Clinical trial results:
A phase II, randomized, parallel group, placebo-controlled, double-blinded, dose-finding study to evaluate efficacy, safety, tolerability, and pharmacokinetics of ABY-035 in subjects with moderate-to-severe plaque psoriasis (AFFIRM-35)

Summary

EudraCT number	2017-001615-36
Trial protocol	DE
Global end of trial date	03 December 2021

Results information

Result version number	v1 (current)
This version publication date	15 December 2022
First version publication date	15 December 2022

Trial information

Trial identification

Sponsor protocol code	ABY-035-002

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03591887
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Affibody AB
Sponsor organisation address	Sheeles väg 2, Solna, Sweden, 171 65
Public contact	Director Regulatory Affairs, Affibody AB, +46 8 59 88 38 00, camilla.sandell@affibody.se
Scientific contact	Director Regulatory Affairs, Affibody AB, +46 8 59 88 38 00, camilla.sandell@affibody.se

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	03 December 2021
Is this the analysis of the primary completion data?	Yes
Primary completion date	27 March 2019
Global end of trial reached?	Yes
Global end of trial date	03 December 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the efficacy, defined as Psoriasis Area and Severity Index (PASI) 90 response, of different dose levels of ABY-035 compared to placebo in subjects with moderate-to-severe plaque psoriasis after 12 weeks of treatment.

Protection of trial subjects:

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

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	07 March 2018
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Germany: 108
Worldwide total number of subjects	108
EEA total number of subjects	108

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	107
From 65 to 84 years	1
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The Phase 2 study was conducted in approx. 20 sites in Germany. It consists of a 52-week Core study and 2 optional 52-week periods, Extension and Prolongation of Extension. The Core study consists of 3 periods: Induction (placebo-controlled, Week 0-12), Optimization (Week 12-24) and Individualization (Week 24-52)

Pre-assignment

Screening details:

The enrollment phase lasted for up to 4 weeks to determine main baseline characteristics.

Period 1

Period 1 title	Core Study
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Data analyst, Assessor

Blinding implementation details:

The Core study is randomized, parallel group, double-blind, double-dummy, placebo-controlled and consists of 3 periods: Induction (placebo-controlled, Week 0-12), Optimization (Week 12-24) and Individualization (Week 24-52). The dosing regimen (the dose level and dose interval) were adjusted in the Optimization and Individualization periods according to clinical response in a blinded manner.

Arms

Are arms mutually exclusive?	Yes
Arm title	ABY-035 2 mg - 2/20 mg Q2W - 20/80 mg Q4W/Q8W

Arm description:

Subjects randomized to ABY-035 2 mg Q2W in Induction period, then received either 2 mg Q2W or 20 mg Q2W in Optimization period, and 20 mg Q4W or Q8W, or 80 mg Q4W or Q8W in the Individualization period based on treatment response

Arm type	Experimental
Investigational medicinal product name	ABY-035
Investigational medicinal product code	
Other name	izokibep
Pharmaceutical forms	Solution for injection in vial
Routes of administration	Subcutaneous use

Dosage and administration details:

The IMP, ABY-035, was supplied by the Sponsor and distributed by the Service Provider in charge. The IMP was provided frozen in 2 mL glass vials filled with 1.2 or 1.3 mL (depending on the batch used) IMP with the nominal concentrations of 20 mg/mL and 80 mg/mL ± 10%.

Arm title	ABY-035 20 mg - 20/80 mg Q2W - 20/80 mg Q4W/Q8W

Arm description:

Subjects randomized to ABY-035 20 mg Q2W in Induction period, receiving either 20 mg Q2W or 80 mg Q2W in Optimization period, and 20 mg Q4W or Q8W, or 80 mg Q4W or Q8W in the Individualization period based on treatment response

Arm type	Experimental
Investigational medicinal product name	ABY-035
Investigational medicinal product code	
Other name	izokibep
Pharmaceutical forms	Solution for injection in vial
Routes of administration	Subcutaneous use

Dosage and administration details:

The IMP, ABY-035, was supplied by the Sponsor and distributed by the Service Provider in charge. The

IMP was provided frozen in 2 mL glass vials filled with 1.2 or 1.3 mL (depending on the batch used) IMP with the nominal concentrations of 20 mg/mL and 80 mg/mL ± 10%.

Arm title	ABY-035 80 mg - 80/160 mg Q2W - 80/160 mg Q4W/Q8W

Arm description:

Subjects randomized to ABY-035 80 mg Q2W in Induction period, receiving either 80 mg Q2W or 160 mg Q2W in Optimization period, and 80 mg Q4W or Q8W, or 160 mg Q8W in the Individualization period based on treatment response

Arm type	Experimental
Investigational medicinal product name	ABY-035
Investigational medicinal product code	
Other name	izokibep
Pharmaceutical forms	Solution for injection in vial
Routes of administration	Subcutaneous use

Dosage and administration details:

The IMP, ABY-035, was supplied by the Sponsor and distributed by the Service Provider in charge. The IMP was provided frozen in 2 mL glass vials filled with 1.2 or 1.3 mL (depending on the batch used) IMP with the nominal concentrations of 20 mg/mL and 80 mg/mL ± 10%.

Arm title	ABY-035 160 mg - 160 mg Q2W/Q4W - 160 mg Q4W/Q8W

Arm description:

Subjects randomized to ABY-035 160 mg Q2W in Induction period, receiving either 160 mg Q2W or Q4W in Optimization period, and 160 mg Q4W or Q8W in the Individualization period based on treatment response

Arm type	Experimental
Investigational medicinal product name	ABY-035
Investigational medicinal product code	
Other name	izokibep
Pharmaceutical forms	Solution for injection in vial
Routes of administration	Subcutaneous use

Dosage and administration details:

The IMP, ABY-035, was supplied by the Sponsor and distributed by the Service Provider in charge. The IMP was provided frozen in 2 mL glass vials filled with 1.2 or 1.3 mL (depending on the batch used) IMP with the nominal concentrations of 20 mg/mL and 80 mg/mL ± 10%.

Arm title	Placebo - 80 mg Q4W - 80 mg Q4W/Q8W

Arm description:

Subjects randomized to Placebo in Induction period, receiving 80 mg Q4W in Optimization period, and 80 mg Q4W or Q8W in the Individualization period based on treatment response

Arm type	Placebo + experimental
Investigational medicinal product name	Placebo + Experimental
Investigational medicinal product code	
Other name	placebo, izokibep
Pharmaceutical forms	Solution for injection in vial
Routes of administration	Subcutaneous use

Dosage and administration details:

Saline solution was used as placebo. ABY-035, was supplied by the Sponsor and distributed by the Service Provider in charge. The
IMP was provided frozen in 2 mL glass vials filled with 1.2 or 1.3 mL (depending on the batch used) IMP with the nominal concentrations of 20 mg/mL and 80 mg/mL ± 10%.

Number of subjects in period 1	ABY-035 2 mg - 2/20 mg Q2W - 20/80 mg Q4W/Q8W	ABY-035 20 mg - 20/80 mg Q2W - 20/80 mg Q4W/Q8W	ABY-035 80 mg - 80/160 mg Q2W - 80/160 mg Q4W/Q8W
Started	21	22	21
Completed	17	17	17
Not completed	4	5	4
Consent withdrawn by subject	2	1	1
Physician decision	-	1	-
Adverse event, non-fatal	-	2	2
Lost to follow-up	1	-	1
Violation of inclusion criteria	-	1	-
Lack of efficacy	1	-	-

Number of subjects in period 1	ABY-035 160 mg - 160 mg Q2W/Q4W - 160 mg Q4W/Q8W	Placebo - 80 mg Q4W - 80 mg Q4W/Q8W
Started	22	22
Completed	19	18
Not completed	3	4
Consent withdrawn by subject	1	2
Physician decision	-	-
Adverse event, non-fatal	2	1
Lost to follow-up	-	-
Violation of inclusion criteria	-	-
Lack of efficacy	-	1

Period 2

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

Blinding implementation details:

Subjects completing the Core study period were offered to participate in the Extension period. The dose level and dosing interval in place at Week 48 of Core study were carried over into the Extension period. After an amendment and upon subject consent, changes in dose level or dose interval in the Extension period were performed based on PASI response.

Arms

Are arms mutually exclusive?	Yes

Arm title	ABY-035 20 mg Q4W

Arm description:

Subjects starting the optional Extension period on ABY-035 20 mg Q4W. After an amendment, dose could be changed based on PASI response, to 80 mg Q4W or further to 160 mg Q4W

Arm type	Experimental
Investigational medicinal product name	ABY-035
Investigational medicinal product code	
Other name	izokibep
Pharmaceutical forms	Solution for injection in vial
Routes of administration	Subcutaneous use

Dosage and administration details:

The IMP, ABY-035, was supplied by the Sponsor and distributed by the Service Provider in charge. The IMP was provided frozen in 2 mL glass vials filled with 1.2 or 1.3 mL (depending on the batch used) IMP with the nominal concentrations of 20 mg/mL and 80 mg/mL ± 10%.

Arm title	ABY-035 20 mg Q8W

Arm description:

Subjects starting the optional Extension period on ABY-035 20 mg Q8W. After an amendment, dose could be changed based on PASI response, to 80 mg Q4W or further to 160 mg Q4W

Arm type	Experimental
Investigational medicinal product name	ABY-035
Investigational medicinal product code	
Other name	izokibep
Pharmaceutical forms	Solution for injection in vial
Routes of administration	Subcutaneous use

Dosage and administration details:

The IMP, ABY-035, was supplied by the Sponsor and distributed by the Service Provider in charge. The IMP was provided frozen in 2 mL glass vials filled with 1.2 or 1.3 mL (depending on the batch used) IMP with the nominal concentrations of 20 mg/mL and 80 mg/mL ± 10%.

Arm title	ABY-035 80 mg Q4W

Arm description:

Subjects starting the optional Extension period on ABY-035 80 mg Q4W. After an amendment, dose could be changed based on PASI response, to 160 mg Q4W

Arm type	Experimental
Investigational medicinal product name	ABY-035
Investigational medicinal product code	
Other name	izokibep
Pharmaceutical forms	Solution for injection in vial
Routes of administration	Subcutaneous use

Dosage and administration details:

The IMP, ABY-035, was supplied by the Sponsor and distributed by the Service Provider in charge. The IMP was provided frozen in 2 mL glass vials filled with 1.2 or 1.3 mL (depending on the batch used) IMP with the nominal concentrations of 20 mg/mL and 80 mg/mL ± 10%.

Arm title	ABY-035 80 mg Q8W

Arm description:

Subjects starting the optional Extension period on ABY-035 80 mg Q8W. After an amendment, dose could be changed based on PASI response, to 80 mg Q4W or further to 160 mg Q4W

Arm type	Experimental
Investigational medicinal product name	ABY-035
Investigational medicinal product code	
Other name	izokibep
Pharmaceutical forms	Solution for injection in vial
Routes of administration	Subcutaneous use

Dosage and administration details:

The IMP, ABY-035, was supplied by the Sponsor and distributed by the Service Provider in charge. The IMP was provided frozen in 2 mL glass vials filled with 1.2 or 1.3 mL (depending on the batch used) IMP with the nominal concentrations of 20 mg/mL and 80 mg/mL ± 10%.

Arm title	ABY-035 160 mg Q4W

Arm description:

Subjects treated with ABY-035 160 mg Q4W in the optional Extension period

Arm type	Experimental
Investigational medicinal product name	ABY-035
Investigational medicinal product code	
Other name	izokibep
Pharmaceutical forms	Solution for injection in vial
Routes of administration	Subcutaneous use

Dosage and administration details:

The IMP, ABY-035, was supplied by the Sponsor and distributed by the Service Provider in charge. The IMP was provided frozen in 2 mL glass vials filled with 1.2 or 1.3 mL (depending on the batch used) IMP with the nominal concentrations of 20 mg/mL and 80 mg/mL ± 10%.

Arm title	ABY-035 160 mg Q8W

Arm description:

Subjects starting the optional Extension period on ABY-035 160 mg Q8W. After an amendment, dose could be changed based on PASI response, to 160 mg Q4W

Arm type	Experimental
Investigational medicinal product name	ABY-035
Investigational medicinal product code	
Other name	izokibep
Pharmaceutical forms	Solution for injection in vial
Routes of administration	Subcutaneous use

Dosage and administration details:

The IMP, ABY-035, was supplied by the Sponsor and distributed by the Service Provider in charge. The IMP was provided frozen in 2 mL glass vials filled with 1.2 or 1.3 mL (depending on the batch used) IMP with the nominal concentrations of 20 mg/mL and 80 mg/mL ± 10%.

Number of subjects in period 2[1]	ABY-035 20 mg Q4W	ABY-035 20 mg Q8W	ABY-035 80 mg Q4W
Started	7	5	36
Completed	6	5	29
Not completed	1	0	7
Consent withdrawn by subject	-	-	3
Adverse event, non-fatal	1	-	1
Lost to follow-up	-	-	1
Lack of efficacy	-	-	2

Number of subjects in period 2[1]	ABY-035 80 mg Q8W	ABY-035 160 mg Q4W	ABY-035 160 mg Q8W
Started	15	8	12

Completed	12	7	12
Not completed	3	1	0
Consent withdrawn by subject	2	-	-
Adverse event, non-fatal	-	-	-
Lost to follow-up	-	-	-
Lack of efficacy	1	1	-

Notes:

[1] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.
Justification: The number of subjects starting the Extension period is different from the number of subjects completing the Core study as the Extension period was optional

Period 3

Period 3 title	Prolongation of Extension
Is this the baseline period?	No
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Blinding implementation details:

Subjects completing the Extension period were offered to participate in the Prolongation of Extension period. ABY-035 treatment could be intensified in up to two steps depending on PASI response during the period. Subjects were analyzed according to their highest dose / shortest interval received during the Prolongation of Extension period.

Arms

Are arms mutually exclusive?	Yes
Arm title	ABY-035 80 mg Q4W

Arm description:

Subjects that in the optional Prolongation of Extension period received ABY-035 80 mg Q4W as highest dose / shortest interval

Arm type	Experimental
Investigational medicinal product name	ABY-035
Investigational medicinal product code	
Other name	izokibep
Pharmaceutical forms	Solution for injection in vial
Routes of administration	Subcutaneous use

Dosage and administration details:

The IMP, ABY-035, was supplied by the Sponsor and distributed by the Service Provider in charge. The IMP was provided frozen in 2 mL glass vials filled with 1.2 or 1.3 mL (depending on the batch used) IMP with the nominal concentrations of 20 mg/mL and 80 mg/mL ± 10%.

Arm title	ABY-035 80 mg Q8W

Arm description:

Subjects that in the optional Prolongation of Extension period received ABY-035 80 mg Q8W as highest dose / shortest interval

Arm type	Experimental
Investigational medicinal product name	ABY-035
Investigational medicinal product code	
Other name	izokibep
Pharmaceutical forms	Solution for injection in vial
Routes of administration	Subcutaneous use

Dosage and administration details:

The IMP, ABY-035, was supplied by the Sponsor and distributed by the Service Provider in charge. The IMP was provided frozen in 2 mL glass vials filled with 1.2 or 1.3 mL (depending on the batch used) IMP with the nominal concentrations of 20 mg/mL and 80 mg/mL ± 10%.

Arm title	ABY-035 160 mg Q4W

Arm description:

Subjects that in the optional Prolongation of Extension period received ABY-035 160 mg Q4W as highest dose / shortest interval

Arm type	Experimental
Investigational medicinal product name	ABY-035
Investigational medicinal product code	
Other name	izokibep
Pharmaceutical forms	Solution for injection in vial
Routes of administration	Subcutaneous use

Dosage and administration details:

The IMP, ABY-035, was supplied by the Sponsor and distributed by the Service Provider in charge. The IMP was provided frozen in 2 mL glass vials filled with 1.2 or 1.3 mL (depending on the batch used) IMP with the nominal concentrations of 20 mg/mL and 80 mg/mL ± 10%.

Arm title	ABY-035 160 mg Q8W

Arm description:

Subjects that in the optional Prolongation of Extension period received ABY-035 160 mg Q8W as highest dose / shortest interval

Arm type	Experimental
Investigational medicinal product name	ABY-035
Investigational medicinal product code	
Other name	izokibep
Pharmaceutical forms	Solution for injection in vial
Routes of administration	Subcutaneous use

Dosage and administration details:

The IMP, ABY-035, was supplied by the Sponsor and distributed by the Service Provider in charge. The IMP was provided frozen in 2 mL glass vials filled with 1.2 or 1.3 mL (depending on the batch used) IMP with the nominal concentrations of 20 mg/mL and 80 mg/mL ± 10%.

Number of subjects in period 3[2]	ABY-035 80 mg Q4W	ABY-035 80 mg Q8W	ABY-035 160 mg Q4W
Started	20	3	39
Completed	13	2	22
Not completed	7	1	17
Consent withdrawn by subject	1	-	2
Physician decision	-	-	1
Secondary lack of efficacy	1	-	-
Lost to follow-up	-	-	1
Sponsor terminated study	5	1	13

Number of subjects in period 3[2]	ABY-035 160 mg Q8W
Started	6
Completed	4
Not completed	2
Consent withdrawn by subject	1
Physician decision	-

Secondary lack of efficacy	-
Lost to follow-up	-
Sponsor terminated study	1

Notes:

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

Justification: The number of subjects starting the Prolongation of Extension period is different from the number of subjects completing the Extension period as the Prolongation of Extension period was optional

Baseline characteristics

Reporting groups	
Reporting group title	ABY-035 2 mg - 2/20 mg Q2W - 20/80 mg Q4W/Q8W
Reporting group description:	
Subjects randomized to ABY-035 2 mg Q2W in Induction period, then received either 2 mg Q2W or 20 mg Q2W in Optimization period, and 20 mg Q4W or Q8W, or 80 mg Q4W or Q8W in the Individualization period based on treatment response	
Reporting group title	ABY-035 20 mg - 20/80 mg Q2W - 20/80 mg Q4W/Q8W
Reporting group description:	
Subjects randomized to ABY-035 20 mg Q2W in Induction period, receiving either 20 mg Q2W or 80 mg Q2W in Optimization period, and 20 mg Q4W or Q8W, or 80 mg Q4W or Q8W in the Individualization period based on treatment response	
Reporting group title	ABY-035 80 mg - 80/160 mg Q2W - 80/160 mg Q4W/Q8W
Reporting group description:	
Subjects randomized to ABY-035 80 mg Q2W in Induction period, receiving either 80 mg Q2W or 160 mg Q2W in Optimization period, and 80 mg Q4W or Q8W, or 160 mg Q8W in the Individualization period based on treatment response	
Reporting group title	ABY-035 160 mg - 160 mg Q2W/Q4W - 160 mg Q4W/Q8W
Reporting group description:	
Subjects randomized to ABY-035 160 mg Q2W in Induction period, receiving either 160 mg Q2W or Q4W in Optimization period, and 160 mg Q4W or Q8W in the Individualization period based on treatment response	
Reporting group title	Placebo - 80 mg Q4W - 80 mg Q4W/Q8W
Reporting group description:	
Subjects randomized to Placebo in Induction period, receiving 80 mg Q4W in Optimization period, and 80 mg Q4W or Q8W in the Individualization period based on treatment response	

Reporting group values	ABY-035 2 mg - 2/20 mg Q2W - 20/80 mg Q4W/Q8W	ABY-035 20 mg - 20/80 mg Q2W - 20/80 mg Q4W/Q8W	ABY-035 80 mg - 80/160 mg Q2W - 80/160 mg Q4W/Q8W
Number of subjects	21	22	21
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	21	22	21
From 65-84 years	0	0	0
85 years and over	0	0	0
Age continuous Units: years			
arithmetic mean	41.6	44.7	42.0
standard deviation	± 13.8	± 12.3	± 13.8
Gender categorical Units: Subjects			
Female	9	6	7

Male	12	16	14

Race Units: Subjects			
White	21	22	20
Black or African American			
Asian			1
BMI			
Body Mass Index			
Units: kg/m2			
arithmetic mean	30.5	30.4	26.0
standard deviation	± 5.5	± 6.6	± 3.6
PASI			
The PASI (Psoriasis Area and Severity Index) is a scoring method that was used for the assessment and grading of the severity of the subject's psoriasis. The severity of the disease was calculated by scoring the signs of the disease (erythema, induration and scaling) for each body region. Overall scores ranged from 0 (no psoriasis) to 72 (the most severe disease).			
Units: Score			
arithmetic mean	18.4	20.1	22.7
standard deviation	± 7.0	± 8.4	± 10.1

Reporting group values	ABY-035 160 mg - 160 mg Q2W/Q4W - 160 mg Q4W/Q8W	Placebo - 80 mg Q4W - 80 mg Q4W/Q8W	Total
Number of subjects	22	22	108
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	22	21	107
From 65-84 years	0	1	1
85 years and over	0	0	0
Age continuous Units: years			
arithmetic mean	43.2	38.4	
standard deviation	± 11.4	± 13.0	-
Gender categorical Units: Subjects			
Female	10	7	39
Male	12	15	69
Race Units: Subjects			
White	22	20	105
Black or African American		1	1
Asian		1	2

BMI			
Body Mass Index			
Units: kg/m2			
arithmetic mean	28.5	29.3	
standard deviation	± 6.7	± 5.4	-
PASI			
The PASI (Psoriasis Area and Severity Index) is a scoring method that was used for the assessment and grading of the severity of the subject's psoriasis. The severity of the disease was calculated by scoring the signs of the disease (erythema, induration and scaling) for each body region. Overall scores ranged from 0 (no psoriasis) to 72 (the most severe disease).			
Units: Score			
arithmetic mean	17.9	18.9	
standard deviation	± 6.6	± 8.2	-

Subject analysis sets

Subject analysis set title	ABY-035 2 mg Q2W 0-12 weeks
Subject analysis set type	Full analysis
Subject analysis set description:	
ABY-035 2 mg Q2W. The Full Analysis Set included all randomized subjects who received at least one dose of study drug and had at least one PASI result after baseline.	
Subject analysis set title	ABY-035 20 mg Q2W 0-12 weeks
Subject analysis set type	Full analysis
Subject analysis set description:	
ABY-035 20 mg Q2W. The Full Analysis Set included all randomized subjects who received at least one dose of study drug and had at least one PASI result after baseline.	
Subject analysis set title	ABY-035 80 mg Q2W 0-12 weeks
Subject analysis set type	Full analysis
Subject analysis set description:	
ABY-035 80 mg Q2W. The Full Analysis Set included all randomized subjects who received at least one dose of study drug and had at least one PASI result after baseline.	
Subject analysis set title	ABY-035 160 mg Q2W 0-12 weeks
Subject analysis set type	Full analysis
Subject analysis set description:	
ABY-035 160 mg Q2W. The Full Analysis Set included all randomized subjects who received at least one dose of study drug and had at least one PASI result after baseline.	
Subject analysis set title	Placebo 0-12 weeks
Subject analysis set type	Full analysis
Subject analysis set description:	
Placebo Q2W. The Full Analysis Set included all randomized subjects who received at least one dose of study drug and had at least one PASI result after baseline.	

Reporting group values	ABY-035 2 mg Q2W 0-12 weeks	ABY-035 20 mg Q2W 0-12 weeks	ABY-035 80 mg Q2W 0-12 weeks
Number of subjects	20	21	21
Age categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0

Adults (18-64 years)	20	21	21
From 65-84 years	0	0	0
85 years and over	0	0	0
Age continuous			
Units: years			
arithmetic mean	40.5	45.0	42.0
standard deviation	± 13.1	± 12.5	± 13.8
Gender categorical			
Units: Subjects			
Female	8	6	7
Male	12	15	14
Race			
Units: Subjects			
White	20	21	20
Black or African American			
Asian			1
BMI			
Body Mass Index			
Units: kg/m2			
arithmetic mean	30.2	29.8	26.0
standard deviation	± 5.5	± 6.2	± 3.6
PASI			
The PASI (Psoriasis Area and Severity Index) is a scoring method that was used for the assessment and grading of the severity of the subject's psoriasis. The severity of the disease was calculated by scoring the signs of the disease (erythema, induration and scaling) for each body region. Overall scores ranged from 0 (no psoriasis) to 72 (the most severe disease).			
Units: Score			
arithmetic mean	18.0	20.2	22.7
standard deviation	± 6.9	± 8.6	± 10.1

Reporting group values	ABY-035 160 mg Q2W 0-12 weeks	Placebo 0-12 weeks	
Number of subjects	22	22	
Age categorical			
Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	22	22	
From 65-84 years	0	0	
85 years and over	0	0	
Age continuous			
Units: years			
arithmetic mean	43.2	38.4	
standard deviation	± 11.4	± 13.0	
Gender categorical			
Units: Subjects			
Female	10	7	

Male	12	15	

Race Units: Subjects			
White	22	20	
Black or African American		1	
Asian		1	
BMI			
Body Mass Index			
Units: kg/m2			
arithmetic mean	28.5	29.3	
standard deviation	± 6.7	± 5.4	
PASI			
The PASI (Psoriasis Area and Severity Index) is a scoring method that was used for the assessment and grading of the severity of the subject’s psoriasis. The severity of the disease was calculated by scoring the signs of the disease (erythema, induration and scaling) for each body region. Overall scores ranged from 0 (no psoriasis) to 72 (the most severe disease).			
Units: Score			
arithmetic mean	17.9	18.9	
standard deviation	± 6.6	± 8.2	

End points

End points reporting groups

Reporting group title	ABY-035 2 mg - 2/20 mg Q2W - 20/80 mg Q4W/Q8W
Reporting group description:	
Subjects randomized to ABY-035 2 mg Q2W in Induction period, then received either 2 mg Q2W or 20 mg Q2W in Optimization period, and 20 mg Q4W or Q8W, or 80 mg Q4W or Q8W in the Individualization period based on treatment response	
Reporting group title	ABY-035 20 mg - 20/80 mg Q2W - 20/80 mg Q4W/Q8W
Reporting group description:	
Subjects randomized to ABY-035 20 mg Q2W in Induction period, receiving either 20 mg Q2W or 80 mg Q2W in Optimization period, and 20 mg Q4W or Q8W, or 80 mg Q4W or Q8W in the Individualization period based on treatment response	
Reporting group title	ABY-035 80 mg - 80/160 mg Q2W - 80/160 mg Q4W/Q8W
Reporting group description:	
Subjects randomized to ABY-035 80 mg Q2W in Induction period, receiving either 80 mg Q2W or 160 mg Q2W in Optimization period, and 80 mg Q4W or Q8W, or 160 mg Q8W in the Individualization period based on treatment response	
Reporting group title	ABY-035 160 mg - 160 mg Q2W/Q4W - 160 mg Q4W/Q8W
Reporting group description:	
Subjects randomized to ABY-035 160 mg Q2W in Induction period, receiving either 160 mg Q2W or Q4W in Optimization period, and 160 mg Q4W or Q8W in the Individualization period based on treatment response	
Reporting group title	Placebo - 80 mg Q4W - 80 mg Q4W/Q8W
Reporting group description:	
Subjects randomized to Placebo in Induction period, receiving 80 mg Q4W in Optimization period, and 80 mg Q4W or Q8W in the Individualization period based on treatment response	
Reporting group title	ABY-035 20 mg Q4W
Reporting group description:	
Subjects starting the optional Extension period on ABY-035 20 mg Q4W. After an amendment, dose could be changed based on PASI response, to 80 mg Q4W or further to 160 mg Q4W	
Reporting group title	ABY-035 20 mg Q8W
Reporting group description:	
Subjects starting the optional Extension period on ABY-035 20 mg Q8W. After an amendment, dose could be changed based on PASI response, to 80 mg Q4W or further to 160 mg Q4W	
Reporting group title	ABY-035 80 mg Q4W
Reporting group description:	
Subjects starting the optional Extension period on ABY-035 80 mg Q4W. After an amendment, dose could be changed based on PASI response, to 160 mg Q4W	
Reporting group title	ABY-035 80 mg Q8W
Reporting group description:	
Subjects starting the optional Extension period on ABY-035 80 mg Q8W. After an amendment, dose could be changed based on PASI response, to 80 mg Q4W or further to 160 mg Q4W	
Reporting group title	ABY-035 160 mg Q4W
Reporting group description:	
Subjects treated with ABY-035 160 mg Q4W in the optional Extension period	
Reporting group title	ABY-035 160 mg Q8W
Reporting group description:	
Subjects starting the optional Extension period on ABY-035 160 mg Q8W. After an amendment, dose could be changed based on PASI response, to 160 mg Q4W	
Reporting group title	ABY-035 80 mg Q4W
Reporting group description:	
Subjects that in the optional Prolongation of Extension period received ABY-035 80 mg Q4W as highest dose / shortest interval	
Reporting group title	ABY-035 80 mg Q8W

Reporting group description:

Subjects that in the optional Prolongation of Extension period received ABY-035 80 mg Q8W as highest dose / shortest interval

Reporting group title	ABY-035 160 mg Q4W

Reporting group description:

Subjects that in the optional Prolongation of Extension period received ABY-035 160 mg Q4W as highest dose / shortest interval

Reporting group title	ABY-035 160 mg Q8W

Reporting group description:

Subjects that in the optional Prolongation of Extension period received ABY-035 160 mg Q8W as highest dose / shortest interval

Subject analysis set title	ABY-035 2 mg Q2W 0-12 weeks
Subject analysis set type	Full analysis

Subject analysis set description:

ABY-035 2 mg Q2W. The Full Analysis Set included all randomized subjects who received at least one dose of study drug and had at least one PASI result after baseline.

Subject analysis set title	ABY-035 20 mg Q2W 0-12 weeks
Subject analysis set type	Full analysis

Subject analysis set description:

ABY-035 20 mg Q2W. The Full Analysis Set included all randomized subjects who received at least one dose of study drug and had at least one PASI result after baseline.

Subject analysis set title	ABY-035 80 mg Q2W 0-12 weeks
Subject analysis set type	Full analysis

Subject analysis set description:

ABY-035 80 mg Q2W. The Full Analysis Set included all randomized subjects who received at least one dose of study drug and had at least one PASI result after baseline.

Subject analysis set title	ABY-035 160 mg Q2W 0-12 weeks
Subject analysis set type	Full analysis

Subject analysis set description:

ABY-035 160 mg Q2W. The Full Analysis Set included all randomized subjects who received at least one dose of study drug and had at least one PASI result after baseline.

Subject analysis set title	Placebo 0-12 weeks
Subject analysis set type	Full analysis

Subject analysis set description:

Placebo Q2W. The Full Analysis Set included all randomized subjects who received at least one dose of study drug and had at least one PASI result after baseline.

Primary: Proportion of subjects who achieved a ≥90% reduction in PASI score (PASI 90 response) at Week 12

End point title	Proportion of subjects who achieved a ≥90% reduction in PASI score (PASI 90 response) at Week 12[1]

End point description:

The PASI (Psoriasis Area and Severity Index) is a scoring method that was used for the assessment and grading of the severity of the subject's psoriasis. The severity of the disease was calculated by scoring the signs of the disease (erythema, induration and scaling) for each body region. Overall scores range from 0 (no psoriasis) to 72 (the most severe disease). The primary efficacy variable, PASI 90 response, was defined as having an improvement (reduction) of ≥90% in PASI score compared to Baseline.

End point type	Primary

End point timeframe:

Baseline to Week 12 in the Induction period

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive statistics were performed, no inferential statistical analysis was performed

End point values	ABY-035 2 mg Q2W 0-12 weeks	ABY-035 20 mg Q2W 0-12 weeks	ABY-035 80 mg Q2W 0-12 weeks	ABY-035 160 mg Q2W 0-12 weeks
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	20	21	21	22
Units: Percentage Responders				
number (not applicable)	5.0	19.0	71.4	59.1

End point values	Placebo 0-12 weeks			
Subject group type	Subject analysis set			
Number of subjects analysed	22			
Units: Percentage Responders				
number (not applicable)	0.0			

Statistical analyses

No statistical analyses for this end point

Secondary: Proportion of subjects who achieved sPGA score of 0 or 1 at Week 12

End point title	Proportion of subjects who achieved sPGA score of 0 or 1 at Week 12

End point description:

The sPGA (Static Physician’s Global Assessment) is the assessment by the Investigator of the overall disease severity at the time of evaluation. The sPGA is a 5-point scale ranging from 0 (clear) to 4 (severe), incorporating an assessment of the severity of the three primary signs of the disease: erythema, scaling, and plaque elevation.

End point type	Secondary

End point timeframe:

Baseline to Week 12 in the Induction period

End point values	ABY-035 2 mg Q2W 0-12 weeks	ABY-035 20 mg Q2W 0-12 weeks	ABY-035 80 mg Q2W 0-12 weeks	ABY-035 160 mg Q2W 0-12 weeks
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	20	21	21	22
Units: Percentage of subjects				
number (not applicable)	5.0	23.8	61.9	63.6

End point values	Placebo 0-12 weeks			
Subject group type	Subject analysis set			
Number of subjects analysed	22			
Units: Percentage of subjects				

number (not applicable)	0.0			

Statistical analyses

No statistical analyses for this end point

Secondary: Proportion of subjects who achieved DLQI score of 0 or 1 at Week 12

End point title	Proportion of subjects who achieved DLQI score of 0 or 1 at Week 12

End point description:

The DLQI (Dermatology Life Quality Index) is a questionnaire where subjects are asked about the impact of their disease and the respective treatment on their lives. The DLQI score is calculated by summing the score of each question resulting in a maximum of 30 and a minimum of 0. The higher the score, the more quality of life was impaired.

End point type	Secondary

End point timeframe:

Baseline to Week 12 in the Induction period

End point values	ABY-035 2 mg Q2W 0-12 weeks	ABY-035 20 mg Q2W 0-12 weeks	ABY-035 80 mg Q2W 0-12 weeks	ABY-035 160 mg Q2W 0-12 weeks
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	20	21	21	22
Units: Percentage of subjects				
number (not applicable)	10.0	47.6	57.1	68.2

End point values	Placebo 0-12 weeks			
Subject group type	Subject analysis set			
Number of subjects analysed	22			
Units: Percentage of subjects				
number (not applicable)	4.5			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Serious Adverse Events were recorded from the signing of informed consent and Adverse Events were recorded from the first administration of ABY-035/placebo until the End of Study Visit.

Adverse event reporting additional description:

Summary tables for adverse events are provided in a time-dependent manner, Weeks 0-12, Weeks 12-24, Weeks 24-52, and Weeks 0-52 in each Extension period.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	20.1

Reporting groups

Reporting group title	Week 0-12: ABY-035 2 mg

Reporting group description:

Induction period Week 0-12, subjects receiving ABY-035 2 mg Q2W

Reporting group title	Week 0-12: ABY-035 20 mg

Reporting group description:

Induction period Week 0-12, subjects receiving ABY-035 20 mg Q2W

Reporting group title	Week 0-12: ABY-035 80 mg

Reporting group description:

Induction period Week 0-12, subjects receiving ABY-035 80 mg Q2W

Reporting group title	Week 0-12: ABY-035 160 mg

Reporting group description:

Induction period Week 0-12, subjects receiving ABY-035 160 mg Q2W

Reporting group title	Week 0-12: Placebo

Reporting group description:

Induction period Week 0-12, subjects receiving Placebo Q2W

Reporting group title	Week 12-24: ABY-035 2 mg - 2/20 mg Q2W

Reporting group description:

Optimization period Week 12-24. ABY-035 2 mg in Induction, receiving either 2 mg Q2W or 20 mg Q2W in Optimization

Reporting group title	Week 12-24: ABY-035 20 mg - 20/80 mg Q2W

Reporting group description:

Optimization period Week 12-24. ABY-035 20 mg Q2W in Induction, receiving either 20 mg Q2W or 80 mg Q2W in Optimization

Reporting group title	Week 12-24: ABY-035 80 mg - 80/160 mg Q2W

Reporting group description:

Optimization period Week 12-24. ABY-035 80 mg Q2W in Induction, receiving either 80 mg Q2W or 160 mg Q2W in Optimization

Reporting group title	Week 12-24: ABY-035 160 mg - 160 mg Q2W/Q4W

Reporting group description:

Optimization period Week 12-24. ABY-035 160 mg Q2W in Induction, receiving either 160 mg Q2W or Q4W in Optimization

Reporting group title	Week 12-24: Placebo - 80 mg Q4W

Reporting group description:

Optimization period Week 12-24. Placebo in Induction, receiving 80 mg Q4W in Optimization

Reporting group title	Week 24-52: ABY-035 2 mg - 2/20 mg Q2W - 2/20/80 mg Q4W/Q8W

Reporting group description:

Individualization period Week 24-52. ABY-035 2 mg Q2W in Induction, receiving either 2 mg Q2W or 20 mg Q2W in Optimization, treatment could be further individualized to 20 mg Q4W or Q8W, or 80 mg

Q4W or Q8W based on treatment response

Reporting group title	Week 24-52: ABY-035 20 mg - 20/80 mg Q2W - 20/80 mg Q4W/Q8W

Reporting group description:

Individualization period Week 24-52. ABY-035 20 mg Q2W in Induction, receiving either 20 mg Q2W or 80 mg Q2W in Optimization, treatment could be further individualized to 20 mg Q4W or Q8W, or 80 mg Q4W or Q8W based on treatment response

Reporting group title	Week 24-52: ABY-035 80 mg - 80/160 mg Q2W - 80/160 mg Q4W/Q8W

Reporting group description:

ABY-035 80 mg Q2W in Induction, receiving either 80 mg Q2W or 160 mg Q2W in Optimization, treatment could be further individualized to 80 mg Q4W or Q8W, or 160 mg Q4W or Q8W based on treatment response

Reporting group title	Week 24-52: ABY-035 160 mg - 160 mg Q2W/Q4W - 160 mg Q4W/Q8W

Reporting group description:

ABY-035 160 mg Q2W in Induction, receiving either 160 mg Q2W or Q4W in Optimization, treatment could be further individualized to 160 mg Q4W or Q8W based on treatment response

Reporting group title	Week 24-52: Placebo - 80 mg Q4W - 80 mg Q4W/Q8W

Reporting group description:

Placebo in Induction, receiving 80 mg Q4W in Optimization, treatment could be further individualized to 80 mg Q4W or Q8W based on treatment response

Reporting group title	Extension period ABY-035

Reporting group description:

All subjects continuing in the optional Extension period. The dose level/interval could be adjusted based on the PASI response

Reporting group title	Prolongation of Extension period ABY-035

Reporting group description:

All subjects continuing in the optional Prolongation of Extension period. The dose level/interval could be adjusted based on the PASI response

Serious adverse events	Week 0-12: ABY-035 2 mg	Week 0-12: ABY-035 20 mg	Week 0-12: ABY-035 80 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 21 (0.00%)	0 / 22 (0.00%)	1 / 21 (4.76%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Fibroadenoma of breast			
subjects affected / exposed	0 / 21 (0.00%)	0 / 22 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endometrial adenocarcinoma			
subjects affected / exposed	0 / 21 (0.00%)	0 / 22 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural			

complications			
Meniscus injury			
subjects affected / exposed	0 / 21 (0.00%)	0 / 22 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chemical peritonitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 22 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypertensive emergency			
subjects affected / exposed	0 / 21 (0.00%)	0 / 22 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 21 (0.00%)	0 / 22 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery disease			
subjects affected / exposed	0 / 21 (0.00%)	0 / 22 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	0 / 21 (0.00%)	0 / 22 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 21 (0.00%)	0 / 22 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular fibrillation			

subjects affected / exposed	0 / 21 (0.00%)	0 / 22 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 22 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			
subjects affected / exposed	0 / 21 (0.00%)	0 / 22 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Thyroidectomy			
subjects affected / exposed	0 / 21 (0.00%)	0 / 22 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Syncope			
subjects affected / exposed	0 / 21 (0.00%)	0 / 22 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Sarcoidosis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 22 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 21 (0.00%)	0 / 22 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urogenital fistula			

subjects affected / exposed	0 / 21 (0.00%)	0 / 22 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 21 (0.00%)	0 / 22 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Osteoarthritis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 22 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc protrusion			
subjects affected / exposed	0 / 21 (0.00%)	0 / 22 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Tonsillitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 22 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 22 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 22 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subcutaneous abscess			
subjects affected / exposed	0 / 21 (0.00%)	0 / 22 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Chronic sinusitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 22 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Week 0-12: ABY-035 160 mg	Week 0-12: Placebo	Week 12-24: ABY-035 2 mg - 2/20 mg Q2W
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 22 (4.55%)	2 / 22 (9.09%)	0 / 21 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Fibroadenoma of breast			
subjects affected / exposed	0 / 22 (0.00%)	1 / 22 (4.55%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endometrial adenocarcinoma			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Meniscus injury			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chemical peritonitis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypertensive emergency			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			

Atrial fibrillation			
subjects affected / exposed	0 / 22 (0.00%)	1 / 22 (4.55%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery disease			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular fibrillation			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Thyroidectomy			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			

Syncope			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Sarcoidosis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urogenital fistula			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Osteoarthritis			
subjects affected / exposed	1 / 22 (4.55%)	0 / 22 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc protrusion			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Tonsillitis			

subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subcutaneous abscess			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic sinusitis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Week 12-24: ABY-035 20 mg - 20/80 mg Q2W	Week 12-24: ABY-035 80 mg - 80/160 mg Q2W	Week 12-24: ABY-035 160 mg - 160 mg Q2W/Q4W
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 22 (4.55%)	0 / 21 (0.00%)	0 / 22 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Fibroadenoma of breast			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endometrial adenocarcinoma			

subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Meniscus injury			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chemical peritonitis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypertensive emergency			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery disease			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Ventricular fibrillation			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Thyroidectomy			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Syncope			
subjects affected / exposed	1 / 22 (4.55%)	0 / 21 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Sarcoidosis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urogenital fistula			

subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Osteoarthritis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc protrusion			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Tonsillitis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subcutaneous abscess			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Chronic sinusitis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Week 12-24: Placebo - 80 mg Q4W	Week 24-52: ABY-035 2 mg - 2/20 mg Q2W - 2/20/80 mg Q4W/Q8W	Week 24-52: ABY-035 20 mg - 20/80 mg Q2W - 20/80 mg Q4W/Q8W
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	3 / 22 (13.64%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Fibroadenoma of breast			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endometrial adenocarcinoma			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Meniscus injury			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chemical peritonitis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypertensive emergency			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			

Atrial fibrillation			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery disease			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular fibrillation			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Thyroidectomy			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			

Syncope			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Sarcoidosis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urogenital fistula			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Osteoarthritis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc protrusion			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Tonsillitis			

subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subcutaneous abscess			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic sinusitis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Week 24-52: ABY-035 80 mg - 80/160 mg Q2W - 80/160 mg Q4W/Q8W	Week 24-52: ABY-035 160 mg - 160 mg Q2W/Q4W - 160 mg Q4W/Q8W	Week 24-52: Placebo - 80 mg Q4W - 80 mg Q4W/Q8W
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 21 (4.76%)	1 / 22 (4.55%)	1 / 22 (4.55%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Fibroadenoma of breast			
subjects affected / exposed	0 / 21 (0.00%)	0 / 22 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endometrial adenocarcinoma			

subjects affected / exposed	1 / 21 (4.76%)	0 / 22 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Meniscus injury			
subjects affected / exposed	0 / 21 (0.00%)	0 / 22 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chemical peritonitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 22 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypertensive emergency			
subjects affected / exposed	0 / 21 (0.00%)	0 / 22 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 21 (0.00%)	0 / 22 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery disease			
subjects affected / exposed	0 / 21 (0.00%)	1 / 22 (4.55%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	0 / 21 (0.00%)	0 / 22 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 21 (0.00%)	0 / 22 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Ventricular fibrillation			
subjects affected / exposed	0 / 21 (0.00%)	0 / 22 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 22 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			
subjects affected / exposed	0 / 21 (0.00%)	0 / 22 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Thyroidectomy			
subjects affected / exposed	0 / 21 (0.00%)	0 / 22 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Syncope			
subjects affected / exposed	0 / 21 (0.00%)	0 / 22 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Sarcoidosis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 22 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 21 (0.00%)	0 / 22 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urogenital fistula			

subjects affected / exposed	1 / 21 (4.76%)	0 / 22 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 21 (0.00%)	0 / 22 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Osteoarthritis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 22 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc protrusion			
subjects affected / exposed	0 / 21 (0.00%)	0 / 22 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Tonsillitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 22 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 22 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 22 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subcutaneous abscess			
subjects affected / exposed	0 / 21 (0.00%)	0 / 22 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Chronic sinusitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 22 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Extension period ABY-035	Prolongation of Extension period ABY-035	
Total subjects affected by serious adverse events			
subjects affected / exposed	7 / 83 (8.43%)	3 / 68 (4.41%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Fibroadenoma of breast			
subjects affected / exposed	0 / 83 (0.00%)	0 / 68 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endometrial adenocarcinoma			
subjects affected / exposed	0 / 83 (0.00%)	0 / 68 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Meniscus injury			
subjects affected / exposed	0 / 83 (0.00%)	0 / 68 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chemical peritonitis			
subjects affected / exposed	0 / 83 (0.00%)	0 / 68 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Hypertensive emergency			
subjects affected / exposed	1 / 83 (1.20%)	0 / 68 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			

Atrial fibrillation			
subjects affected / exposed	0 / 83 (0.00%)	0 / 68 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery disease			
subjects affected / exposed	0 / 83 (0.00%)	0 / 68 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac arrest			
subjects affected / exposed	0 / 83 (0.00%)	0 / 68 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial infarction			
subjects affected / exposed	1 / 83 (1.20%)	0 / 68 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular fibrillation			
subjects affected / exposed	1 / 83 (1.20%)	0 / 68 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericarditis			
subjects affected / exposed	1 / 83 (1.20%)	0 / 68 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericardial effusion			
subjects affected / exposed	1 / 83 (1.20%)	0 / 68 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical and medical procedures			
Thyroidectomy			
subjects affected / exposed	0 / 83 (0.00%)	1 / 68 (1.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			

Syncope			
subjects affected / exposed	0 / 83 (0.00%)	0 / 68 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Sarcoidosis			
subjects affected / exposed	1 / 83 (1.20%)	0 / 68 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 83 (0.00%)	0 / 68 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urogenital fistula			
subjects affected / exposed	0 / 83 (0.00%)	0 / 68 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Depression			
subjects affected / exposed	1 / 83 (1.20%)	0 / 68 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Osteoarthritis			
subjects affected / exposed	1 / 83 (1.20%)	0 / 68 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc protrusion			
subjects affected / exposed	1 / 83 (1.20%)	0 / 68 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Tonsillitis			

subjects affected / exposed	0 / 83 (0.00%)	0 / 68 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	0 / 83 (0.00%)	0 / 68 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infection			
subjects affected / exposed	0 / 83 (0.00%)	0 / 68 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subcutaneous abscess			
subjects affected / exposed	0 / 83 (0.00%)	1 / 68 (1.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic sinusitis			
subjects affected / exposed	0 / 83 (0.00%)	1 / 68 (1.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Week 0-12: ABY-035 2 mg	Week 0-12: ABY-035 20 mg	Week 0-12: ABY-035 80 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	12 / 21 (57.14%)	11 / 22 (50.00%)	12 / 21 (57.14%)
Investigations			
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 21 (0.00%)	0 / 22 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 21 (0.00%)	2 / 22 (9.09%)	1 / 21 (4.76%)
occurrences (all)	0	2	1
Nervous system disorders			

Headache			
subjects affected / exposed	3 / 21 (14.29%)	3 / 22 (13.64%)	1 / 21 (4.76%)
occurrences (all)	5	3	1
Dizziness			
subjects affected / exposed	0 / 21 (0.00%)	0 / 22 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Injection site reaction			
subjects affected / exposed	4 / 21 (19.05%)	2 / 22 (9.09%)	8 / 21 (38.10%)
occurrences (all)	4	4	30
Fatigue			
subjects affected / exposed	1 / 21 (4.76%)	0 / 22 (0.00%)	1 / 21 (4.76%)
occurrences (all)	1	0	1
Injection site erythema			
subjects affected / exposed	0 / 21 (0.00%)	0 / 22 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	2 / 21 (9.52%)	1 / 22 (4.55%)	2 / 21 (9.52%)
occurrences (all)	4	1	2
tooth ache			
subjects affected / exposed	0 / 21 (0.00%)	0 / 22 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	1 / 21 (4.76%)	0 / 22 (0.00%)	2 / 21 (9.52%)
occurrences (all)	1	0	2
Vomiting			
subjects affected / exposed	0 / 21 (0.00%)	0 / 22 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 21 (4.76%)	2 / 22 (9.09%)	0 / 21 (0.00%)
occurrences (all)	1	2	0
Skin and subcutaneous tissue disorders			
Pruritus			

subjects affected / exposed	1 / 21 (4.76%)	0 / 22 (0.00%)	1 / 21 (4.76%)
occurrences (all)	2	0	1
Psoriasis			
subjects affected / exposed	0 / 21 (0.00%)	1 / 22 (4.55%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 22 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	1 / 21 (4.76%)	0 / 22 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Muscle tightness			
subjects affected / exposed	0 / 21 (0.00%)	0 / 22 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Tendonitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 22 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	3 / 21 (14.29%)	4 / 22 (18.18%)	3 / 21 (14.29%)
occurrences (all)	4	7	3
Urinary tract infection			
subjects affected / exposed	1 / 21 (4.76%)	1 / 22 (4.55%)	1 / 21 (4.76%)
occurrences (all)	1	2	1
Oral herpes			
subjects affected / exposed	1 / 21 (4.76%)	0 / 22 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Bronchitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 22 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 22 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Week 0-12: ABY-035 160 mg	Week 0-12: Placebo	Week 12-24: ABY-035 2 mg - 2/20 mg

			Q2W
Total subjects affected by non-serious adverse events			
subjects affected / exposed	20 / 22 (90.91%)	12 / 22 (54.55%)	9 / 21 (42.86%)
Investigations			
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	2 / 22 (9.09%)	0 / 22 (0.00%)	1 / 21 (4.76%)
occurrences (all)	3	0	1
Dizziness			
subjects affected / exposed	1 / 22 (4.55%)	0 / 22 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
Injection site reaction			
subjects affected / exposed	15 / 22 (68.18%)	3 / 22 (13.64%)	2 / 21 (9.52%)
occurrences (all)	49	3	2
Fatigue			
subjects affected / exposed	4 / 22 (18.18%)	0 / 22 (0.00%)	0 / 21 (0.00%)
occurrences (all)	4	0	0
Injection site erythema			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	5 / 22 (22.73%)	0 / 22 (0.00%)	1 / 21 (4.76%)
occurrences (all)	6	0	1
tooth ache			
subjects affected / exposed	1 / 22 (4.55%)	0 / 22 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Abdominal pain upper			

subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	2 / 22 (9.09%)	0 / 22 (0.00%)	1 / 21 (4.76%)
occurrences (all)	3	0	1
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 22 (4.55%)	1 / 22 (4.55%)	1 / 21 (4.76%)
occurrences (all)	1	2	1
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	2 / 22 (9.09%)	0 / 22 (0.00%)	0 / 21 (0.00%)
occurrences (all)	2	0	0
Psoriasis			
subjects affected / exposed	1 / 22 (4.55%)	0 / 22 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 22 (9.09%)	0 / 22 (0.00%)	0 / 21 (0.00%)
occurrences (all)	2	0	0
Back pain			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Muscle tightness			
subjects affected / exposed	0 / 22 (0.00%)	1 / 22 (4.55%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Tendonitis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	9 / 22 (40.91%)	7 / 22 (31.82%)	1 / 21 (4.76%)
occurrences (all)	9	8	1
Urinary tract infection			
subjects affected / exposed	1 / 22 (4.55%)	3 / 22 (13.64%)	1 / 21 (4.76%)
occurrences (all)	1	4	1

Oral herpes			
subjects affected / exposed	2 / 22 (9.09%)	0 / 22 (0.00%)	1 / 21 (4.76%)
occurrences (all)	2	0	1
Bronchitis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 22 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	1 / 22 (4.55%)	1 / 22 (4.55%)	0 / 21 (0.00%)
occurrences (all)	1	1	0

Non-serious adverse events	Week 12-24: ABY-035 20 mg - 20/80 mg Q2W	Week 12-24: ABY-035 80 mg - 80/160 mg Q2W	Week 12-24: ABY-035 160 mg - 160 mg Q2W/Q4W
Total subjects affected by non-serious adverse events			
subjects affected / exposed	14 / 22 (63.64%)	12 / 21 (57.14%)	13 / 22 (59.09%)
Investigations			
Blood creatine phosphokinase increased			
subjects affected / exposed	2 / 22 (9.09%)	0 / 21 (0.00%)	0 / 22 (0.00%)
occurrences (all)	2	0	0
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Nervous system disorders			
Headache			
subjects affected / exposed	1 / 22 (4.55%)	1 / 21 (4.76%)	0 / 22 (0.00%)
occurrences (all)	1	1	0
Dizziness			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Injection site reaction			
subjects affected / exposed	4 / 22 (18.18%)	7 / 21 (33.33%)	7 / 22 (31.82%)
occurrences (all)	10	14	11
Fatigue			
subjects affected / exposed	1 / 22 (4.55%)	0 / 21 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Injection site erythema			

subjects affected / exposed	2 / 22 (9.09%)	0 / 21 (0.00%)	0 / 22 (0.00%)
occurrences (all)	2	0	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	1 / 22 (4.55%)	1 / 21 (4.76%)	2 / 22 (9.09%)
occurrences (all)	1	1	3
tooth ache			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	3 / 22 (13.64%)
occurrences (all)	0	0	3
Abdominal pain upper			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Psoriasis			
subjects affected / exposed	1 / 22 (4.55%)	0 / 21 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Back pain			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Muscle tightness			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0

Tendonitis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	8 / 22 (36.36%)	6 / 21 (28.57%)	5 / 22 (22.73%)
occurrences (all)	11	6	5
Urinary tract infection			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Oral herpes			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	2 / 22 (9.09%)
occurrences (all)	0	0	2
Bronchitis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Gastroenteritis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Week 12-24: Placebo - 80 mg Q4W	Week 24-52: ABY-035 2 mg - 2/20 mg Q2W - 2/20/80 mg Q4W/Q8W	Week 24-52: ABY-035 20 mg - 20/80 mg Q2W - 20/80 mg Q4W/Q8W
Total subjects affected by non-serious adverse events			
subjects affected / exposed	9 / 22 (40.91%)	9 / 21 (42.86%)	14 / 22 (63.64%)
Investigations			
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Nervous system disorders			
Headache			
subjects affected / exposed	2 / 22 (9.09%)	1 / 21 (4.76%)	0 / 22 (0.00%)
occurrences (all)	2	1	0
Dizziness			

subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Injection site reaction			
subjects affected / exposed	4 / 22 (18.18%)	0 / 21 (0.00%)	0 / 22 (0.00%)
occurrences (all)	7	0	0
Fatigue			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Injection site erythema			
subjects affected / exposed	0 / 22 (0.00%)	1 / 21 (4.76%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	1 / 22 (4.55%)	0 / 21 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
tooth ache			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Abdominal pain upper			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	2 / 22 (9.09%)
occurrences (all)	0	0	2
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Psoriasis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	2 / 22 (9.09%)
occurrences (all)	0	0	2

Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	2 / 22 (9.09%)
occurrences (all)	0	0	2
Back pain			
subjects affected / exposed	1 / 22 (4.55%)	1 / 21 (4.76%)	0 / 22 (0.00%)
occurrences (all)	1	1	0
Muscle tightness			
subjects affected / exposed	2 / 22 (9.09%)	0 / 21 (0.00%)	0 / 22 (0.00%)
occurrences (all)	2	0	0
Tendonitis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	2 / 22 (9.09%)	8 / 21 (38.10%)	8 / 22 (36.36%)
occurrences (all)	9	12	12
Urinary tract infection			
subjects affected / exposed	1 / 22 (4.55%)	0 / 21 (0.00%)	1 / 22 (4.55%)
occurrences (all)	1	0	1
Oral herpes			
subjects affected / exposed	0 / 22 (0.00%)	1 / 21 (4.76%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Bronchitis			
subjects affected / exposed	1 / 22 (4.55%)	0 / 21 (0.00%)	2 / 22 (9.09%)
occurrences (all)	1	0	2
Gastroenteritis			
subjects affected / exposed	2 / 22 (9.09%)	0 / 21 (0.00%)	0 / 22 (0.00%)
occurrences (all)	2	0	0

Non-serious adverse events	Week 24-52: ABY-035 80 mg - 80/160 mg Q2W - 80/160 mg Q4W/Q8W	Week 24-52: ABY-035 160 mg - 160 mg Q2W/Q4W - 160 mg Q4W/Q8W	Week 24-52: Placebo - 80 mg Q4W - 80 mg Q4W/Q8W
Total subjects affected by non-serious adverse events			
subjects affected / exposed	10 / 21 (47.62%)	11 / 22 (50.00%)	15 / 22 (68.18%)
Investigations			

Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 21 (0.00%)	0 / 22 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Hypertension			
subjects affected / exposed	1 / 21 (4.76%)	0 / 22 (0.00%)	3 / 22 (13.64%)
occurrences (all)	1	0	3
Nervous system disorders			
Headache			
subjects affected / exposed	2 / 21 (9.52%)	2 / 22 (9.09%)	2 / 22 (9.09%)
occurrences (all)	2	2	2
Dizziness			
subjects affected / exposed	0 / 21 (0.00%)	1 / 22 (4.55%)	2 / 22 (9.09%)
occurrences (all)	0	1	2
General disorders and administration site conditions			
Injection site reaction			
subjects affected / exposed	3 / 21 (14.29%)	1 / 22 (4.55%)	3 / 22 (13.64%)
occurrences (all)	4	5	11
Fatigue			
subjects affected / exposed	0 / 21 (0.00%)	0 / 22 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Injection site erythema			
subjects affected / exposed	0 / 21 (0.00%)	0 / 22 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 21 (0.00%)	1 / 22 (4.55%)	0 / 22 (0.00%)
occurrences (all)	0	2	0
tooth ache			
subjects affected / exposed	1 / 21 (4.76%)	0 / 22 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Abdominal pain upper			
subjects affected / exposed	1 / 21 (4.76%)	0 / 22 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Vomiting			

subjects affected / exposed	0 / 21 (0.00%)	0 / 22 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 21 (4.76%)	0 / 22 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	0 / 21 (0.00%)	0 / 22 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Psoriasis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 22 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 21 (0.00%)	2 / 22 (9.09%)	2 / 22 (9.09%)
occurrences (all)	0	2	2
Back pain			
subjects affected / exposed	0 / 21 (0.00%)	0 / 22 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Muscle tightness			
subjects affected / exposed	0 / 21 (0.00%)	0 / 22 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Tendonitis			
subjects affected / exposed	2 / 21 (9.52%)	0 / 22 (0.00%)	0 / 22 (0.00%)
occurrences (all)	2	0	0
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	6 / 21 (28.57%)	8 / 22 (36.36%)	6 / 22 (27.27%)
occurrences (all)	9	8	6
Urinary tract infection			
subjects affected / exposed	0 / 21 (0.00%)	1 / 22 (4.55%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Oral herpes			
subjects affected / exposed	1 / 21 (4.76%)	1 / 22 (4.55%)	0 / 22 (0.00%)
occurrences (all)	3	1	0

Bronchitis			
subjects affected / exposed	0 / 21 (0.00%)	1 / 22 (4.55%)	1 / 22 (4.55%)
occurrences (all)	0	1	1
Gastroenteritis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 22 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1

Non-serious adverse events	Extension period ABY-035	Prolongation of Extension period ABY-035	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	55 / 83 (66.27%)	27 / 68 (39.71%)	
Investigations			
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 83 (0.00%)	1 / 68 (1.47%)	
occurrences (all)	0	1	
Vascular disorders			
Hypertension			
subjects affected / exposed	6 / 83 (7.23%)	1 / 68 (1.47%)	
occurrences (all)	6	1	
Nervous system disorders			
Headache			
subjects affected / exposed	7 / 83 (8.43%)	6 / 68 (8.82%)	
occurrences (all)	11	7	
Dizziness			
subjects affected / exposed	2 / 83 (2.41%)	0 / 68 (0.00%)	
occurrences (all)	3	0	
General disorders and administration site conditions			
Injection site reaction			
subjects affected / exposed	8 / 83 (9.64%)	4 / 68 (5.88%)	
occurrences (all)	44	22	
Fatigue			
subjects affected / exposed	1 / 83 (1.20%)	0 / 68 (0.00%)	
occurrences (all)	1	0	
Injection site erythema			
subjects affected / exposed	0 / 83 (0.00%)	0 / 68 (0.00%)	
occurrences (all)	0	0	
Gastrointestinal disorders			

Diarrhoea			
subjects affected / exposed	1 / 83 (1.20%)	1 / 68 (1.47%)	
occurrences (all)	1	1	
tooth ache			
subjects affected / exposed	0 / 83 (0.00%)	0 / 68 (0.00%)	
occurrences (all)	0	0	
Abdominal pain upper			
subjects affected / exposed	0 / 83 (0.00%)	1 / 68 (1.47%)	
occurrences (all)	0	1	
Vomiting			
subjects affected / exposed	1 / 83 (1.20%)	1 / 68 (1.47%)	
occurrences (all)	1	1	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	5 / 83 (6.02%)	1 / 68 (1.47%)	
occurrences (all)	6	1	
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	1 / 83 (1.20%)	0 / 68 (0.00%)	
occurrences (all)	1	0	
Psoriasis			
subjects affected / exposed	3 / 83 (3.61%)	2 / 68 (2.94%)	
occurrences (all)	3	2	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	3 / 83 (3.61%)	2 / 68 (2.94%)	
occurrences (all)	3	2	
Back pain			
subjects affected / exposed	7 / 83 (8.43%)	4 / 68 (5.88%)	
occurrences (all)	7	6	
Muscle tightness			
subjects affected / exposed	1 / 83 (1.20%)	0 / 68 (0.00%)	
occurrences (all)	1	0	
Tendonitis			
subjects affected / exposed	0 / 83 (0.00%)	0 / 68 (0.00%)	
occurrences (all)	0	0	

Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	36 / 83 (43.37%)	8 / 68 (11.76%)	
occurrences (all)	52	8	
Urinary tract infection			
subjects affected / exposed	2 / 83 (2.41%)	2 / 68 (2.94%)	
occurrences (all)	2	2	
Oral herpes			
subjects affected / exposed	1 / 83 (1.20%)	2 / 68 (2.94%)	
occurrences (all)	1	2	
Bronchitis			
subjects affected / exposed	6 / 83 (7.23%)	1 / 68 (1.47%)	
occurrences (all)	6	1	
Gastroenteritis			
subjects affected / exposed	4 / 83 (4.82%)	0 / 68 (0.00%)	
occurrences (all)	4	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
23 April 2018	The overall aim for this amendment was to clarify items that were not previously explained with sufficient detail for the Investigators; inclusion criteria, several procedural changes and clarification regarding blinded review of data
10 August 2018	The overall aim for this amendment was to clarify inclusion criteria, and procedural changes with regard to re-screening and replacement of dropouts
25 January 2019	The changes of this amendment affected an eligibility criterion of the study, the upper age limit was increased from 65 to 75 years
08 April 2019	The main reason of this amendment was to include an Extension period of 52 weeks after the Core study to obtain long-term efficacy and safety data.
08 May 2020	The main reason for this amendment was to include a 52-week Prolongation of the Extension period after the current Extension period to obtain further data on long-term efficacy / maintenance of treatment effect, tolerability, safety, immunogenicity and PK of ABY-035.
04 December 2020	The main reason for this amendment was to introduce the optimization of dosing regimen during the Extension and Prolongation of Extension periods, unblinding of subjects as well as some procedural changes
08 July 2021	The main reason for this amendment was to introduce premature termination of the Prolongation of Extension period (last subject last dose at Week 124 instead of Week 152)

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported