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Q4 2022 REPORT

February 23, 2023

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Q4 Highlights

In October Kidney International published the peer reviewed manuscript detailing Part A of our NefIgArd trial.

The general reaction from physicians was very positive, as we experienced first hand at the annual ASN conference held in Orlando, FL in early November.

A key focus from the many nephrologists we interacted with was the disease modifying potential borne out by the durability of proteinuria response off drug and the stabilisation of eGFR in patients at risk of rapid disease progression.

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Q4 Highlights: TARPEYO

In Q4 we had total revenues of SEK 429m, with net sales of SEK 167.3 million ($16.1m) from TARPEYO in the US. This resulted in SEK 802.9m of total revenues for the year of 2022, an increase of 250%, out of which TARPEYO net sales represented SEK 372.2 m, which was in line with our guidance provided in November.

Unique prescribing nephrologists continue to grow

We ended the year with a total of 642 unique prescribers and 1 039 enrolments, reflecting record average weekly enrolments towards the end of the year.

MEDICAL AFFAIRS

The expansion of our sales team, which has now been brought in house as Calliditas employees, has already had an impact. They and our medical affairs team continue to educate nephrologists on:

- the ease of use of TARPEYO on top of standard of care
- the strong proteinuria reduction shown versus physicians choice of optimised RAS blockade
- stabilisation of eGFR in patients at high risk of rapid progression
- the well established safety profile

Source: Data on file

Q4 Highlights

- In December we reported that we had out licensed Nefecon to Viatris for the Japanese market in a transaction worth up to $100m. This resulted in a $20m upfront payment with up to $80m of additional development, regulatory and commercial milestones.
- In November, the China NMPA accepted Everest Medicines' NDA filing, and in December recommended Priority Review for Nefecon
- As site activations have picked up, the recruitment rate in our head and neck cancer trial has significantly improved and we are presently targeting delivery biomarker data around the middle of the year. PBC remains challenging and we have implemented a range of activities in Q4 and Q1 to try to address this.
- We reported positive operating profit in Q4 of SEK 32.5m and ended the year in a strong financial position with cash amounting to SEK 1 249m ($119m). We believe that we are funded to profitability based on continued delivery of sales from TARPEYO and the broader Nefecon franchise

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Post period events

- On February 2nd the MHRA reported that they had granted a Conditional Marketing Authorisation (CMA) of Kinpeygo for the United Kingdom.
- The CMA is in process of being transferred to STADA, who holds the commercial rights in the UK, Switzerland, and the European Economic Area (EEA).

- Based on date of completion of the last visit by the last subject in our Phase 3 trial NefIgArd we are targeting the middle of March for release of our top line data
- This readout will provide long term eGFR data, complementing our statistically significant and clinically meaningful eGFR data from 9 months.

- For the year of 2023 we believe that net US revenues of TARPEYO will reach between $120 and 150m.
- We believe that strong top line data from Part B could provide momentum to uptake as the long term eGFR data will provide insight into disease modifying activity.

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Q4 Update: Kidney International Publication

Results of Nef-301 (NefIgArd) Part A Published

Published online in Kidney International on 19th October 2022

www.kidney-international.org

clinical trial

Results from part A of the multi-center, double-blind, randomized, placebo-controlled NefIgArd trial, which evaluated targeted-release formulation of budesonide for the treatment of primary immunoglobulin A nephropathy

see commentary on page 258

OPEN

Jonathan Barratt[1], Richard Lafayette[2], Jens Kristensen[3], Andrew Stone[4], Daniel Cattran[5], Jürgen Floege[6], Vladimir Tesar[7], Hernán Trimarchi[8], Hong Zhang[9], Necmi Eren[10], Alexander Paliege[11] and Brad H. Rovin[12]; for the NefIgArd Trial Investigators[13]

Kidney International (2023) 103, 391–402

Results from part A of the multi-center, double-blind, randomized, placebo-controlled NefIgArd trial, which evaluated targeted-release formulation of budesonide for the treatment of primary immunoglobulin A nephropathy

kidney INTERNATIONAL

ISN INTERNATIONAL SOCIETY OF NEPHROLOGY

Cohort and intervention

Randomised

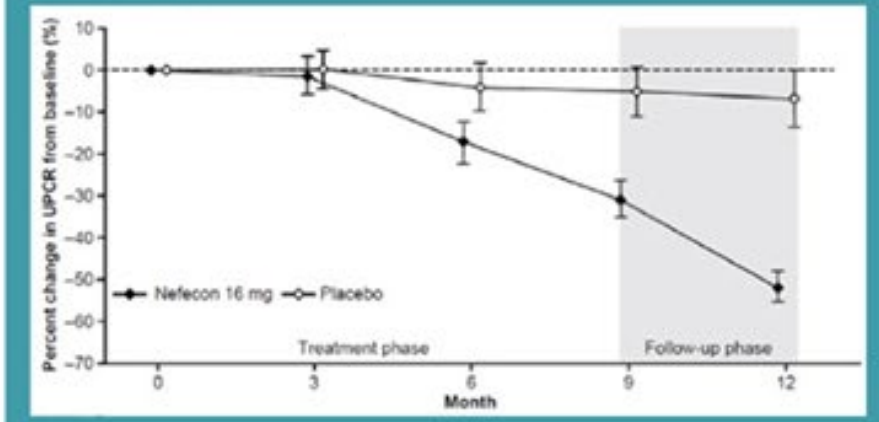
- 201 patients with **IgAN**
- **Nefecon** 16 mg od: n=97
- **Placebo**: n=102

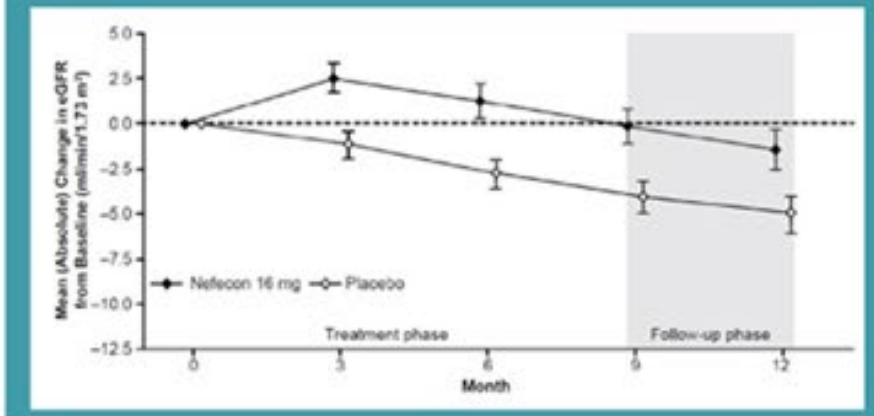
9-month treatment ➔ 3-month follow-up

Key baseline characteristics

- Optimised RAS blockade: **ALL**
- Median UPCR: **1.26 g/g**
- Median proteinuria: **2.26 g/24 h**
- ≥2g/24h proteinuria: **58%**
- Median eGFR: **55 ml/min/1.73 m²**

Outcomes





UPCR:

- At 9 months: **27% reduction** vs placebo ($P = 0.0003$)
- At 12 months: **48% reduction** vs placebo ($P < 0.0001$)

eGFR:

- At 9 months: **3.87** ml/min/1.73 m² **treatment benefit** ($P = 0.0014$)
- 1-year eGFR slope **improvement**: **3.37** ml/min/1.73 m² ($P = 0.0111$)

Safety:

- Patients with **TEAEs**: 86.6% with Nefecon vs 73.0% with placebo, mostly mild or moderate
- **No severe infections requiring hospitalisation**

Barratt et al, 2022

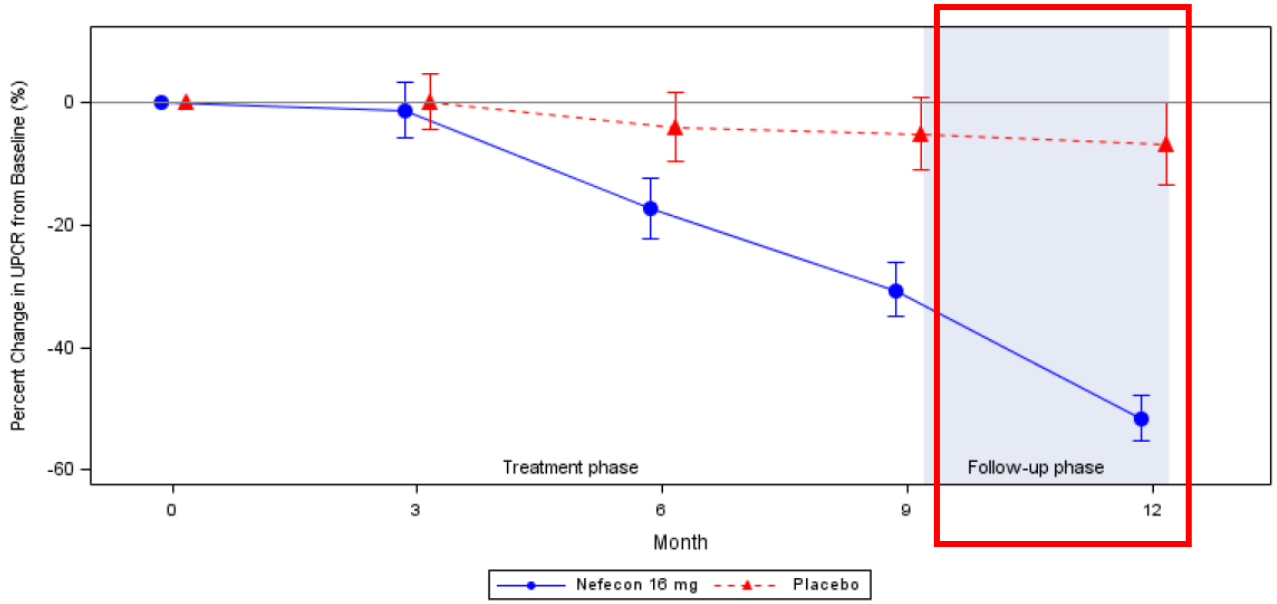
CONCLUSION

9 months of treatment with Nefecon, in addition to optimised and stable RAS blockade, was well tolerated and resulted in clinically important improvements in UPCR, UACR, and eGFR compared with optimised supportive care alone

Effect of Nefecon on Proteinuria During Treatment

The effects in Nef-301 Part A were not immediate, but rather were delayed and are cumulative

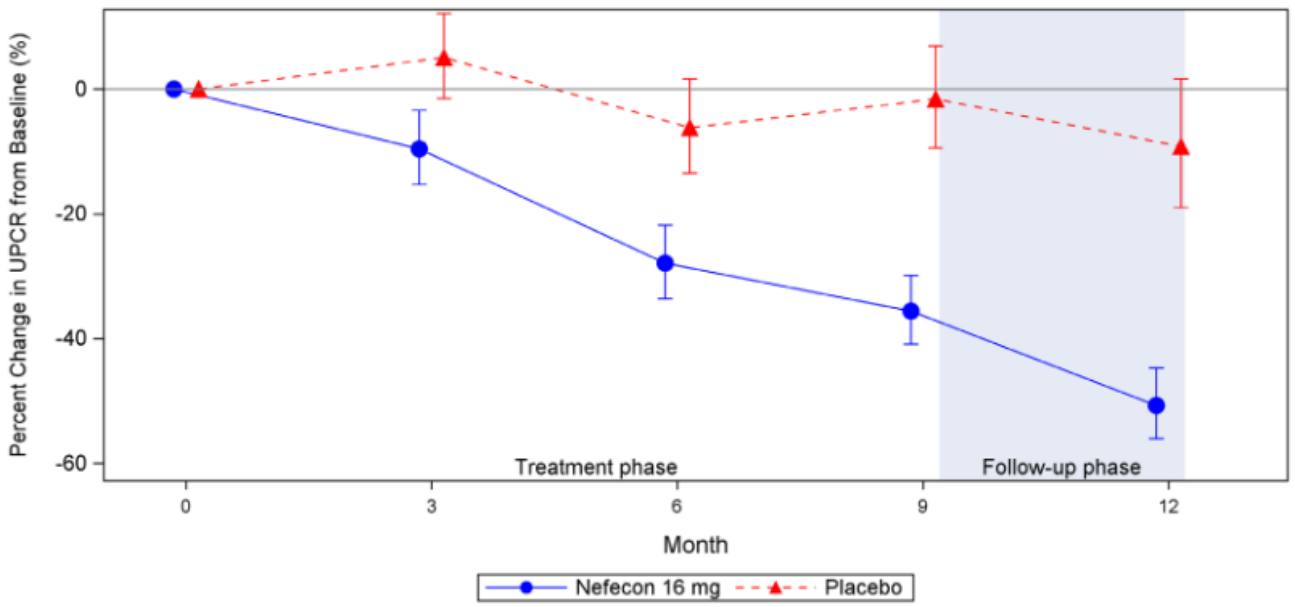
- The effect of Nefecon on proteinuria was not observed immediately, but became clearly apparent after 6 months of treatment and continued to accumulate at 9 months and 12 months
- At 12 months, there was a 52% reduction in proteinuria (UPCR) versus baseline (48% versus placebo)



Effect of Nefecon on Proteinuria During Treatment

In patients with higher baseline proteinuria, an earlier effect of Nefecon is apparent

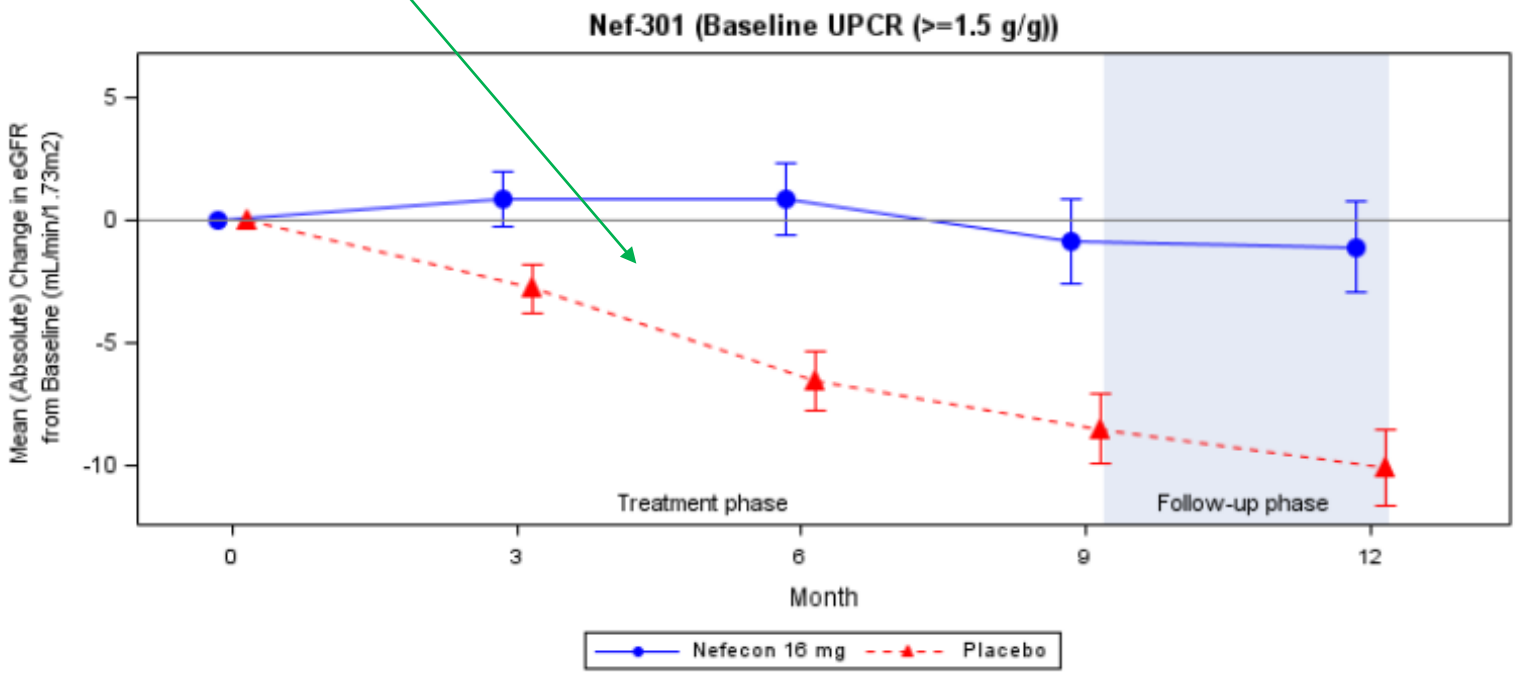
- In patients with baseline UPCR ≥1.5 g/gram, an earlier impact on proteinuria is apparent
- After 3 months of treatment with Nefecon, there was a 14% reduction in proteinuria (UPCR) in Nefecon-treated versus placebo-treated patients



Effect of Nefecon on eGFR During Treatment

In patients with higher baseline proteinuria, eGFR trajectories diverge

Early separation of UPCR curves translates to early and divergent separation of eGFR curves



eGFR declined by 10.1 mL/min/1.73 m^2 over 12 months in the placebo group, compared to a reduction of 1.1 mL/min/1.73 m^2 in the Nefecon group, a difference of 8.98 mL/min/1.73 m^2 at 12 months

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Summary of Part A data

- Nefecon met primary and key secondary endpoints in the NefIgArd trial Part A
- The effects of Nefecon on proteinuria are gradual and cumulative, with continued improvement after discontinuation of treatment
- In patients with higher baseline proteinuria, an earlier beneficial effect on proteinuria is observed, which translates to clearly divergent eGFR trajectories, with stabilisation of eGFR in Nefecon-treated patients

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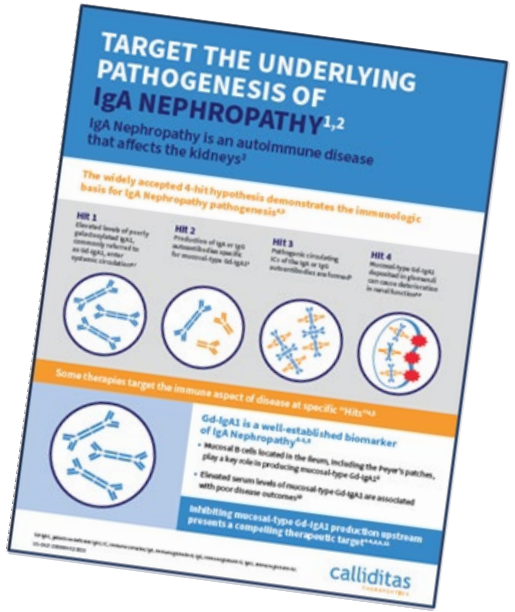
Q4 Update: Commercial Overview

A strong finish to a solid first year…

- $16.1 M net sales from TARPEYO in Q4
- 310 Q4 enrollments reflecting the early impact of field expansion
- 1,039 enrollments in 2022 written by 642 unique prescribers
- Market Access achievements reaching goal of more than 90% of US lives covered (mid-year)
- TARPEYO Touchpoints increasing efficiencies and exceeding industry standards in patient services
- Nephrologist awareness over 90%
- Increasing clinical evidence and positive outcomes for a growing number of patients taking TARPEYO

What to look forward to in 2023 and beyond

- Increasing patient success stories
- Full impact of expanded reach and growth of the field team
- Part B results and further demonstration of the impact on eGFR with TARPEYO®
- Increasing global presence and KOL experience



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Q4 Update: Financial Overview

Financial Overview – Key Takeaways from Q4 2022

- Revenue
  - Tarpeyo net sales in Q4 amounted to SEK 167.3 M ($16.1 M), a growth of 36% from Q3.
  - Revenues from partners (Viatris, Stada and Everest) amounted to SEK 260.2 M in Q4.
- Operating expenses were SEK 388.7 MSEK for Q4, a SEK 96.7 M increase in operating expense over Q3.
- Operating profit amounted to SEK 32.5 MSEK in Q4.
- Positive Q4 cash flow from operations of SEK 230 M driven by partner payments and increased TARPEYO sales.
- Calliditas is well funded with a cash position of SEK 1,249.1 M as of end of December.
  - we believe that we are, based on our guidance for TARPEYO, funded to profitability and well prepared to capitalize on growth and opportunities in 2023.

Financial Overview – Full Year 2022

MSEK	Jan-Dec 2022	Jan-Dec 2021
Net sales	802,9	229,3
Gross profit	787,7	229,3
Operating loss	-421,9	-524,5
Loss for the period	-412,3	-509,5
Cash Position	1249,1	955,5

- Revenues for FY 2022 of SEK 802.9 M vs SEK 229.3 M for 2021.
  - Significant growth of 250% year over year
  - Whereof SEK 372.2 M in net sales from TARPEYO for 2022.
  - Whereof SEK 427.4 M from our partners in 2022.
- Operating expenses FY 2022 amounted to SEK 1,209.6 M vs SEK 753.8 M for 2021.
- Operating loss FY 2022 amounted to SEK 421.9 M vs SEK 524.5 M for 2021.
- Cash used in operating activities for FY 2022 amounted to SEK 311.4 M vs SEK 461.6 for 2021.
- Cash from financing activities for FY 2022 amounted to SEK 576 M vs 435.2 M for 2021.
- The cash position per end of year 2022 was SEK 1,249 M vs SEK 736.2 M per end of September 2022.

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Key takeaways

- Revenues of SEK 429m ($42.4m) of which net product revenues of $16.1m in the US for the quarter. Total revenues for 2022 amounted to SEK 802.9m, whereof TARPEYO revenues for 2022 were $36.8m
- Broad interest from physicians at ASN Kidney Week following publication of Part A data in Kidney International
- Expanded sales force footprint in place as of early November; continued penetration into prescriber base
- Partnership in Japan with Viatris for Nefecon in IgAN, resulting in an additional non-dilutive cash raise of $20m in upfront payment
- China NMPA accepted NDA for Nefecon and granted priority review
- Expected net sales of TARPEYO of $120 to 150m for 2023
- Strong cash position of SEK 1 249m ($119m) end of December 2022