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Nef-301
Summary of Full Phase 3 Trial Results

March 13, 2023

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Primary endpoint successfully met in Phase 3 NefIgArd study

Beneficial eGFR treatment effect observed, irrespective of UPCR baseline. **Primary endpoint achieved - highly statistically significant with p-value <0.0001**

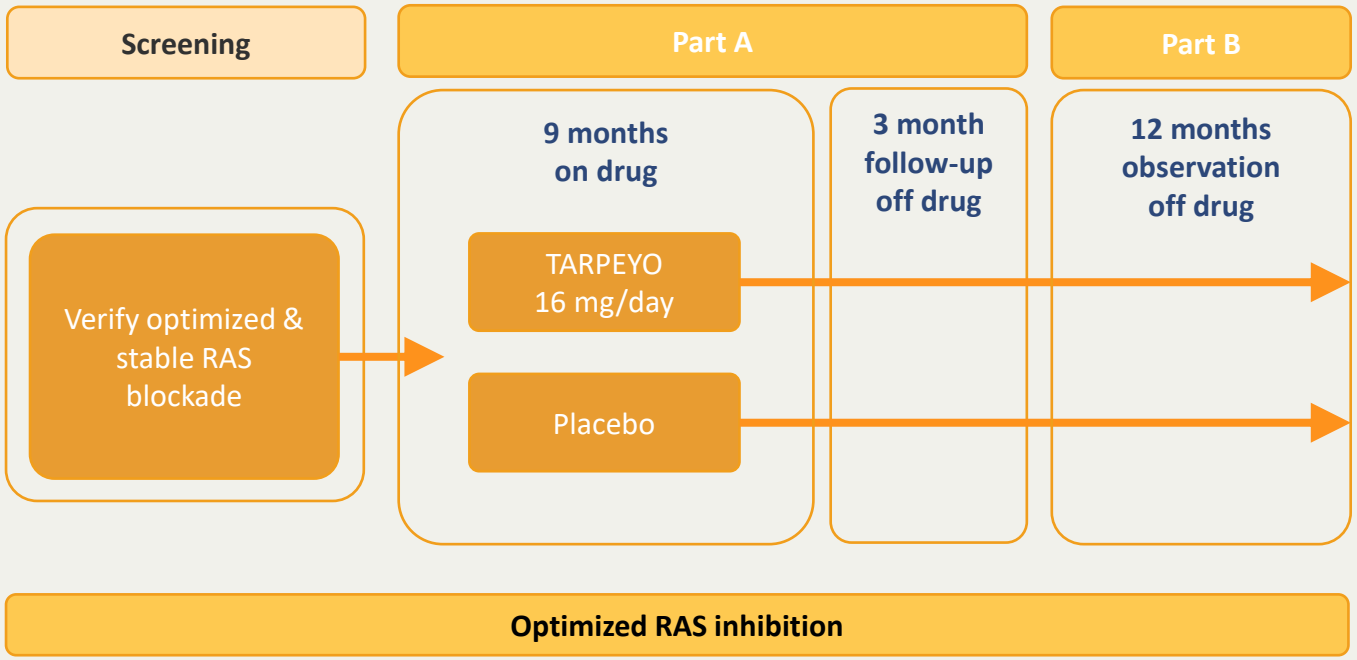
Supportive eGFR slope analyses over 2 years highly statistically significant. All estimates well in excess of the difference per year in 2 year eGFR total slope required to **predict clinically meaningful treatment effects** on the composite endpoint of ESRD, eGFR<15 mL/min/1.73 m^2 or sustained doubling of serum creatinine (Inker et al 2019)

A single treatment course of 9 months **slowed the loss of kidney function by 50%** compared to placebo at 24 months

UPCR effect of 30%+ reduction shown to be **durable for the entire 15 month follow up period**, with maximum effect observed at 12 months (three months after final dose)

The Company believes that the dataset is supportive of **filing for full regulatory approval for entire study population**

NefIgArd study design



Base inclusion criteria:

- Biopsy proven IgAN; > 1 gram of proteinuria; > 35 eGFR < 90 ml/min 36o patients, including 200 from Part A
- Patients were required to have well-controlled blood pressure of <140/90 mmHg to enter into the study, to ensure no BP confounding effects on proteinuria reduction.
- No immunosuppressive drugs were permitted during the study; changes to anti-hypertensive medications were discouraged.

Part A

- 200 patients in 19 countries with >145 sites
- Primary endpoint: proteinuria
  Key secondary endpoint: eGFR
- Read out positive data in November 2020

Full Phase 3 trial

- Part A and post approval commitment
  - confirm the long-term renal benefit of observed proteinuria reduction
- 360 patients, including 200 from Part A
- Primary endpoint: average difference in kidney function as measured by eGFR over the 2-year period
- Read out positive data in March 2023

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Disposition, Demographics and Baseline Characteristics

Disposition

	Nefecon 16 mg	Placebo	Total
All randomised	197	198	395
Safety Analysis Set [a]	195	194	389
Full Analysis Set [b]	182	182	364
Early discontinuation of study	24	19	43

[a] The Safety Analysis Set includes all randomized patients who received at least 1 dose of study treatment.

[b] The Part B Full Analysis Set excludes 29 patients enrolled for regulatory purposes in China after global recruitment was complete.

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Demographic characteristics

- **Demographic characteristics are representative of the intended primary IgAN population. Disease characteristics describe a clinically relevant high-risk IgAN population.**
- **Treatment groups were balanced with regards to baseline characteristics.**
- **Blood pressure was well controlled at study entry.**

	Nef-301 Phase 3 Full Analysis Set		
	Nefecon 16 mg (N=182)	**Placebo (N=182)**	**Total (N=364)**
Age (years) (Median [range])	43 [21, 69]	42 [34, 49]	43 [20, 73]
Sex (n, % male)	117 (64%)	123 (68%)	240 (66%)
Race (n, % White)	138 (76%)	137 (75%)	275 (76%)
(n, % Asian)	43 (24%)	40 (22%)	83 (23%)
Systolic BP/Diastolic BP (Median)	126/79	124/79	125/79
UPCR (g/gram) (Median)	1.28	1.25	1.26
eGFR CKD-EPI (mL/min/1.73 m^2) (Median)	56.1	55.1	55.5

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Efficacy Results

Primary analysis of eGFR: Effect of Nefecon averaged over 2 years

Time-weighted average change from baseline in eGFR during 9 months of treatment and 15 months of observation

- Averaged over the 2-year period of treatment and observation, the mean decline in eGFR was 2.47 mL/min/1.73 m^2 for patients who received Nefecon compared with 7.52 mL/min/1.73 m^2 for patients who received placebo
- Averaged over the 2-year period of treatment and observation, there was a 5.05 mL/min/1.73 m^2 eGFR treatment benefit in favour of Nefecon compared to placebo (p<0.0001)

Nef-301 Primary analysis of eGFR (Full Analysis Set N=364)		
	Nefecon 16 mg (N=182)	**Placebo (N=182)**
Mean change from baseline in eGFR averaged over 2 years (mL/min/1.73 m^2)	-2.47 (-3.88 to -1.02)	-7.52 (-8.83 to -6.18)
Nefecon 16 mg versus Placebo treatment effect		
Average difference in eGFR over 2 years (mL/min/1.73 m^2)	5.05 (p<0.0001)	

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Supportive eGFR Analysis

eGFR 2-year slope analysis

- **Supportive analyses of eGFR 2-year slope were statistically significant and clinically relevant**
- **The improvement in total 2-year eGFR slope was estimated to be 1.8 to 3.0 mL/min/1.73 m^2 per year for Nefecon 16 mg once daily compared to placebo, depending on the analysis method used**
- **All estimates are well in excess of the difference per year in 2 year eGFR total slope required to predict clinically meaningful treatment effects on the composite endpoint of ESRD, eGFR<15 mL/min/1.73 m^2 or sustained doubling of serum creatinine (Inker et al 2019)**

Nef-301 Part B eGFR 2-year Analyses (Full Analysis Set N=364)		
Difference between Nefecon 16 mg and Placebo in 2-year eGFR total slope (mL/min/1.73 m^2 per year) 1-sided p-value	Absolute change in eGFR from baseline at 24 months	
	Nefecon 16 mg (N=182)	Placebo (N=182)
1.8 – 3.0 with p-values <0.0001 - 0.0035	-6mL/min/1.73 m^2	-12mL/min/1.73 m^2

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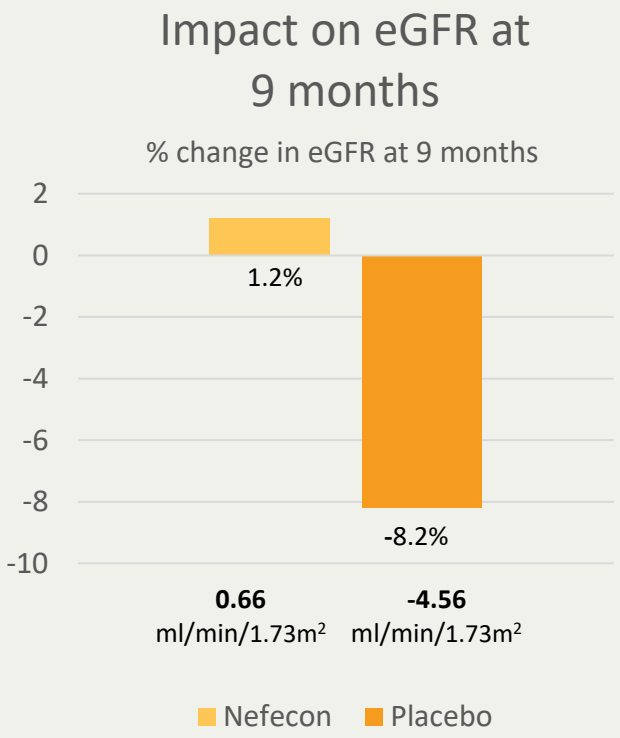
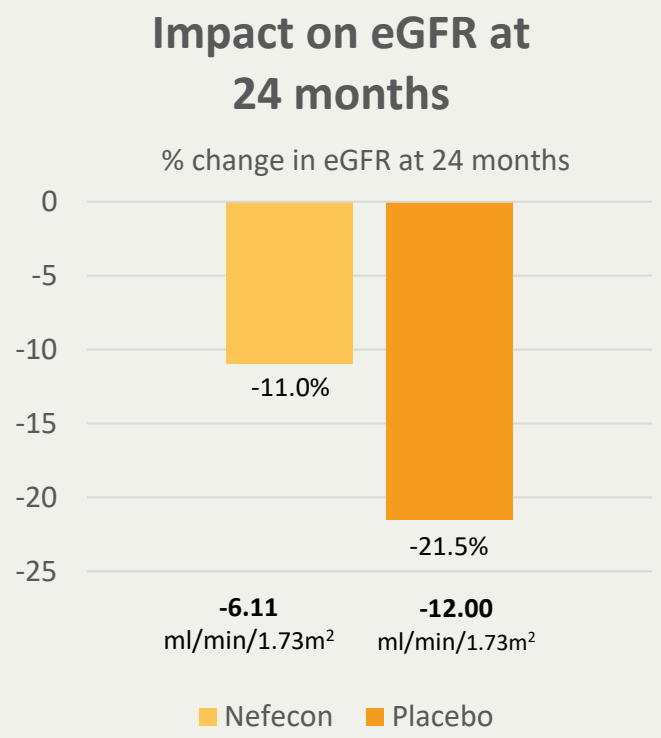
eGFR Phase 3 Data

Sustained eGFR effect observed at 24 months

9 months of dosing with 16mg Nefecon in 364 patients resulted in 50% less loss of kidney function vs placebo at 24 months.





Efficacy Findings

- Statistically significant eGFR stabilization with Nefecon (16 mg) compared to placebo following 9 months treatment ($p < 0.0001$)
- After 9 months:
  - eGFR increase for Nefecon treated patients: 0.66 ml/min/1.73m^2
  - eGFR decline for placebo: 4.56ml/min/1.73m^2
- After 24 months:
  - eGFR decline for Nefecon treated patients: 6ml/min/1.73m^2
  - eGFR decline for placebo: 12ml/min/1.73m^2

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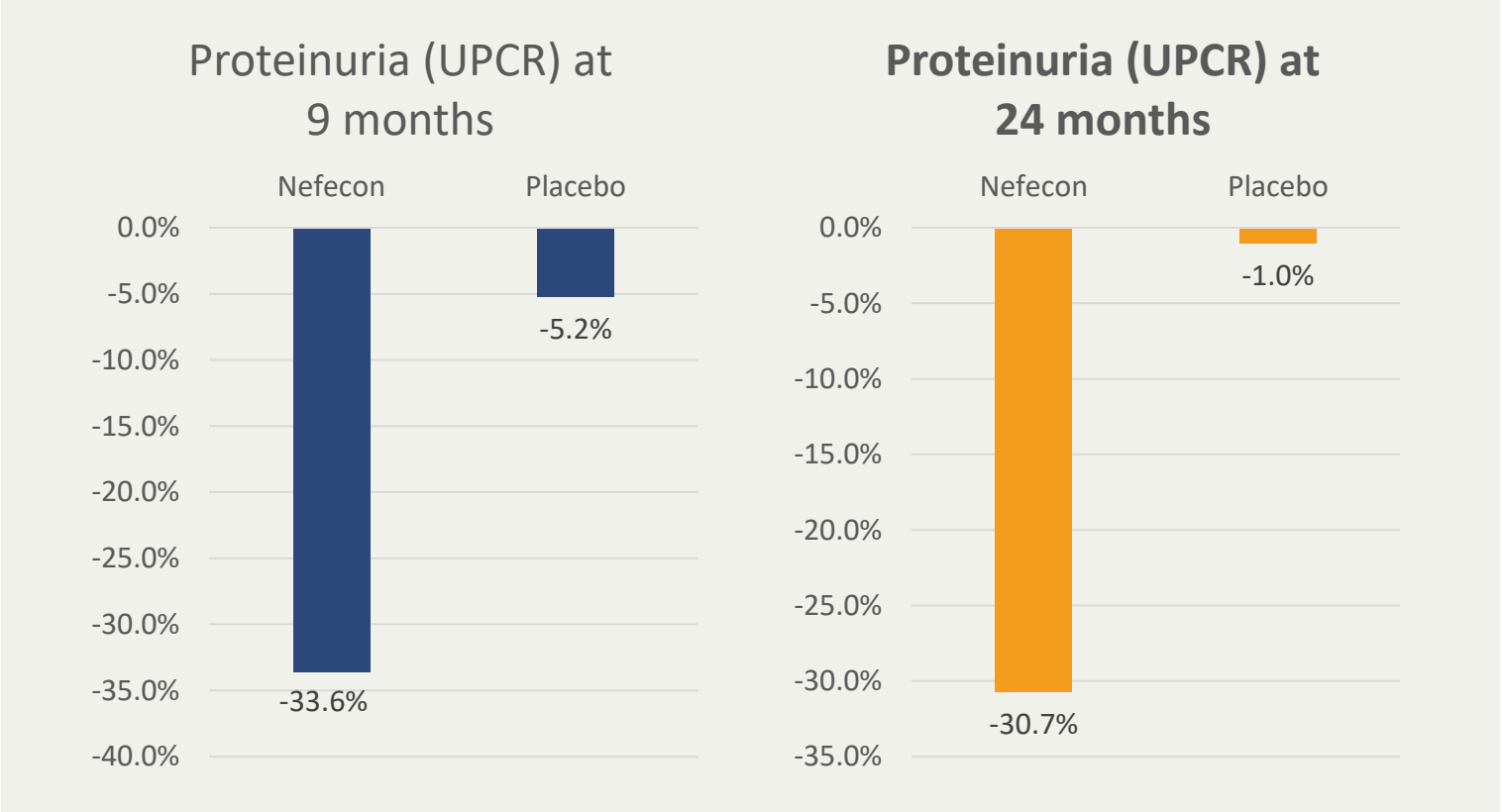
UPCR Phase 3 Data

Effect on UPCR maintained at 9 month level, or lower, from the end of treatment through 24 months

- The percent reduction in UPCR for Nefecon 16 mg versus placebo increased over time from 3 to 12 months, and thereafter returned to end of treatment (9 month) levels at the end of the follow-up period (15 months).



Efficacy Summary

The Phase 3 **Primary Endpoint of eGFR AUC(0-2) was met,** showing **high statistical significance** of Nefecon (TARPEYO / Kinpeygo) compared to placebo ($p<0.0001$)

Supportive **analyses of 2-year eGFR total slope were statistically significant and clinically relevant**, showing a magnitude ranging from approximately 1.8 – 3.0mL/min/1.73 m^2 per year (active compared to placebo), with p-values ranging from <0.0001 to 0.0035

All estimates are **well in excess of the threshold required** to predict clinically meaningful treatment effects

A **treatment benefit** on eGFR was apparent **across baseline UPCR subgroups**

Sustained proteinuria effects and **long lasting eGFR treatment benefit** even after 15 months after discontinuation, **supporting disease modification**

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Safety Results

Phase 3 safety summary – Full Safety Analysis Set (treatment period)

(≥5% Nefecon-treated patients and ≥2% higher than placebo)

	Nef-301 Part B	
Adverse event N (%)	**Nefecon 16 mg (N=195)**	**Placebo (N=194)**
Peripheral edema	33 (16.9)	10 (5.2)
Hypertension	23 (11.8)	6 (3.1)
Muscle spasms	23 (11.8)	8 (4.1)
Acne	22 (11.3)	2 (1.0)
URTI	16 (8.2)	12 (6.2)
Face edema	15 (7.7)	1 (0.5)
Weight increased	13 (6.7)	6 (3.1)
Dyspepsia	13 (6.7)	4 (2.1)
Arthralgia	12 (6.2)	4 (2.1)
WBC increased	11 (5.6)	1 (0.5)

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Safety Summary

Nefecon was generally well tolerated

Objective measures of mean weight and BP showed non-clinically relevant, fully reversible changes

The adverse event profile was similar to that reported in Part A:

- The most commonly reported TEAEs observed with an increased frequency compared to placebo were oedema peripheral, hypertension, muscle spasms, and acne**.**
- **The majority of TEAEs were of mild or moderate severity.**
- TEAEs led to discontinuation of study drug in <10% of Nefecon-treated patients.

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