



Clinical trial results:

An Open-Label Extension (OLE) Study to Evaluate the Efficacy and Safety of Nefecon Treatment in Patients With IgA Nephropathy Who Have Completed Study Nef-301

Summary

EudraCT number	2020-003308-14
Trial protocol	CZ SE PL BE FR GB GR FI IT
Global end of trial date	24 April 2024

Results information

Result version number	v1 (current)
This version publication date	25 December 2024
First version publication date	25 December 2024

Trial information

Trial identification

Sponsor protocol code	Nef-301OLE
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04541043
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Calliditas Therapeutics AB
Sponsor organisation address	Kungsbron 1, D5, Stockholm, Sweden, 111 22
Public contact	Clinical Operations, Calliditas Therapeutics AB, +46 737456451, kristin.onnestam@calliditas.com
Scientific contact	Clinical Operations, Calliditas Therapeutics AB, +46 737456451, kristin.onnestam@calliditas.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	26 February 2024
Is this the analysis of the primary completion data?	Yes
Primary completion date	26 February 2024
Global end of trial reached?	Yes
Global end of trial date	24 April 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

- To assess the effect of 9 months of retreatment with Nefecon on urine protein to creatinine ratio (UPCR) and estimated glomerular filtration rate (eGFR) in patients who completed Study Nef 301 with Nefecon treatment; and
- To assess the effect of 9 months of treatment with Nefecon on UPCR and eGFR in patients who completed Study Nef-301 with placebo treatment.

Protection of trial subjects:

Open label study, all study patients received Nefecon 16 mg daily for 9 months. Regular visits to the study site with safety assessments. Possible to reduce dose at the discretion of the Investigator if warranted due to side effects.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	14 November 2020
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	Australia: 9
Country: Number of subjects enrolled	Argentina: 9
Country: Number of subjects enrolled	Belarus: 2
Country: Number of subjects enrolled	Canada: 14
Country: Number of subjects enrolled	Korea, Democratic People's Republic of: 6
Country: Number of subjects enrolled	Türkiye: 2
Country: Number of subjects enrolled	United States: 11
Country: Number of subjects enrolled	Poland: 3
Country: Number of subjects enrolled	Spain: 2
Country: Number of subjects enrolled	Sweden: 3
Country: Number of subjects enrolled	United Kingdom: 6
Country: Number of subjects enrolled	Belgium: 7
Country: Number of subjects enrolled	Czechia: 15
Country: Number of subjects enrolled	Finland: 4
Country: Number of subjects enrolled	France: 4
Country: Number of subjects enrolled	Germany: 11
Country: Number of subjects enrolled	Greece: 8

Country: Number of subjects enrolled	Italy: 3
Worldwide total number of subjects	119
EEA total number of subjects	60

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)	116
From 65 to 84 years	3
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Study participants completing the Nef-301 study and fulfilling inclusion/exclusion criteria for the Nef-301-OLE study were invited to be seamlessly enrolled in this open label study where all study participants received treatment with 16 mg Nefecon daily treatment for 9 months.

Pre-assignment

Screening details:

Study participants completing the Nef-301 study and fulfilling inclusion/exclusion criteria for the Nef-301-OLE study were invited to be seamlessly enrolled in this open label study where all study participants received treatment with 16 mg Nefecon daily treatment for 9 months.

Period 1

Period 1 title	Nefecon 16mg daily (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Blinding implementation details:

Not applicable. Open label study.

Arms

Arm title	Nefecon 16mg daily
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Arm description:

Nefecon 16 mg once daily for 9 months and 3 months follow-up (total study duration 12 months).

Arm type	Experimental
Investigational medicinal product name	Nefecon
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Nefecon 16 mg once daily by mouth for 9 months. Capsules to be swallowed whole.

Number of subjects in period 1	Nefecon 16mg daily
Started	119
Completed	113
Not completed	6
Consent withdrawn by subject	3
Not specified	2
Sponsor decision	1

Baseline characteristics

Reporting groups

Reporting group title	Nefecon 16mg daily
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Reporting group description: -

Reporting group values	Nefecon 16mg daily	Total	
Number of subjects	119	119	
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)	116	116	
From 65-84 years	3	3	
85 years and over	0	0	
Age continuous			
Units: years			
arithmetic mean	45.5		
standard deviation	± 9.82	-	
Gender categorical			
Units: Subjects			
Female	25	25	
Male	94	94	

Subject analysis sets

Subject analysis set title	Retreatment - Previously Treated With Nefecon in Nef-301 Study
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Subject analysis set type	Full analysis
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Subject analysis set description:

Nef-301-OLE study is an extension study to the Nef-301 study. Study results are analyzed based on treatment in the previous Nef-301 study where patients were randomized to receive either Nefecon or Placebo. Thus, in this Nef-301-OLE study the patients are either retreated with Nefecon or receiving Nefecon for the first time

Subject analysis set title	Delayed Treatment - Previously Treated With Placebo in Nef-301
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Subject analysis set type	Full analysis
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Subject analysis set description:

Nef-301-OLE study is an extension study to the Nef-301 study. Study results are analyzed based on treatment in the previous Nef-301 study where patients were randomized to receive either Nefecon or Placebo. Thus, in this Nef-301-OLE study the patients are either retreated with Nefecon or receiving Nefecon for the first time.

Reporting group values	Retreatment - Previously Treated With Nefecon in Nef- 301 Study	Delayed Treatment - Previously Treated With Placebo in Nef- 301	
Number of subjects	45	74	
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)	43	73	
From 65-84 years	2	1	
85 years and over	0	0	
Age continuous			
Units: years			
arithmetic mean	46.7	44.8	
standard deviation	± 9.21	± 10.16	
Gender categorical			
Units: Subjects			
Female	6	19	
Male	39	55	

End points

End points reporting groups

Reporting group title	Nefecon 16mg daily
Reporting group description: Nefecon 16 mg once daily for 9 months and 3 months follow-up (total study duration 12 months).	
Subject analysis set title	Retreatment - Previously Treated With Nefecon in Nef-301 Study
Subject analysis set type	Full analysis
Subject analysis set description: Nef-301-OLE study is an extension study to the Nef-301 study. Study results are analyzed based on treatment in the previous Nef-301 study where patients were randomized to receive either Nefecon or Placebo. Thus, in this Nef-301-OLE study the patients are either retreated with Nefecon or receiving Nefecon for the first time	
Subject analysis set title	Delayed Treatment - Previously Treated With Placebo in Nef-301
Subject analysis set type	Full analysis
Subject analysis set description: Nef-301-OLE study is an extension study to the Nef-301 study. Study results are analyzed based on treatment in the previous Nef-301 study where patients were randomized to receive either Nefecon or Placebo. Thus, in this Nef-301-OLE study the patients are either retreated with Nefecon or receiving Nefecon for the first time.	

Primary: Ratio of Urine Protein to Creatine Ratio (UPCR) at 9 Months Compared to Baseline

End point title	Ratio of Urine Protein to Creatine Ratio (UPCR) at 9 Months Compared to Baseline ^[1]
End point description: These results are from the MMRM analysis. Log-transformed post-baseline to baseline ratios at month 3, 6, 9, and 12 are analyzed using MMRM with Nef-301 treatment, visit, Nef-301 treatment by visit interaction as fixed factors; and log-baseline and log-baseline by visit interaction as covariates; and patient as a random effect. An unstructured covariance matrix is used to model the within-subject correlation of data. The Kenward-Roger's degrees-of-freedom adjustment is used. Geometric least squares (LS) means, ratio of geometric LS means, and 95% confidence intervals (CIs) are transformed back into the original scale from MMRM estimates.	
End point type	Primary
End point timeframe: 9 months	

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: There is no statistical comparison of groups since open-label single arm study. The presented results are from the MMRM analysis. Log-transformed post-baseline to baseline ratios at month 3, 6, 9, and 12 are analyzed using MMRM with Nef-301 treatment, visit, Nef-301 treatment by visit interaction as fixed factors; and log-baseline and log-baseline by visit interaction as covariates; and patient as a random effect.

End point values	Retreatment - Previously Treated With Nefecon in Nef-301 Study	Delayed Treatment - Previously Treated With Placebo in Nef-301		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	44	69		
Units: Ratio				

least squares mean (confidence interval 95%)	0.67 (0.56 to 0.80)	0.69 (0.60 to 0.80)		
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Statistical analyses

No statistical analyses for this end point

Secondary: Ratio of Estimated Glomerular Filtration Rate (eGFR) at 9 Months Compared to Baseline

End point title	Ratio of Estimated Glomerular Filtration Rate (eGFR) at 9 Months Compared to Baseline
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End point description:

eGFR is calculated by the central laboratory using the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) formula.

To handle missing data, multiple imputation (MI) is performed with 20 imputations in two steps: non-monotone followed by monotone missing pattern. MI is based on log-transformed baseline, log-transformed post-baseline at month 3, 6, 9, and 12. For

each imputation dataset, ratio of eGFR at each post-baseline visit to baseline is analyzed using Robust Regression with

independent variables of Nef-301 treatment and log-transformed baseline eGFR. M-estimation is used with Huber weights and a cut-off value of 2 with the median method used to estimate the scale parameter. Results averaged over imputations using Rubin's

rules. Estimated means, ratio of estimated geometric means, and 95% confidence intervals (CIs) are transformed back into the original scale from M-estimates.

End point type	Secondary
End point timeframe:	9 months

End point values	Retreatment - Previously Treated With Nefecon in Nef-301 Study	Delayed Treatment - Previously Treated With Placebo in Nef-301		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	44	69		
Units: Ratio				
least squares mean (confidence interval 95%)	0.97 (0.94 to 1.01)	0.97 (0.94 to 1.00)		

Statistical analyses

No statistical analyses for this end point

Secondary: Ratio of Urine Albumin to Creatinine Ratio (UACR) at 9 Months Compared to Baseline

End point title	Ratio of Urine Albumin to Creatinine Ratio (UACR) at 9 Months Compared to Baseline
End point description: Log-transformed post-baseline to baseline ratios at month 3, 6, 9, and 12 are analyzed using MMRM with Nef-301 treatment, visit, Nef-301 treatment by visit interaction as fixed factors; and log-baseline and log-baseline by visit interaction as covariates; and patient as a random effect. An unstructured covariance matrix is used to model the within-subject correlation of data. The Kenward-Roger's degrees-of-freedom adjustment is used. Geometric least squares (LS) means, ratio of geometric LS means, and 95% confidence intervals (CIs) are transformed back into the original scale from MMRM estimates.	
End point type	Secondary
End point timeframe: 9 months	

End point values	Retreatment - Previously Treated With Nefecon in Nef-301 Study	Delayed Treatment - Previously Treated With Placebo in Nef-301		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	44	69		
Units: Ratio				
least squares mean (confidence interval 95%)	0.60 (0.49 to 0.75)	0.65 (0.55 to 0.77)		

Statistical analyses

No statistical analyses for this end point

Secondary: Short Form 36 (SF-36) Quality of Life Assessment at 12 Months Compared to Baseline

End point title	Short Form 36 (SF-36) Quality of Life Assessment at 12 Months Compared to Baseline
End point description: Short Form 36 (SF-36) quality of life assessment at 12 months compared to baseline. The 36-item short form health survey (SF-36) is a set of generic, coherent, and easily administered quality-of-life measures. These measures rely upon patient self-reporting. It consists of eight health concepts: physical functioning, bodily pain, role limitations due to physical health problems, role limitations due to personal or emotional problems, emotional well-being, social functioning, energy/fatigue, and general health perceptions. Higher score indicates better health. Score represent the percentage of total possible score achieved.	
End point type	Secondary
End point timeframe: 12 months	

End point values	Retreatment - Previously Treated With Nefecon in Nef-301 Study	Delayed Treatment - Previously Treated With Placebo in Nef-301		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	44	70		
Units: Score				
arithmetic mean (standard deviation)				
Bodily Pain	-4.518 (\pm 10.0522)	-3.756 (\pm 9.9213)		
General Health	-4.290 (\pm 7.4076)	-3.301 (\pm 5.8211)		
Mental Component Summary	-2.282 (\pm 7.1270)	-1.061 (\pm 6.6251)		
Mental Health	-1.725 (\pm 7.1576)	-1.570 (\pm 6.3522)		
Physical Component Summary	-3.952 (\pm 6.6367)	-3.403 (\pm 6.1115)		
Physical Functioning	-2.697 (\pm 7.4670)	-1.996 (\pm 6.6726)		
Role Emotional	-2.928 (\pm 7.2390)	-0.747 (\pm 7.4962)		
Role Physical	-3.421 (\pm 7.1914)	-2.793 (\pm 7.6901)		
Social Function	-4.102 (\pm 8.4631)	-2.364 (\pm 6.3713)		
Vitality	-2.633 (\pm 7.6406)	-2.376 (\pm 7.6968)		

Statistical analyses

No statistical analyses for this end point

Secondary: Proportion of Patients With Microhematuria at 9 Months Compared to Baseline

End point title	Proportion of Patients With Microhematuria at 9 Months Compared to Baseline
End point description:	
Patients with microhematuria at baseline is defined as patients' urine dipstick result returns a valid result excluding any of the following results at the last visit prior to first dose of OLE study drug: negative, trace, or 0.03 mg/dL.	
Patients with microhematuria at specified post-baseline visit is defined as patients' urine dipstick result returns a valid result excluding any of the following results during the corresponding visit window: negative, trace, or 0.03 mg/dL.	
End point type	Secondary
End point timeframe:	
9 months	

End point values	Retreatment - Previously Treated With Nefecon in Nef-301 Study	Delayed Treatment - Previously Treated With Placebo in Nef-301		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	45	74		
Units: Participants	11	17		

Statistical analyses

No statistical analyses for this end point

Secondary: Proportion of Patients Receiving Rescue Treatment

End point title	Proportion of Patients Receiving Rescue Treatment
End point description:	
End point type	Secondary
End point timeframe:	
12 months	

End point values	Retreatment - Previously Treated With Nefecon in Nef-301 Study	Delayed Treatment - Previously Treated With Placebo in Nef-301		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	45	74		
Units: Participants	1	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Proportion of Patients on Dialysis, Undergoing Kidney Transplantation, or With eGFR <15 mL/Min Per 1.73 m2

End point title	Proportion of Patients on Dialysis, Undergoing Kidney Transplantation, or With eGFR <15 mL/Min Per 1.73 m2
End point description:	
End point type	Secondary
End point timeframe:	
12 months	

End point values	Retreatment - Previously Treated With Nefecon in Nef-301 Study	Delayed Treatment - Previously Treated With Placebo in Nef-301		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	45	74		
Units: Participants	2	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Cortisol Suppression at 9 Months Compared to Baseline

End point title	Cortisol Suppression at 9 Months Compared to Baseline
End point description:	
End point type	Secondary
End point timeframe:	
9 months	

End point values	Retreatment - Previously Treated With Nefecon in Nef-301 Study	Delayed Treatment - Previously Treated With Placebo in Nef-301		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	44	66		
Units: ug/day				
arithmetic mean (standard deviation)	-24.122 (\pm 25.1690)	-32.126 (\pm 30.6978)		

Statistical analyses

No statistical analyses for this end point

Secondary: Cortisol Suppression at 12 Months Compared to Baseline

End point title	Cortisol Suppression at 12 Months Compared to Baseline
End point description:	
End point type	Secondary

End point timeframe:

12 months

End point values	Retreatment - Previously Treated With Nefecon in Nef- 301 Study	Delayed Treatment - Previously Treated With Placebo in Nef- 301		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	41	63		
Units: ug/day				
arithmetic mean (standard deviation)	-7.660 (± 27.4262)	-11.954 (± 25.8052)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

All SAEs are reported from date of informed consent until end of study (approximately 13 months). Non-serious AEs are reported from date of first dose of study treatment to 14 days after the last dose of study treatment (approximately 10 months).

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	22.0
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Reporting groups

Reporting group title	Retreatment - Previously Treated With Nefecon in Nef-301 Study
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Reporting group description:

Nef-301-OLE study is an extension study to the Nef-301 study. Study results are analyzed based on treatment in the previous Nef-301 study where patients were randomized to receive either Nefecon or Placebo. Thus, in this Nef-301-OLE study the patients are either retreated with Nefecon or receiving Nefecon for the first time.

Reporting group title	Delayed Treatment - Previously Treated With Placebo in Nef-301
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Reporting group description:

Nef-301-OLE study is an extension study to the Nef-301 study. Study results are analyzed based on treatment in the previous Nef-301 study where patients were randomized to receive either Nefecon or Placebo. Thus, in this Nef-301-OLE study the patients are either retreated with Nefecon or receiving Nefecon for the first time.

Serious adverse events	Retreatment - Previously Treated With Nefecon in Nef-301 Study	Delayed Treatment - Previously Treated With Placebo in Nef-301	
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 45 (11.11%)	5 / 74 (6.76%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Breast cancer			
subjects affected / exposed	0 / 45 (0.00%)	1 / 74 (1.35%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Joint dislocation			
subjects affected / exposed	1 / 45 (2.22%)	0 / 74 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Scapula fracture			
subjects affected / exposed	0 / 45 (0.00%)	1 / 74 (1.35%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	1 / 45 (2.22%)	0 / 74 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Central nervous system vasculitis			
subjects affected / exposed	1 / 45 (2.22%)	0 / 74 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Headache			
subjects affected / exposed	0 / 45 (0.00%)	1 / 74 (1.35%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Lymphadenopathy			
subjects affected / exposed	1 / 45 (2.22%)	0 / 74 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Monoclonal B-cell lymphocytosis			
subjects affected / exposed	0 / 45 (0.00%)	1 / 74 (1.35%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Chorioretinopathy			
subjects affected / exposed	0 / 45 (0.00%)	1 / 74 (1.35%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Vomiting			

subjects affected / exposed	0 / 45 (0.00%)	1 / 74 (1.35%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Haematuria			
subjects affected / exposed	1 / 45 (2.22%)	0 / 74 (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 / 45 (2.22%)	0 / 74 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Retreatment - Previously Treated With Nefecon in Nef- 301 Study	Delayed Treatment - Previously Treated With Placebo in Nef- 301	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	40 / 45 (88.89%)	60 / 74 (81.08%)	
Investigations			
Weight increased			
subjects affected / exposed	3 / 45 (6.67%)	8 / 74 (10.81%)	
occurrences (all)	3	8	
Vascular disorders			
Hypertension			
subjects affected / exposed	8 / 45 (17.78%)	12 / 74 (16.22%)	
occurrences (all)	9	13	
Nervous system disorders			
Headache			
subjects affected / exposed	4 / 45 (8.89%)	3 / 74 (4.05%)	
occurrences (all)	6	3	
General disorders and administration site conditions			
Oedema peripheral			

subjects affected / exposed occurrences (all)	1 / 45 (2.22%) 1	10 / 74 (13.51%) 12	
Fatigue subjects affected / exposed occurrences (all)	4 / 45 (8.89%) 4	2 / 74 (2.70%) 2	
Pyrexia subjects affected / exposed occurrences (all)	0 / 45 (0.00%) 0	4 / 74 (5.41%) 4	
Gastrointestinal disorders Nausea subjects affected / exposed occurrences (all)	3 / 45 (6.67%) 3	2 / 74 (2.70%) 3	
Skin and subcutaneous tissue disorders Acne subjects affected / exposed occurrences (all)	3 / 45 (6.67%) 4	6 / 74 (8.11%) 7	
Psychiatric disorders Insomnia subjects affected / exposed occurrences (all)	3 / 45 (6.67%) 3	6 / 74 (8.11%) 6	
Renal and urinary disorders Proteinuria subjects affected / exposed occurrences (all)	4 / 45 (8.89%) 4	5 / 74 (6.76%) 5	
Endocrine disorders Cushingoid subjects affected / exposed occurrences (all)	2 / 45 (4.44%) 2	6 / 74 (8.11%) 6	
Musculoskeletal and connective tissue disorders Muscle spasms subjects affected / exposed occurrences (all)	6 / 45 (13.33%) 8	5 / 74 (6.76%) 6	
Arthralgia subjects affected / exposed occurrences (all)	4 / 45 (8.89%) 4	3 / 74 (4.05%) 3	
Back pain			

subjects affected / exposed occurrences (all)	3 / 45 (6.67%) 3	3 / 74 (4.05%) 4	
Infections and infestations			
Corona virus infection			
subjects affected / exposed	12 / 45 (26.67%)	13 / 74 (17.57%)	
occurrences (all)	12	14	
Nasopharyngitis			
subjects affected / exposed	1 / 45 (2.22%)	4 / 74 (5.41%)	
occurrences (all)	1	4	
Upper respiratory tract infection			
subjects affected / exposed	3 / 45 (6.67%)	2 / 74 (2.70%)	
occurrences (all)	3	3	
Folliculitis			
subjects affected / exposed	0 / 45 (0.00%)	4 / 74 (5.41%)	
occurrences (all)	0	4	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported