 0.570)** |
| **Day 15 (n=28,12,11,5)** | **-1.7094 (-2.485 to -0.934)** | **-2.1256 (-3.317 to -0.934)** | **-1.1263 (-2.376 to 0.124)** | **-0.6417 (-2.199 to 0.915)** |
| **Day 29 (n=28,12,11,6)** | **-2.2530 (-3.096 to -1.410)** | **-2.4237 (-3.722 to -1.126)** | **-1.3886 (-2.750 to -0.028)** | **-0.7839 (-2.464 to 0.896)** |
| **Week 6 (n=26,11,11,3)** | **-1.8713 (-2.691 to -1.051)** | **-2.0151 (-3.275 to -0.755)** | **-1.2002 (-2.514 to 0.113)** | **-1.0577 (-2.893 to 0.777)** |
| **Week 8 (n=26,11,11,3)** | **-1.3863 (-2.189 to -0.584)** | **-1.6994 (-2.933 to -0.466)** | **-1.2020 (-2.485 to 0.081)** | **-1.4619 (-3.401 to 0.477)** |
| **Week 10 (n=24,11,9,3)** | **-1.6246 (-2.389 to -0.860)** | **-1.7402 (-2.909 to -0.571)** | **-1.0800 (-2.313 to 0.153)** | **-0.8527 (-2.558 to 0.853)** |
| **Week 12 (n=24,12,11,3)** | **-1.4744 (-2.336 to -0.613)** | **-1.3755 (-2.688 to -0.063)** | **-1.6834 (-3.059 to -0.307)** | **-1.3529 (-3.354 to 0.648)** |
| **Week 16 (n=24,10,8,3)** | **-1.3990 (-2.237 to -0.562)** | **-2.3081 (-3.589 to -1.027)** | **-1.7628 (-3.143 to -0.383)** | **-1.4083 (-3.415 to 0.598)** |
| **Week 20 (n=21,9,6,3)** | **-1.2072 (-2.011 to -0.403)** | **-1.4070 (-2.632 to -0.183)** | **-1.1596 (-2.521 to 0.202)** | **-1.5864 (-3.385 to 0.212)** |
| **Week 24 (n=20,8,5,3)** | **-1.1318 (-2.001 to -0.262)** | **-1.0035 (-2.343 to 0.336)** | **-0.8020 (-2.305 to 0.701)** | **-1.2048 (-3.201 to 0.792)** |
| **Week 28 (n=28,11,11,5)** | **-0.7373 (-1.487 to 0.012)** | **-0.8980 (-2.057 to 0.261)** | **-1.2227 (-2.432 to -0.013)** | **-0.9722 (-2.526 to 0.582)** |

**No statistical analysis provided for Change From Baseline in Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) in Part 1 and 2**

20. Secondary: Mean Change in Maastricht Ankylosing Spondylitis Enthesitis Score (MASES) in Part 1 [ Time Frame: Baseline, day 8,15,29,week, 6, 8,10,12,16,20,24,28 ]

| | |
|---|---|
| **Measure Type** | Secondary |
| **Measure Title** | Mean Change in Maastricht Ankylosing Spondylitis Enthesitis Score (MASES) in Part 1 |
| **Measure Description** | MASES is measured by scoring of entheses of 0 (no tenderness) to 3 (severe tenderness) at 13 sites on the body. |

| | |
|---|---|
| | The score was derived as the sum of the 13 scores divided by 3 and the total range is 0 (no tenderness) to 13 (severe tenderness). |
| **Time Frame** | Baseline, day 8,15,29,week, 6, 8,10,12,16,20,24,28 |
| **Safety Issue** | No |

**Population Description**

| **Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.** |
|---|
| Pharmacodynamic Analysis set: All patients with a least one evaluable post-treatment PD measurement and no major protocol deviations with impact on PD data were included. One subjects was excluded from the PD set in the AIN457 10mg/kg Part 1 due to protocol deviation |

**Reporting Groups**

| | **Description** |
|---|---|
| **Part 1 - AIN457A 10 mg/kg** | AIN457A 10.0 mg/kg was administered intravenously as a single dose. |
| **Part 1 - Placebo** | Placebo to AIN457A was administered intravenously as a single dose |

**Measured Values**

| | **Part 1 - AIN457A 10 mg/kg** | **Part 1 - Placebo** |
|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **23** | **6** |
| **Mean Change in Maastricht Ankylosing Spondylitis Enthesitis Score (MASES) in Part 1 [units: Score] Mean (Standard Deviation)** | | |
| **Day 8 (n=23,6)** | **-1.3 (2.46)** | **0.7 (1.37)** |
| **Day 15 (n=23,5)** | **-1.3 (2.53)** | **2.4 (2.51)** |
| **Day 29 (n=23,6)** | **-1.0 (2.80)** | **-0.3 (1.97)** |
| **Week 6 (n=22,3)** | **-1.5 (3.10)** | **-0.3 (0.58)** |
| **Week 8 (n=21,3)** | **-1.0 (2.77)** | **0.0 (0.0)** |
| **Week 10 (n=20,3)** | **-1.3 (3.24)** | **-0.3 (0.58)** |
| **Week 12 (n=20,3)** | **-1.2 (3.09)** | **-0.3 (0.58)** |
| **Week 16 (n=30,3)** | **-0.9 (3.69)** | **-0.3 (0.58)** |
| **Week 20 (n=18,3)** | **0.2 (3.55)** | **0.3 (1.53)** |
| **Week 24 (n=17,3)** | **-1.3 (2.11)** | **-0.3 (0.58)** |
| **Week 28 (n=23,5)** | **-0.4 (3.86)** | **1.2 (1.30)** |

**No statistical analysis provided for Mean Change in Maastricht Ankylosing Spondylitis Enthesitis Score (MASES) in Part 1**

21. Secondary: Mean Change in Maastricht Ankylosing Spondylitis Enthesitis Score (MASES) in Part 1 and 2 [ Time Frame: Day 8,15,29,week, 6, 10,12,16,20,24,28 ]

| | |
|---|---|
| **Measure Type** | Secondary |
| **Measure Title** | Mean Change in Maastricht Ankylosing Spondylitis Enthesitis Score (MASES) in Part 1 and 2 |
| **Measure Description** | MASES is measured by scoring of entheses of 0 (no tenderness) to 3 (severe tenderness) at 13 sites on the body. The score was derived as the sum of the 13 scores divided by 3 and the total range is 0 (no tenderness) to 13 (severe tenderness). |
| **Time Frame** | Day 8,15,29,week, 6, 10,12,16,20,24,28 |
| | |

| | |
|---|---|
| **Safety Issue** | No |

**Population Description**

| |
|---|
| **Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.** |
| Pharmacodynamic Analysis set: All patients with a least one evaluable post-treatment PD measurement and no major protocol deviations with impact on PD data were included. One subjects was excluded from the PD set in the AIN457 10mg/kg Part 2 due to the absence of available post-baseline PD measurements |

**Reporting Groups**

| | **Description** |
|---|---|
| **Parts 1 and 2 - AIN457A 10 mg/kg** | AIN457A 10 mg/kg was administered intravenously as 2 doses 21 days apart, i.e. the first dose on day 1 and the second dose on day 22. |
| **Part 1 and 2 - AIN457 1.0 mg/kg** | AIN457A 1.0 mg/kg was administered intravenously as 2 doses 21 days apart, i.e. the first dose on day 1 and the second dose on day 22 |
| **Part 1 and 2 - AIN457 0.1 mg/kg** | AIN457A 0.1 mg/kg was administered intravenously as 2 doses 21 days apart, i.e. the first dose on day 1 and the second dose on day 22 |
| **Part 1 and 2 - Placebo** | Placebo to AIN457A was administered intravenously as a single dose |

**Measured Values**

| | **Parts 1 and 2 - AIN457A 10 mg/kg** | **Part 1 and 2 - AIN457 1.0 mg/kg** | **Part 1 and 2 - AIN457 0.1 mg/kg** | **Part 1 and 2 - Placebo** |
|---|---|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **28** | **12** | **12** | **6** |
| **Mean Change in Maastricht Ankylosing Spondylitis Enthesitis Score (MASES) in Part 1 and 2 [units: Score] Mean (Standard Deviation)** | | | | |
| **Day 8 (n=28,12,12,6)** | **-1.321 (2.7763)** | **-1.917 (2.2344)** | **-0.583 (1.0836)** | **0.667 (1.3663)** |
| **Day 15 (n=28,12,12,5)** | **-1.393 (2.7667)** | **-1.167 (1.9924)** | **-1.167 (1.9462)** | **2.400 (2.5100)** |
| **Day 29 (n=28,12,11,6)** | **-1.143 (2.9779)** | **-2.083 (2.2344)** | **-0.545 (0.6876)** | **-0.333 (1.9664)** |
| **Week 6 (n=27,11,11,3)** | **-1.556 (3.2026)** | **-0.339 (3.1318)** | **-0.364 (1.0269)** | **-0.333 (0.5774)** |
| **Week 8 (n=26,11,11,3)** | **-1.154 (2.9758)** | **-1.273 (1.6787)** | **0.455 (2.2523)** | **0.0 (0.0)** |
| **Week 10 (n=25,11,10,3)** | **-1.360 (3.3277)** | **-1.091 (3.1450)** | **-0.800 (0.9189)** | **-0.333 (0.5774)** |
| **Week 12 (n=25,12,11,3)** | **-1.280 (3.2342)** | **-1.167 (4.1304)** | **-0.636 (1.8040)** | **-0.333 (0.5774)** |
| **Week 16 (n=24,10,8,3)** | **-1.042 (3.7819)** | **-0.600 (3.4705)** | **0.500 (1.6903)** | **-0.333 (0.5774)** |
| **Week 20 (n=21,9,6,3)** | **-0.238 (3.8458)** | **-0.333 (3.7749)** | **-0.667 (1.3663)** | **0.333 (1.5275)** |
| **Week 24 (n=20,8,5,3)** | **-1.400 (2.2572)** | **-1.000 (3.7417)** | **0.600 (1.9494)** | **-0.333 (0.5774)** |

**No statistical analysis provided for Mean Change in Maastricht Ankylosing Spondylitis Enthesitis Score (MASES) in Part 1 and 2**

22. Secondary: Change From Baseline in the Health Related Quality of Life (HRQoL) by Using the SF-36 Physical Component, and the ASQoL (Ankylosing Spondylitis Quality of Life Instrument) in Part 1. [ Time Frame: SF-36:Baseline, week 12, week 28; ASQoL: Baseline, Day 29, week 12, week 28 ]

| | |
|---|---|
| **Measure Type** | Secondary |
| **Measure Title** | Change From Baseline in the Health Related Quality of Life (HRQoL) by Using the SF-36 Physical Component, and the ASQoL (Ankylosing Spondylitis Quality of Life Instrument) in Part 1. |
| **Measure Description** | The Short Form (36) Health Survey (SF-36) measures the impact of disease on overall quality of life and consists of eight subscales (physical function, pain, general and mental health, vitality, social function, physical and emotional health) which can be aggregated to derive a physical-component summary score and a mental-component summary score. Scores range for each subscale from 0 to 10, and the composite score ranges from 0 to 100, with higher scores indicative of better health. ASQoL determined subject's quality of life and is comprised of 18 questions (yes or no) to be completed by the subject. Each statement on the ASQoL is given a score of "1" or "0." All item scores were summed to give a total score or index. Total scores ranged from 0 (good quality of life) to 18 (poor quality of life) related to ability to cope, relationships, mood, sleep, motivation, activities of everyday living, independence, and social life. Decrease in ASQoL score represents improvement. |
| **Time Frame** | SF-36:Baseline, week 12, week 28; ASQoL: Baseline, Day 29, week 12, week 28 |
| **Safety Issue** | No |

**Population Description**

| |
|---|
| **Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.** |
| Pharmacodynamic Analysis set: All patients with a least one evaluable post-treatment PD measurement and no major protocol deviations with impact on PD data were included. One subjects was excluded from the PD set in the AIN457 10mg/kg Part 2 due to the absence of available post-baseline PD measurements |

**Reporting Groups**

| | **Description** |
|---|---|
| **Part 1 - AIN457A 10 mg/kg** | AIN457A 10.0 mg/kg was administered intravenously as a single dose. |
| **Part 1 - Placebo** | Placebo to AIN457A was administered intravenously as a single dose |

**Measured Values**

| | **Part 1 - AIN457A 10 mg/kg** | **Part 1 - Placebo** |
|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **23** | **6** |
| **Change From Baseline in the Health Related Quality of Life (HRQoL) by Using the SF-36 Physical Component, and the ASQoL (Ankylosing Spondylitis Quality of Life Instrument) in Part 1. [units: Score] Mean (Standard Deviation)** | | |
| **Baseline SF36 Mental component (n= 22,6)** | **38.71 (10.78)** | **39.57 (14.63)** |
| **Baseline SF36 physical component (n=22,6)** | **31.42 (5.2)** | **30.11 (6.71)** |
| **Week 12 SF36 Mental component (n=20,3)** | **43.45 (10.56)** | **56.57 (5.39)** |
| **Week 12 SF36 Physical component (n=20,3)** | **32.84 (6.39)** | **28.95 (1.8)** |
| **Week 28 SF36 Mental component (n=21,4)** | **41.65 (9.86)** | **40.51 (15.22)** |
| **Week 28 SF36 Physical component (n=21,4)** | **32.2 (5.68)** | **33.96 (8.73)** |

| | | |
|---|---|---|
| **Change from Baseline to Day 29 ASQoL (n=21,6)** | **-2.9 (4.04)** | **-0.7 (2.58)** |
| **Change from Baseline to Week 12 ASQoL (n=18,3)** | **-2.3 (3.05)** | **0.0 (1.00)** |
| **Change from Baseline to Week 28 ASQoL (n=20,4)** | **-1.2 (3.71)** | **-1.3 (2.06)** |

**No statistical analysis provided for Change From Baseline in the Health Related Quality of Life (HRQoL) by Using the SF-36 Physical Component, and the ASQoL (Ankylosing Spondylitis Quality of Life Instrument) in Part 1.**

23. Secondary: Change From Baseline in the Health Related Quality of Life (HRQoL) by Using the SF-36 Physical Component, and the ASQoL (Ankylosing Spondylitis Quality of Life Instrument) in Part 1 and 2. [ Time Frame: SF-36: Baseline, week 12, week 28; ASQoL: Baseline, day 29, week 12, week 8 ]

| | |
|---|---|
| **Measure Type** | Secondary |
| **Measure Title** | Change From Baseline in the Health Related Quality of Life (HRQoL) by Using the SF-36 Physical Component, and the ASQoL (Ankylosing Spondylitis Quality of Life Instrument) in Part 1 and 2. |
| **Measure Description** | The SF-36 measures the impact of disease on overall quality of life and consists of eight subscales (physical function, pain, general and mental health, vitality, social function, physical and emotional health) which can be aggregated to derive a physical-component summary score and a mental-component summary score. ASQoL determined subject's quality of life and is comprised of 18 questions (yes or no) to be completed by the subject. Each statement on the ASQoL is given a score of "1" or "0." All item scores were summed to give a total score or index. Total scores ranged from 0 (good quality of life) to 18 (poor quality of life) related to ability to cope, relationships, mood, sleep, motivation, activities of everyday living, independence, and social life. Decrease in ASQoL score represents improvement. |
| **Time Frame** | SF-36: Baseline, week 12, week 28; ASQoL: Baseline, day 29, week 12, week 8 |
| **Safety Issue** | No |

**Population Description**

| |
|---|
| **Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.** |
| Pharmacodynamic Analysis set: All patients with a least one evaluable post-treatment PD measurement and no major protocol deviations with impact on PD data were included. One subjects was excluded from the PD set in the AIN457 10mg/kg Part 2 due to the absence of available post-baseline PD measurements |

**Reporting Groups**

| | **Description** |
|---|---|
| **Parts 1 and 2 - AIN457A 10 mg/kg** | AIN457A 10 mg/kg was administered intravenously as 2 doses 21 days apart, i.e. the first dose on day 1 and the second dose on day 22. |
| **Part 1 and 2 - AIN457 1.0 mg/kg** | AIN457A 1.0 mg/kg was administered intravenously as 2 doses 21 days apart, i.e. the first dose on day 1 and the second dose on day 22 |
| **Part 1 and 2 - AIN457 0.1 mg/kg** | AIN457A 0.1 mg/kg was administered intravenously as 2 doses 21 days apart, i.e. the first dose on day 1 and the second dose on day 22 |
| **Part 1 and 2 - Placebo** | Placebo to AIN457A was administered intravenously as a single dose |

**Measured Values**

| | **Parts 1 and 2 - AIN457A 10 mg/kg** | **Part 1 and 2 - AIN457 1.0 mg/kg** | **Part 1 and 2 - AIN457 0.1 mg/kg** | **Part 1 and 2 - Placebo** |
|---|---|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **28** | **12** | **12** | **6** |
| **Change From Baseline in the Health Related Quality of Life (HRQoL) by Using the** | | | | |

| | | | | |
|---|---|---|---|---|
| **SF-36 Physical Component, and the ASQoL (Ankylosing Spondylitis Quality of Life Instrument) in Part 1 and 2.<br>[units: Score]<br>Mean (Standard Deviation)** | | | | |
| **Baseline SF36 Mental component (n=27,12,12,6)** | **38.97 (10.91)** | **39.46 (11.95)** | **51.9 (8.7)** | **39.57 (14.63)** |
| **Baseline SF36 Physical component (n=27,12,12,6)** | **30.95 (6.34)** | **26.17 (7.63)** | **33.53 (7.47)** | **30.11 (6.71)** |
| **Week 12 SF36 Mental component (n=25,11,10,3)** | **44.37 (11.05)** | **38.45 (10.13)** | **49.7 (11.74)** | **56.57 (5.39)** |
| **Week 12 SF36 Physical component (n=25,11,10,3)** | **32.71 (6.24)** | **31.3 (7.67)** | **35.81 (5.29)** | **28.05 (1.8)** |
| **Week 28 SF36 Mental component (n=26,11,10,4)** | **40.94 (10.56)** | **36.6 (10.3)** | **46.96 (9.67)** | **40.51 (15.22)** |
| **Week 28 SF36 Physical component (n=26,11,10,4)** | **31.85 (5.3)** | **29.95 (6.92)** | **35.54 (5.9)** | **33.96 (8.73)** |
| **Change from Baseline to Day 29 ASQoL(n=26,11,10,6)** | **-3.2 (3.78)** | **-3.1 (2.63)** | **-0.7 (2.26)** | **-0.7 (2.58)** |
| **Change from Baseline to Week 12 ASQoL(n=23,11,9,3)** | **-2.7 (2.91)** | **-2.7 (4.71)** | **-1.3 (3.16)** | **0.0 (1.00)** |
| **Change from Baseline to Week 28 ASQoL(n=25,11,9,4)** | **-1.4 (3.37)** | **-1.3 (3.66)** | **-0.9 (2.15)** | **-1.3 (2.06)** |

**No statistical analysis provided for Change From Baseline in the Health Related Quality of Life (HRQoL) by Using the SF-36 Physical Component, and the ASQoL (Ankylosing Spondylitis Quality of Life Instrument) in Part 1 and 2.**

## Serious Adverse Events

Hide Serious Adverse Events

| | |
|---|---|
| **Time Frame** | No text entered. |
| **Additional Description** | No text entered. |

**Reporting Groups**

| | Description |
|---|---|
| **AIN457 2x10mg/kg** | AIN457A 1.0 mg/kg was administered intravenously as 2 doses 21 days apart, i.e. the first dose on day 1 and the second dose on day 22 |
| **AIN457 2x1.0mg/kg** | AIN457A 1.0 mg/kg was administered intravenously as 2 doses 21 days apart, i.e. the first dose on day 1 and the second dose on day 22 |
| **AIN457 2x0.1mg/kg** | AIN457A 0.1 mg/kg was administered intravenously as 2 doses 21 days apart, i.e. the first dose on day 1 and the second dose on day 22 |
| **Placebo** | Placebo to AIN457A was administered intravenously as a single dose |

**Serious Adverse Events**

| | AIN457 2x10mg/kg | AIN457 2x1.0mg/kg | AIN457 2x0.1mg/kg | Placebo |
|---|---|---|---|---|
| **Total, serious adverse events** | | | | |
| **# participants affected / at risk** | **2/30 (6.67%)** | **1/12 (8.33%)** | **0/12 (0.00%)** | **1/6 (16.67%)** |
| **Immune system disorders** | | | | |
| **Anaphylactic reaction † [1]** | | | | |
| **# participants affected / at risk** | **1/30 (3.33%)** | **0/12 (0.00%)** | **0/12 (0.00%)** | **0/6 (0.00%)** |

| | | | | |
|---|---|---|---|---|
| **Infections and infestations** | | | | |
| **Cytomegalovirus infection † 1** | | | | |
| **# participants affected / at risk** | **0/30 (0.00%)** | **1/12 (8.33%)** | **0/12 (0.00%)** | **0/6 (0.00%)** |
| **Subcutaneous abscess † 1** | | | | |
| **# participants affected / at risk** | **1/30 (3.33%)** | **0/12 (0.00%)** | **0/12 (0.00%)** | **0/6 (0.00%)** |
| **Investigations** | | | | |
| **Blood pressure increased † 1** | | | | |
| **# participants affected / at risk** | **0/30 (0.00%)** | **0/12 (0.00%)** | **0/12 (0.00%)** | **1/6 (16.67%)** |

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA

## Other Adverse Events

Hide Other Adverse Events

| | |
|---|---|
| **Time Frame** | No text entered. |
| **Additional Description** | No text entered. |

**Frequency Threshold**

| | |
|---|---|
| **Threshold above which other adverse events are reported** | 5% |

**Reporting Groups**

| | **Description** |
|---|---|
| **AIN457 2x10mg/kg** | AIN457A 1.0 mg/kg was administered intravenously as 2 doses 21 days apart, i.e. the first dose on day 1 and the second dose on day 22 |
| **AIN457 2x1.0mg/kg** | AIN457A 1.0 mg/kg was administered intravenously as 2 doses 21 days apart, i.e. the first dose on day 1 and the second dose on day 22 |
| **AIN457 2x0.1mg/kg** | AIN457A 0.1 mg/kg was administered intravenously as 2 doses 21 days apart, i.e. the first dose on day 1 and the second dose on day 22 |
| **Placebo** | Placebo to AIN457A was administered intravenously as a single dose |

**Other Adverse Events**

| | **AIN457 2x10mg/kg** | **AIN457 2x1.0mg/kg** | **AIN457 2x0.1mg/kg** | **Placebo** |
|---|---|---|---|---|
| **Total, other (not including serious) adverse events** | | | | |
| **# participants affected / at risk** | **27/30 (90.00%)** | **10/12 (83.33%)** | **9/12 (75.00%)** | **5/6 (83.33%)** |
| **Blood and lymphatic system disorders** | | | | |
| **Anaemia † 1** | | | | |
| **# participants affected / at risk** | **0/30 (0.00%)** | **1/12 (8.33%)** | **0/12 (0.00%)** | **0/6 (0.00%)** |
| **Cardiac disorders** | | | | |
| **Cardiovascular insufficiency † 1** | | | | |
| **# participants affected / at risk** | **0/30 (0.00%)** | **0/12 (0.00%)** | **1/12 (8.33%)** | **0/6 (0.00%)** |
| **Palpitations † 1** | | | | |
| **# participants affected / at risk** | **0/30 (0.00%)** | **0/12 (0.00%)** | **0/12 (0.00%)** | **1/6 (16.67%)** |
| **Ear and labyrinth disorders** | | | | |
| **Vertigo † 1** | | | | |

| | | | | |
|---|---|---|---|---|
| # participants affected / at risk | 2/30 (6.67%) | 1/12 (8.33%) | 0/12 (0.00%) | 1/6 (16.67%) |
| **Eye disorders** | | | | |
| Eye swelling † 1 | | | | |
| # participants affected / at risk | 0/30 (0.00%) | 1/12 (8.33%) | 0/12 (0.00%) | 0/6 (0.00%) |
| Vision blurred † 1 | | | | |
| # participants affected / at risk | 0/30 (0.00%) | 1/12 (8.33%) | 0/12 (0.00%) | 0/6 (0.00%) |
| Vitreous floaters † 1 | | | | |
| # participants affected / at risk | 0/30 (0.00%) | 1/12 (8.33%) | 1/12 (8.33%) | 0/6 (0.00%) |
| **Gastrointestinal disorders** | | | | |
| Abdominal discomfort † 1 | | | | |
| # participants affected / at risk | 0/30 (0.00%) | 0/12 (0.00%) | 1/12 (8.33%) | 0/6 (0.00%) |
| Abdominal pain † 1 | | | | |
| # participants affected / at risk | 1/30 (3.33%) | 1/12 (8.33%) | 0/12 (0.00%) | 0/6 (0.00%) |
| Abdominal pain upper † 1 | | | | |
| # participants affected / at risk | 2/30 (6.67%) | 0/12 (0.00%) | 0/12 (0.00%) | 0/6 (0.00%) |
| Aphthous stomatitis † 1 | | | | |
| # participants affected / at risk | 1/30 (3.33%) | 1/12 (8.33%) | 0/12 (0.00%) | 0/6 (0.00%) |
| Colitis † 1 | | | | |
| # participants affected / at risk | 0/30 (0.00%) | 1/12 (8.33%) | 0/12 (0.00%) | 0/6 (0.00%) |
| Diarrhoea † 1 | | | | |
| # participants affected / at risk | 7/30 (23.33%) | 0/12 (0.00%) | 2/12 (16.67%) | 0/6 (0.00%) |
| Frequent bowel movements † 1 | | | | |
| # participants affected / at risk | 0/30 (0.00%) | 0/12 (0.00%) | 1/12 (8.33%) | 0/6 (0.00%) |
| Gastrointestinal haemorrhage † 1 | | | | |
| # participants affected / at risk | 0/30 (0.00%) | 1/12 (8.33%) | 0/12 (0.00%) | 0/6 (0.00%) |
| Gastrooesophageal reflux disease † 1 | | | | |
| # participants affected / at risk | 0/30 (0.00%) | 1/12 (8.33%) | 1/12 (8.33%) | 1/6 (16.67%) |
| Mouth ulceration † 1 | | | | |
| # participants affected / at risk | 2/30 (6.67%) | 0/12 (0.00%) | 0/12 (0.00%) | 0/6 (0.00%) |
| Nausea † 1 | | | | |
| # participants affected / at risk | 6/30 (20.00%) | 1/12 (8.33%) | 1/12 (8.33%) | 1/6 (16.67%) |
| Oral mucosal eruption † 1 | | | | |
| # participants affected / at risk | 0/30 (0.00%) | 1/12 (8.33%) | 0/12 (0.00%) | 0/6 (0.00%) |
| Pancreatic enlargement † 1 | | | | |
| # participants affected / at risk | 0/30 (0.00%) | 1/12 (8.33%) | 0/12 (0.00%) | 0/6 (0.00%) |
| Stomatitis † 1 | | | | |
| # participants affected / at risk | 1/30 (3.33%) | 1/12 (8.33%) | 0/12 (0.00%) | 0/6 (0.00%) |
| Vomiting † 1 | | | | |
| # participants affected / at risk | 1/30 (3.33%) | 1/12 (8.33%) | 0/12 (0.00%) | 1/6 (16.67%) |
| **General disorders** | | | | |
| Chills † 1 | | | | |
| # participants affected / at risk | 0/30 (0.00%) | 0/12 (0.00%) | 1/12 (8.33%) | 1/6 (16.67%) |
| Fatigue † 1 | | | | |
| # participants affected / at risk | 3/30 (10.00%) | 0/12 (0.00%) | 3/12 (25.00%) | 1/6 (16.67%) |

| | | | | |
|---|---|---|---|---|
| **Influenza like illness** † 1 | | | | |
| **# participants affected / at risk** | **0/30 (0.00%)** | **1/12 (8.33%)** | **0/12 (0.00%)** | **0/6 (0.00%)** |
| **Malaise** † 1 | | | | |
| **# participants affected / at risk** | **2/30 (6.67%)** | **0/12 (0.00%)** | **0/12 (0.00%)** | **0/6 (0.00%)** |
| **Pain** † 1 | | | | |
| **# participants affected / at risk** | **0/30 (0.00%)** | **0/12 (0.00%)** | **1/12 (8.33%)** | **0/6 (0.00%)** |
| **Pyrexia** † 1 | | | | |
| **# participants affected / at risk** | **5/30 (16.67%)** | **0/12 (0.00%)** | **0/12 (0.00%)** | **0/6 (0.00%)** |
| **Temperature intolerance** † 1 | | | | |
| **# participants affected / at risk** | **0/30 (0.00%)** | **1/12 (8.33%)** | **0/12 (0.00%)** | **0/6 (0.00%)** |
| **Infections and infestations** | | | | |
| **Bronchitis** † 1 | | | | |
| **# participants affected / at risk** | **2/30 (6.67%)** | **0/12 (0.00%)** | **0/12 (0.00%)** | **0/6 (0.00%)** |
| **Fungal skin infection** † 1 | | | | |
| **# participants affected / at risk** | **0/30 (0.00%)** | **1/12 (8.33%)** | **0/12 (0.00%)** | **0/6 (0.00%)** |
| **Gastroenteritis** † 1 | | | | |
| **# participants affected / at risk** | **2/30 (6.67%)** | **0/12 (0.00%)** | **0/12 (0.00%)** | **0/6 (0.00%)** |
| **Gastroenteritis viral** † 1 | | | | |
| **# participants affected / at risk** | **0/30 (0.00%)** | **1/12 (8.33%)** | **0/12 (0.00%)** | **0/6 (0.00%)** |
| **Influenza** † 1 | | | | |
| **# participants affected / at risk** | **3/30 (10.00%)** | **1/12 (8.33%)** | **1/12 (8.33%)** | **0/6 (0.00%)** |
| **Nasopharyngitis** † 1 | | | | |
| **# participants affected / at risk** | **8/30 (26.67%)** | **0/12 (0.00%)** | **1/12 (8.33%)** | **0/6 (0.00%)** |
| **Oral candidiasis** † 1 | | | | |
| **# participants affected / at risk** | **2/30 (6.67%)** | **1/12 (8.33%)** | **0/12 (0.00%)** | **0/6 (0.00%)** |
| **Oral herpes** † 1 | | | | |
| **# participants affected / at risk** | **2/30 (6.67%)** | **0/12 (0.00%)** | **0/12 (0.00%)** | **1/6 (16.67%)** |
| **Otitis externa** † 1 | | | | |
| **# participants affected / at risk** | **2/30 (6.67%)** | **0/12 (0.00%)** | **0/12 (0.00%)** | **0/6 (0.00%)** |
| **Otitis media** † 1 | | | | |
| **# participants affected / at risk** | **1/30 (3.33%)** | **0/12 (0.00%)** | **1/12 (8.33%)** | **0/6 (0.00%)** |
| **Pharyngitis** † 1 | | | | |
| **# participants affected / at risk** | **0/30 (0.00%)** | **0/12 (0.00%)** | **1/12 (8.33%)** | **0/6 (0.00%)** |
| **Rhinitis** † 1 | | | | |
| **# participants affected / at risk** | **2/30 (6.67%)** | **0/12 (0.00%)** | **0/12 (0.00%)** | **0/6 (0.00%)** |
| **Sinusitis** † 1 | | | | |
| **# participants affected / at risk** | **1/30 (3.33%)** | **0/12 (0.00%)** | **1/12 (8.33%)** | **0/6 (0.00%)** |
| **Upper respiratory tract infection** † 1 | | | | |
| **# participants affected / at risk** | **2/30 (6.67%)** | **1/12 (8.33%)** | **1/12 (8.33%)** | **0/6 (0.00%)** |
| **Vulvovaginal mycotic infection** † 1 | | | | |
| **# participants affected / at risk** | **0/30 (0.00%)** | **0/12 (0.00%)** | **1/12 (8.33%)** | **0/6 (0.00%)** |
| **Injury, poisoning and procedural complications** | | | | |
| **Epicondylitis** † 1 | | | | |
| **# participants affected / at risk** | **0/30 (0.00%)** | **0/12 (0.00%)** | **1/12 (8.33%)** | **0/6 (0.00%)** |

| | | | | |
|---|---|---|---|---|
| **Limb injury** † 1 | | | | |
| **# participants affected / at risk** | **0/30 (0.00%)** | **1/12 (8.33%)** | **0/12 (0.00%)** | **0/6 (0.00%)** |
| **Investigations** | | | | |
| **Aortic bruit** † 1 | | | | |
| **# participants affected / at risk** | **0/30 (0.00%)** | **0/12 (0.00%)** | **1/12 (8.33%)** | **0/6 (0.00%)** |
| **Metabolism and nutrition disorders** | | | | |
| **Hypercholesterolaemia** † 1 | | | | |
| **# participants affected / at risk** | **0/30 (0.00%)** | **0/12 (0.00%)** | **1/12 (8.33%)** | **0/6 (0.00%)** |
| **Hypomagnesaemia** † 1 | | | | |
| **# participants affected / at risk** | **0/30 (0.00%)** | **1/12 (8.33%)** | **0/12 (0.00%)** | **0/6 (0.00%)** |
| **Musculoskeletal and connective tissue disorders** | | | | |
| **Ankylosing spondylitis** † 1 | | | | |
| **# participants affected / at risk** | **1/30 (3.33%)** | **0/12 (0.00%)** | **1/12 (8.33%)** | **2/6 (33.33%)** |
| **Arthralgia** † 1 | | | | |
| **# participants affected / at risk** | **4/30 (13.33%)** | **0/12 (0.00%)** | **0/12 (0.00%)** | **0/6 (0.00%)** |
| **Back pain** † 1 | | | | |
| **# participants affected / at risk** | **3/30 (10.00%)** | **0/12 (0.00%)** | **1/12 (8.33%)** | **1/6 (16.67%)** |
| **Bone pain** † 1 | | | | |
| **# participants affected / at risk** | **0/30 (0.00%)** | **1/12 (8.33%)** | **0/12 (0.00%)** | **0/6 (0.00%)** |
| **Bone swelling** † 1 | | | | |
| **# participants affected / at risk** | **0/30 (0.00%)** | **1/12 (8.33%)** | **0/12 (0.00%)** | **0/6 (0.00%)** |
| **Groin pain** † 1 | | | | |
| **# participants affected / at risk** | **0/30 (0.00%)** | **0/12 (0.00%)** | **1/12 (8.33%)** | **0/6 (0.00%)** |
| **Joint swelling** † 1 | | | | |
| **# participants affected / at risk** | **0/30 (0.00%)** | **1/12 (8.33%)** | **0/12 (0.00%)** | **0/6 (0.00%)** |
| **Muscular weakness** † 1 | | | | |
| **# participants affected / at risk** | **0/30 (0.00%)** | **1/12 (8.33%)** | **1/12 (8.33%)** | **0/6 (0.00%)** |
| **Musculoskeletal chest pain** † 1 | | | | |
| **# participants affected / at risk** | **0/30 (0.00%)** | **1/12 (8.33%)** | **0/12 (0.00%)** | **0/6 (0.00%)** |
| **Myalgia** † 1 | | | | |
| **# participants affected / at risk** | **2/30 (6.67%)** | **0/12 (0.00%)** | **0/12 (0.00%)** | **0/6 (0.00%)** |
| **Pain in extremity** † 1 | | | | |
| **# participants affected / at risk** | **1/30 (3.33%)** | **0/12 (0.00%)** | **1/12 (8.33%)** | **0/6 (0.00%)** |
| **Tendon calcification** † 1 | | | | |
| **# participants affected / at risk** | **0/30 (0.00%)** | **0/12 (0.00%)** | **1/12 (8.33%)** | **0/6 (0.00%)** |
| **Tendonitis** † 1 | | | | |
| **# participants affected / at risk** | **0/30 (0.00%)** | **1/12 (8.33%)** | **0/12 (0.00%)** | **0/6 (0.00%)** |
| **Nervous system disorders** | | | | |
| **Burning sensation** † 1 | | | | |
| **# participants affected / at risk** | **0/30 (0.00%)** | **0/12 (0.00%)** | **1/12 (8.33%)** | **0/6 (0.00%)** |
| **Dizziness** † 1 | | | | |
| **# participants affected / at risk** | **3/30 (10.00%)** | **1/12 (8.33%)** | **0/12 (0.00%)** | **1/6 (16.67%)** |
| **Dysaesthesia** † 1 | | | | |
| **# participants affected / at risk** | **0/30 (0.00%)** | **0/12 (0.00%)** | **1/12 (8.33%)** | **0/6 (0.00%)** |

| | | | | |
|---|---|---|---|---|
| **Dysgeusia** † 1 | | | | |
| **# participants affected / at risk** | **2/30 (6.67%)** | **1/12 (8.33%)** | **0/12 (0.00%)** | **0/6 (0.00%)** |
| **Headache** † 1 | | | | |
| **# participants affected / at risk** | **7/30 (23.33%)** | **1/12 (8.33%)** | **3/12 (25.00%)** | **0/6 (0.00%)** |
| **Paraesthesia** † 1 | | | | |
| **# participants affected / at risk** | **3/30 (10.00%)** | **1/12 (8.33%)** | **0/12 (0.00%)** | **1/6 (16.67%)** |
| **Sinus headache** † 1 | | | | |
| **# participants affected / at risk** | **0/30 (0.00%)** | **1/12 (8.33%)** | **0/12 (0.00%)** | **0/6 (0.00%)** |
| **Tremor** † 1 | | | | |
| **# participants affected / at risk** | **0/30 (0.00%)** | **0/12 (0.00%)** | **1/12 (8.33%)** | **0/6 (0.00%)** |
| **Psychiatric disorders** | | | | |
| **Insomnia** † 1 | | | | |
| **# participants affected / at risk** | **1/30 (3.33%)** | **1/12 (8.33%)** | **0/12 (0.00%)** | **0/6 (0.00%)** |
| **Sleep disorder** † 1 | | | | |
| **# participants affected / at risk** | **0/30 (0.00%)** | **0/12 (0.00%)** | **0/12 (0.00%)** | **1/6 (16.67%)** |
| **Renal and urinary disorders** | | | | |
| **Hydronephrosis** † 1 | | | | |
| **# participants affected / at risk** | **0/30 (0.00%)** | **0/12 (0.00%)** | **1/12 (8.33%)** | **0/6 (0.00%)** |
| **Respiratory, thoracic and mediastinal disorders** | | | | |
| **Cough** † 1 | | | | |
| **# participants affected / at risk** | **2/30 (6.67%)** | **1/12 (8.33%)** | **0/12 (0.00%)** | **0/6 (0.00%)** |
| **Dyspnoea** † 1 | | | | |
| **# participants affected / at risk** | **1/30 (3.33%)** | **1/12 (8.33%)** | **2/12 (16.67%)** | **0/6 (0.00%)** |
| **Oropharyngeal pain** † 1 | | | | |
| **# participants affected / at risk** | **3/30 (10.00%)** | **1/12 (8.33%)** | **1/12 (8.33%)** | **0/6 (0.00%)** |
| **Sinus congestion** † 1 | | | | |
| **# participants affected / at risk** | **1/30 (3.33%)** | **0/12 (0.00%)** | **1/12 (8.33%)** | **0/6 (0.00%)** |
| **Skin and subcutaneous tissue disorders** | | | | |
| **Dyshidrosis** † 1 | | | | |
| **# participants affected / at risk** | **0/30 (0.00%)** | **1/12 (8.33%)** | **0/12 (0.00%)** | **0/6 (0.00%)** |
| **Eczema** † 1 | | | | |
| **# participants affected / at risk** | **0/30 (0.00%)** | **1/12 (8.33%)** | **0/12 (0.00%)** | **0/6 (0.00%)** |
| **Photosensitivity reaction** † 1 | | | | |
| **# participants affected / at risk** | **0/30 (0.00%)** | **0/12 (0.00%)** | **1/12 (8.33%)** | **0/6 (0.00%)** |
| **Pruritus** † 1 | | | | |
| **# participants affected / at risk** | **2/30 (6.67%)** | **0/12 (0.00%)** | **1/12 (8.33%)** | **1/6 (16.67%)** |
| **Rash maculo-papular** † 1 | | | | |
| **# participants affected / at risk** | **0/30 (0.00%)** | **0/12 (0.00%)** | **1/12 (8.33%)** | **0/6 (0.00%)** |
| **Skin irritation** † 1 | | | | |
| **# participants affected / at risk** | **0/30 (0.00%)** | **1/12 (8.33%)** | **0/12 (0.00%)** | **0/6 (0.00%)** |
| **Urticaria** † 1 | | | | |
| **# participants affected / at risk** | **0/30 (0.00%)** | **1/12 (8.33%)** | **0/12 (0.00%)** | **0/6 (0.00%)** |
| **Vascular disorders** | | | | |
| | | | | |

| | | | | |
|---|---|---|---|---|
| **Circulatory collapse † 1** | | | | |
| **# participants affected / at risk** | **2/30 (6.67%)** | **0/12 (0.00%)** | **0/12 (0.00%)** | **0/6 (0.00%)** |
| **Flushing † 1** | | | | |
| **# participants affected / at risk** | **0/30 (0.00%)** | **0/12 (0.00%)** | **1/12 (8.33%)** | **0/6 (0.00%)** |

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA

## Limitations and Caveats

Hide Limitations and Caveats

| **Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data** |
|---|
| No text entered. |

## More Information

Hide More Information

**Certain Agreements:**

Principal Investigators are **NOT** employed by the organization sponsoring the study.

There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

The agreement is:

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.

☑ **Restriction Description:** The terms and conditions of Novartis' agreements with its investigators may vary. However, Novartis does not prohibit any investigator from publishing. Any publications from a single-site are postponed until the publication of the pooled data (i.e., data from all sites) in the clinical trial or disclosure of trial results in their entirety

**Results Point of Contact:**

Name/Title: Study Director
Organization: Novartis
phone: 862-778-8300

**No publications provided by Novartis**

**Publications automatically indexed to this study:**

Baeten D, Baraliakos X, Braun J, Sieper J, Emery P, van der Heijde D, McInnes I, van Laar JM, Landewé R, Wordsworth P, Wollenhaupt J, Kellner H, Paramarta J, Wei J, Brachat A, Bek S, Laurent D, Li Y, Wang YA, Bertolino AP, Gsteiger S, Wright AM, Hueber W. Anti-interleukin-17A monoclonal antibody secukinumab in treatment of ankylosing spondylitis: a randomised, double-blind, placebo-controlled trial. Lancet. 2013 Nov 23;382(9906):1705-13. doi: 10.1016/S0140-6736(13)61134-4. Epub 2013 Sep 13. Erratum in: Lancet. 2014 May 3;383(9928):1548.

Responsible Party: Novartis ( Novartis Pharmaceuticals )
ClinicalTrials.gov Identifier: NCT00809159 History of Changes
Other Study ID Numbers: **CAIN457A2209**
2008-002631-33

| | |
|---|---|
| Study First Received: | December 16, 2008 |
| Results First Received: | January 29, 2015 |
| Last Updated: | December 7, 2015 |
| Health Authority: | United States: Food and Drug Administration |