



Clinical trial results:

A multicenter, randomized, double-blind, parallel group, placebo controlled, Phase 2 study to assess the efficacy and safety of ATX01 (topical amitriptyline hydrochloride 10% and 15% w/w) in comparison to placebo, in cancer survivor adult patients with chemotherapy-induced peripheral neuropathy (CIPN)

Summary

EudraCT number	2022-000435-23
Trial protocol	FR CZ ES BE
Global end of trial date	18 September 2024

Results information

Result version number	v1 (current)
This version publication date	06 April 2025
First version publication date	06 April 2025

Trial information

Trial identification

Sponsor protocol code	ATX01-22-01-CIPN
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	ALGOTHERAPEUTIX SAS
Sponsor organisation address	49 avenue des Nouvelles , Suresnes, France,
Public contact	Philippe Picaut, AlgoTherapeutix, +33 683822424, philippe@algotx.com
Scientific contact	Philippe Picaut, AlgoTherapeutix, +33 683822424, philippe@algotx.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	18 September 2024
Is this the analysis of the primary completion data?	Yes
Primary completion date	18 September 2024
Global end of trial reached?	Yes
Global end of trial date	18 September 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess the efficacy of ATX01 compared to placebo in treating neuropathic pain in target study extremities in patients with CIPN.

Protection of trial subjects:

Subjects recorded daily their pain levels which were regularly monitored by site personnel.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	09 December 2022
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Poland: 23
Country: Number of subjects enrolled	Spain: 72
Country: Number of subjects enrolled	Belgium: 24
Country: Number of subjects enrolled	Czechia: 19
Country: Number of subjects enrolled	France: 34
Country: Number of subjects enrolled	Italy: 32
Country: Number of subjects enrolled	United States: 69
Worldwide total number of subjects	273
EEA total number of subjects	204

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)	164
From 65 to 84 years	109
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

395 patients were screened according to the inclusion and exclusion criteria defined in the protocol. 119 patients were screen failed and 276 patients were randomized with 3 patients never receiving the treatment (273 patients evaluable).

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description: -

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Gel
Routes of administration	Topical

Dosage and administration details:

Twice a day for 12 weeks on hands and/or feet

Arm title	ATX01 15%
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Arm description: -

Arm type	Experimental
Investigational medicinal product name	ATX01 15%
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Gel
Routes of administration	Topical

Dosage and administration details:

Twice a day for 12 weeks on hands and/or feet

Arm title	ATX01 10%
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Arm description: -

Arm type	Experimental
Investigational medicinal product name	ATX01 10%
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Gel
Routes of administration	Topical

Dosage and administration details:

Twice a day for 12 weeks on hands and/or feet

Number of subjects in period 1	Placebo	ATX01 15%	ATX01 10%
Started	89	92	92
Completed	78	79	76
Not completed	11	13	16
Physician decision	1	-	-
Consent withdrawn by subject	6	8	9
Adverse event, non-fatal	4	4	7
Protocol deviation	-	1	-

Baseline characteristics

Reporting groups

Reporting group title	Overall
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Reporting group description: -

Reporting group values	Overall	Total	
Number of subjects	273	273	
Age categorical			
Units: Subjects			
Adults (18-64 years)	164	164	
From 65-84 years	109	109	
Gender categorical			
Units: Subjects			
Female	192	192	
Male	81	81	

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description: -	
Reporting group title	ATX01 15%
Reporting group description: -	
Reporting group title	ATX01 10%
Reporting group description: -	
Subject analysis set title	FAS
Subject analysis set type	Full analysis
Subject analysis set description:	
The Full Analysis Set (FAS) is defined as all randomized patients who applied any amount of study drug and had both a weekly average NPRS derived at Baseline and at least 1 post-baseline 24-hour average pain intensity assessment (i.e. one NPRS diary entry).	

Primary: Change from baseline to Week 12 in the weekly mean of the daily NPRS score assessing average pain intensity in target study extremities related to CIPN in the past 24 hours.

End point title	Change from baseline to Week 12 in the weekly mean of the daily NPRS score assessing average pain intensity in target study extremities related to CIPN in the past 24 hours.
End point description:	
End point type	Primary
End point timeframe:	
Reported daily from baseline to Week 12	

End point values	Placebo	ATX01 15%	ATX01 10%	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	75	74	73	
Units: Not applicable				
arithmetic mean (standard deviation)	-1.55 (± 1.581)	-1.61 (± 1.713)	-1.50 (± 1.560)	

Statistical analyses

Statistical analysis title	Full analysis set
Comparison groups	ATX01 10% v Placebo
Number of subjects included in analysis	148
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.83
Method	ANCOVA

Statistical analysis title	Full analysis set
Comparison groups	Placebo v ATX01 15%
Number of subjects included in analysis	149
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.78
Method	ANCOVA

Secondary: Percentage of patients achieving $\geq 30\%$ pain reduction from baseline in the weekly mean NPRS average pain intensity related to CIPN at Week 12.

End point title	Percentage of patients achieving $\geq 30\%$ pain reduction from baseline in the weekly mean NPRS average pain intensity related to CIPN at Week 12.
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End point description:

End point type	Secondary
End point timeframe:	
Baseline to Week 12	

End point values	Placebo	ATX01 15%	ATX01 10%	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	89	91	92	
Units: Not applicable				
arithmetic mean (standard deviation)	33 ($\pm$ 44)	33 ($\pm$ 45)	27 ($\pm$ 37)	

Statistical analyses

Statistical analysis title	Full analysis set
Comparison groups	Placebo v ATX01 10%
Number of subjects included in analysis	181
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.39
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Full analysis set
Comparison groups	Placebo v ATX01 15%

Number of subjects included in analysis	180
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.92
Method	Cochran-Mantel-Haenszel

Secondary: Percentage of patients achieving $\geq 50\%$ pain reduction from baseline in the weekly mean NPRS average pain intensity related to CIPN at Week 12.

End point title	Percentage of patients achieving $\geq 50\%$ pain reduction from baseline in the weekly mean NPRS average pain intensity related to CIPN at Week 12.
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End point description:

End point type	Secondary
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End point timeframe:

Baseline to Week 12

End point values	Placebo	ATX01 15%	ATX01 10%	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	89	91	92	
Units: Not applicable				
arithmetic mean (standard deviation)	18 ($\pm$ 24)	16 ($\pm$ 22)	13 ($\pm$ 18)	

Statistical analyses

Statistical analysis title	Full analysis set
Comparison groups	Placebo v ATX01 10%
Number of subjects included in analysis	181
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.42
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Full analysis set
Comparison groups	Placebo v ATX01 15%
Number of subjects included in analysis	180
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.76
Method	Cochran-Mantel-Haenszel

Secondary: Mean change from baseline to Week 12 in tingling/pins and needles intensity in target study extremities as measured by the numerical rating scale (NRS) assessing each symptom.

End point title	Mean change from baseline to Week 12 in tingling/pins and needles intensity in target study extremities as measured by the numerical rating scale (NRS) assessing each symptom.
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End point description:

End point type	Secondary
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End point timeframe:

Baseline to Week 12

End point values	Placebo	ATX01 15%	ATX01 10%	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	51	51	46	
Units: Not applicable				
arithmetic mean (standard deviation)	-1.7 ($\pm$ 2.03)	-1.7 ($\pm$ 1.88)	-1.5 ($\pm$ 1.82)	

Statistical analyses

Statistical analysis title	Full analysis set
Comparison groups	Placebo v ATX01 10%
Number of subjects included in analysis	97
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.45
Method	ANCOVA

Statistical analysis title	Full analysis set
Comparison groups	Placebo v ATX01 15%
Number of subjects included in analysis	102
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.72
Method	ANCOVA

Secondary: Change from baseline to Week 4 in the weekly mean of the daily NPRS score assessing average pain intensity in target study extremities related to CIPN in

the past 24 hours.

End point title	Change from baseline to Week 4 in the weekly mean of the daily NPRS score assessing average pain intensity in target study extremities related to CIPN in the past 24 hours.
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End point description:

End point type	Secondary
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End point timeframe:

Baseline to Week 4

End point values	Placebo	ATX01 15%	ATX01 10%	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	84	89	86	
Units: Not applicable				
arithmetic mean (standard deviation)	-0.92 (± 1.281)	-0.93 (± 1.204)	-0.84 (± 1.168)	

Statistical analyses

Statistical analysis title	Full analysis set
Comparison groups	Placebo v ATX01 15%
Number of subjects included in analysis	173
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.98
Method	ANCOVA

Statistical analysis title	Full analysis set
Comparison groups	Placebo v ATX01 10%
Number of subjects included in analysis	170
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.68
Method	ANCOVA

Secondary: Change from baseline to Week 8 in the weekly mean of the daily NPRS score assessing average pain intensity in target study extremities related to CIPN in the past 24 hours.

End point title	Change from baseline to Week 8 in the weekly mean of the daily NPRS score assessing average pain intensity in target study extremities related to CIPN in the past 24 hours.
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End point description:

End point type	Secondary
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End point timeframe:

Baseline to week 8

End point values	Placebo	ATX01 15%	ATX01 10%	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	81	82	78	
Units: not applicable				
arithmetic mean (standard deviation)	-1.17 (± 1.575)	-1.17 (± 1.51)	-1.18 (± 1.336)	

Statistical analyses

Statistical analysis title	Full analysis set
Comparison groups	Placebo v ATX01 10%
Number of subjects included in analysis	159
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.89
Method	ANCOVA

Statistical analysis title	Full analysis set
Comparison groups	Placebo v ATX01 15%
Number of subjects included in analysis	163
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.91
Method	ANCOVA

Secondary: Number of patients with at least “improved” on the Patient Global Impression of Change at week 4.

End point title	Number of patients with at least “improved” on the Patient Global Impression of Change at week 4.
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End point description:

End point type	Secondary
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End point timeframe:

Week 4

End point values	Placebo	ATX01 15%	ATX01 10%	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	75	82	78	
Units: number of patients	37	52	33	

Statistical analyses

Statistical analysis title	Full analysis set
Comparison groups	Placebo v ATX01 10%
Number of subjects included in analysis	153
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.4
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Full analysis set
Comparison groups	Placebo v ATX01 15%
Number of subjects included in analysis	157
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.07
Method	Cochran-Mantel-Haenszel

Secondary: Number of patients with at least "improved" on the Patient Global Impression of Change at week 8

End point title	Number of patients with at least "improved" on the Patient Global Impression of Change at week 8
End point description:	
End point type	Secondary
End point timeframe:	
Week 8	

End point values	Placebo	ATX01 15%	ATX01 10%	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	73	74	70	
Units: Number of patients	38	44	36	

Statistical analyses

Statistical analysis title	Full analysis set
Comparison groups	Placebo v ATX01 10%
Number of subjects included in analysis	143
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.97
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Full analysis set
Comparison groups	Placebo v ATX01 15%
Number of subjects included in analysis	147
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.36
Method	Cochran-Mantel-Haenszel

Secondary: Number of patients with at least "improved" on the Patient Global Impression of Change at week 12

End point title	Number of patients with at least "improved" on the Patient Global Impression of Change at week 12
End point description:	
End point type	Secondary
End point timeframe:	
Week 12	

End point values	Placebo	ATX01 15%	ATX01 10%	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	65	64	58	
Units: Number of patients	39	45	35	

Statistical analyses

Statistical analysis title	Full analysis set
Comparison groups	Placebo v ATX01 10%
Number of subjects included in analysis	123
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.99
Method	Cochran-Mantel-Haenszel

Statistical analysis title	Full analysis set
Comparison groups	Placebo v ATX01 15%
Number of subjects included in analysis	129
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.22
Method	Cochran-Mantel-Haenszel

Secondary: Mean change from baseline to Week 4 in pain interference with daily life using the Brief Pain Inventory-Short Form questionnaire (item 9 only).

End point title	Mean change from baseline to Week 4 in pain interference with daily life using the Brief Pain Inventory-Short Form questionnaire (item 9 only).
End point description:	
End point type	Secondary
End point timeframe:	
Baseline to Week 4	

End point values	Placebo	ATX01 15%	ATX01 10%	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	87	84	88	
Units: not applicable				
arithmetic mean (standard deviation)	-0.97 (± 1.69)	-0.99 (± 2.26)	-0.96 (± 2.12)	

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline to week 8 in pain interference with daily life using the Brief Pain Inventory-Short Form questionnaire (item 9 only).

End point title	Mean change from baseline to week 8 in pain interference with
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daily life using the Brief Pain Inventory-Short Form questionnaire (item 9 only).

End point description:

End point type Secondary

End point timeframe:

Baseline to week 8

End point values	Placebo	ATX01 15%	ATX01 10%	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	82	82	78	
Units: not applicable				
arithmetic mean (standard deviation)	-1.08 ($\pm$ 1.96)	-1.42 ($\pm$ 1.913)	-1.12 ($\pm$ 2.22)	

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline to week 12 in pain interference with daily life using the Brief Pain Inventory-Short Form questionnaire (item 9 only).

End point title Mean change from baseline to week 12 in pain interference with daily life using the Brief Pain Inventory-Short Form questionnaire (item 9 only).

End point description:

End point type Secondary

End point timeframe:

Baseline to week 12

End point values	Placebo	ATX01 15%	ATX01 10%	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	79	78	72	
Units: not applicable				
arithmetic mean (standard deviation)	-1.25 ($\pm$ 2.26)	-1.81 ($\pm$ 1.97)	-1.30 ($\pm$ 2.04)	

Statistical analyses

Statistical analysis title Full analysis set

Comparison groups Placebo v ATX01 10%

Number of subjects included in analysis	151
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.88
Method	ANCOVA

Statistical analysis title	Full analysis set
Comparison groups	Placebo v ATX01 15%
Number of subjects included in analysis	157
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.07
Method	ANCOVA

Secondary: Mean change from baseline to Week 12 in the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-CIPN 20-item scale (EORTC-QLQ-CIPN20).

End point title	Mean change from baseline to Week 12 in the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-CIPN 20-item scale (EORTC-QLQ-CIPN20).
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End point description:

End point type	Secondary
End point timeframe:	Baseline to Week 12

End point values	Placebo	ATX01 15%	ATX01 10%	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	79	78	73	
Units: not applicable				
arithmetic mean (standard deviation)	-5.06 (± 8.28)	-7.40 (± 8.38)	-5.51 (± 8.44)	

Statistical analyses

Statistical analysis title	Full analysis set
Comparison groups	Placebo v ATX01 10%

Number of subjects included in analysis	152
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.74
Method	ANCOVA

Statistical analysis title	Full analysis set
Comparison groups	Placebo v ATX01 15%
Number of subjects included in analysis	157
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.16
Method	ANCOVA

Secondary: Mean change from baseline to Week 12 in numbness intensity in target study extremities as measured by the numerical rating scale (NRS) assessing each symptom.

End point title	Mean change from baseline to Week 12 in numbness intensity in target study extremities as measured by the numerical rating scale (NRS) assessing each symptom.
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End point description:

End point type	Secondary
End point timeframe:	Baseline to Week 12

End point values	Placebo	ATX01 15%	ATX01 10%	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	51	55	49	
Units: not applicable				
arithmetic mean (standard deviation)	-1.4 (± 1.88)	-1.6 (± 2.07)	-1.5 (± 1.77)	

Statistical analyses

Statistical analysis title	Full analysis set
Comparison groups	Placebo v ATX01 15%

Number of subjects included in analysis	106
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.62
Method	ANCOVA

Statistical analysis title	Full analysis set
Comparison groups	Placebo v ATX01 10%
Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.85
Method	ANCOVA

Other pre-specified: Mean change from baseline to Week 12 in Total Neuropathy Score-nurse version (TNSn) total score.

End point title	Mean change from baseline to Week 12 in Total Neuropathy Score-nurse version (TNSn) total score.
End point description:	
End point type	Other pre-specified
End point timeframe:	
Baseline to Week 12	

End point values	Placebo	ATX01 15%	ATX01 10%	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	61	63	57	
Units: not applicable				
arithmetic mean (standard deviation)	-1.57 (± 2.6)	-1.57 (± 2.75)	-1.19 (± 2.64)	

Statistical analyses

Statistical analysis title	Full analysis set
Comparison groups	Placebo v ATX01 10%
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.4
Method	ANCOVA

Statistical analysis title	Full analysis set
Comparison groups	Placebo v ATX01 15%
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.76
Method	ANCOVA

Other pre-specified: Incidence of treatment-emergent adverse events (TEAEs), serious adverse events (SAEs), adverse events (AEs) (or SAEs) leading to discontinuations.

End point title	Incidence of treatment-emergent adverse events (TEAEs), serious adverse events (SAEs), adverse events (AEs) (or SAEs) leading to discontinuations.
End point description:	
End point type	Other pre-specified
End point timeframe:	
Overall study duration	

End point values	Placebo	ATX01 15%	ATX01 10%	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	89	92	92	
Units: number of patients	4	4	7	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Screening to Week 13

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	27
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Reporting groups

Reporting group title	Placebo
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Reporting group description: -

Reporting group title	ATX01 15%
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Reporting group description: -

Reporting group title	ATX01 10%
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Reporting group description: -

Serious adverse events	Placebo	ATX01 15%	ATX01 10%
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 89 (3.37%)	1 / 92 (1.09%)	2 / 92 (2.17%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Metastases to peritoneum			
subjects affected / exposed	0 / 89 (0.00%)	1 / 92 (1.09%)	0 / 92 (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
Metastases to central nervous system			
subjects affected / exposed	0 / 89 (0.00%)	0 / 92 (0.00%)	1 / 92 (1.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenocarcinoma of colon			
subjects affected / exposed	1 / 89 (1.12%)	0 / 92 (0.00%)	0 / 92 (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
General disorders and administration site conditions			

Pyrexia			
subjects affected / exposed	1 / 89 (1.12%)	0 / 92 (0.00%)	0 / 92 (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
Gastrointestinal disorders			
Intestinal obstruction			
subjects affected / exposed	0 / 89 (0.00%)	0 / 92 (0.00%)	1 / 92 (1.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Peritonitis			
subjects affected / exposed	1 / 89 (1.12%)	0 / 92 (0.00%)	0 / 92 (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

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

Non-serious adverse events	Placebo	ATX01 15%	ATX01 10%
Total subjects affected by non-serious adverse events			
subjects affected / exposed	14 / 89 (15.73%)	20 / 92 (21.74%)	15 / 92 (16.30%)
General disorders and administration site conditions			
Application site erythema			
subjects affected / exposed	10 / 89 (11.24%)	11 / 92 (11.96%)	6 / 92 (6.52%)
occurrences (all)	13	13	8
Application site dryness			
subjects affected / exposed	0 / 89 (0.00%)	6 / 92 (6.52%)	7 / 92 (7.61%)
occurrences (all)	0	7	7
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	4 / 89 (4.49%)	3 / 92 (3.26%)	2 / 92 (2.17%)
occurrences (all)	5	3	2

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
06 March 2023	Modified inclusion and exclusion criteria to aid in recruitment of patients. Provided some clarifications on the study conduct.
12 July 2023	Removed the subset of 45 patients (15 per group) for extended PK assessment (12+hours) and added additional PK samples for all patients. Plus, a few modifications of the inclusion and exclusion criteria for easier recruitment.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported