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Q3 2022 REPORT

November 14, 2022

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Q3 Highlights

- On July 15th we received a conditional approval from the European Commission of Kinpeygo, becoming the first and only approved medication for IgA nephropathy in EU for patients with primary IgA with rapid disease progression, UPCR≥1.5g/g.
- Due to the approval and launch of Kinpeygo in EU, Calliditas recorded revenues from STADA Arzneimittel AG of a total EUR 12.5m (SEK 135 m) in Q3.
- In Q3 we had revenues of SEK 260.1m, with net sales of SEK 123.4 million ($12.1m) from TARPEYO in the US, which is in line with our internal plan. We continue to see significant continued interest from physicians, further bolstered by the recent publication of Part A results.
- Based on our revenues achieved to date and the healthy pipeline of RXs in process, we expect to generate total net sales from TARPEYO for 2022 of $35 – 40m.
- We have been impacted by delays in our setanaxib trials, mainly in terms of site activation rates leading to slower than anticipated recruitment. We estimate that the biomarker data in SCCHN will be available in 1H 2023 and the interim analysis in PBC will be carried out in 1H 2024.

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Post period events

- Publication of Part A Neflgard data in Kidney International in October.

- Encouraged by the broad interest from nephrologists at Kidney Week / ASN with special focus on the continued reduction of proteinuria after discontinuation of the drug and the strong eGFR response in patients at risk of rapid disease progression (expressed by the FDA as “generally UPCR of ≥1.5g/gram”)

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Q3 Update

Clinical data presentation

Part A of NefIgArd Trial “In Press”

ARTICLE IN PRESS

www.kidney-international.org clinical trial

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

OPEN

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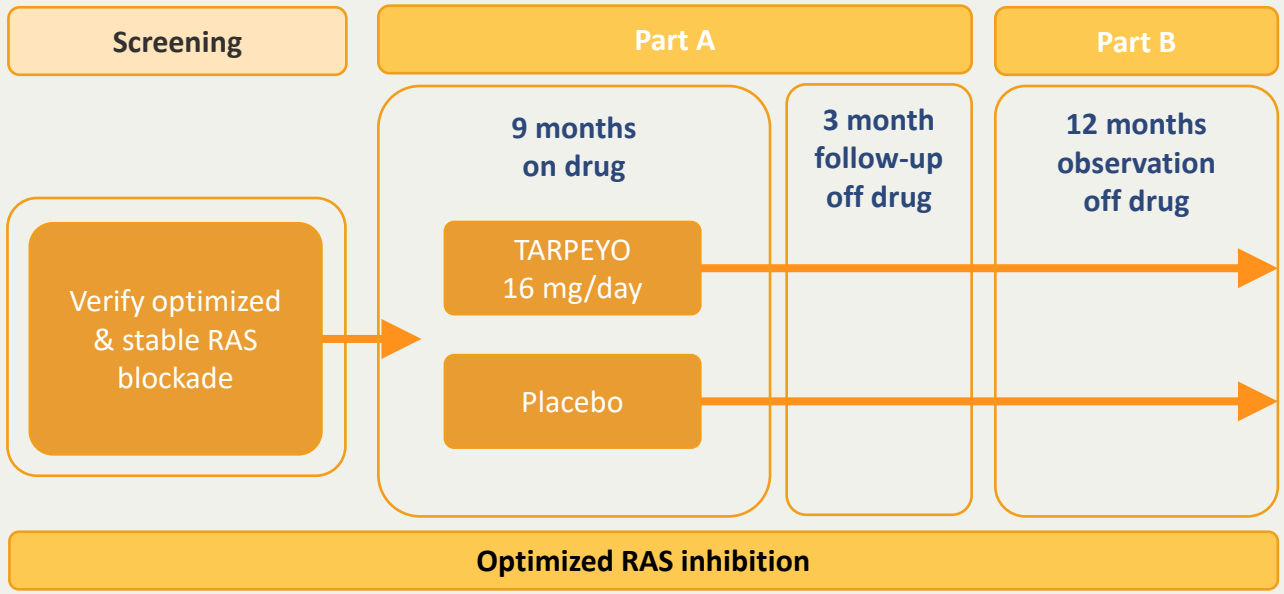
NefIgArd study - basis for FDA's accelerated approval of TARPEYO



BASELINE CHARACTERISTICS	
Age (years) [Median]	44
Sex (n, % male)	135 (67.8%)
Race (n, % White)	171 (85.9%)
Systolic BP/Diastolic BP [Mean]	126 / 79
UPCR (g/gram) [Mean]	1.6
eGFR CKD-EPI (mL/min/1.73 m^2) [Mean]	58

Base inclusion criteria:

- Biopsy proven IgAN; > 1 gram of proteinuria; > 35 eGFR < 90 ml/min 360 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 >100 sites
- Primary endpoint: proteinuria
  Key secondary endpoint: eGFR
- Read out positive data in November 2020

Part B

- Post approval follow up trial design
  - confirm the long-term renal benefit of observed proteinuria reduction

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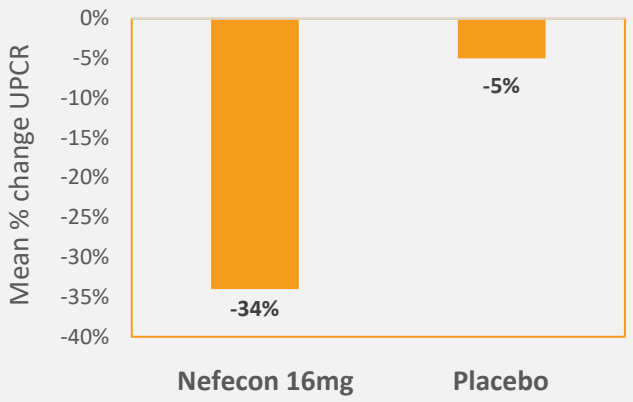
Phase 3 study results – Part A

Topline data readout after 9 months treatment

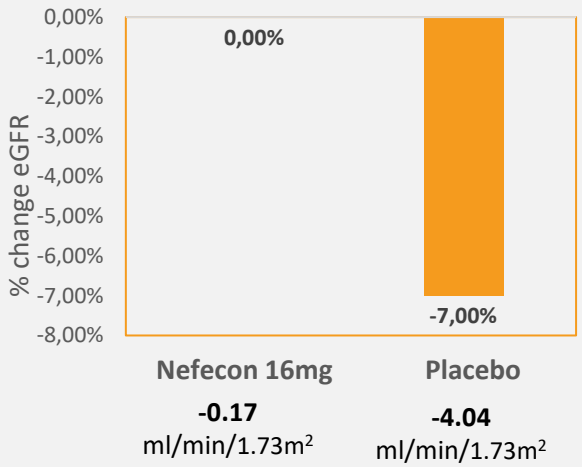
First successful readout of a Phase 3 trial in IgA nephropathy.

9 months of dosing with 16mg TARPEYO in 199 patients demonstrated a statistically significant and clinically meaningful reduction in proteinuria and in eGFR stabilization at 9 months.

Primary endpoint: reduction in proteinuria



Secondary endpoint: eGFR



Efficacy findings

- ✓ At 9 months, reduction in UPCR for TARPEYO-treated patients = 34%; reduction in UPCR for placebo-treated patients = 5%
- ✓ Statistically significant UPCR reduction with TARPEYO (16 mg) compared to placebo following 9 months treatment (p=0.0001)
- ✓ Statistically significant eGFR effect with TARPEYO (16 mg) compared to placebo – 9 months treatment (p=0.0029)

Selected Safety Data

- ✓ The majority of adverse reactions were mild or moderate in severity
- ✓ The most frequently reported adverse reactions (≥5% of TARPEYO treated patients and ≥2% higher than Placebo) were: hypertension, peripheral edema, muscle spasms, acne, dermatitis, weight increased, dyspnea, face edema, dyspepsia, fatigue and hirsutism.

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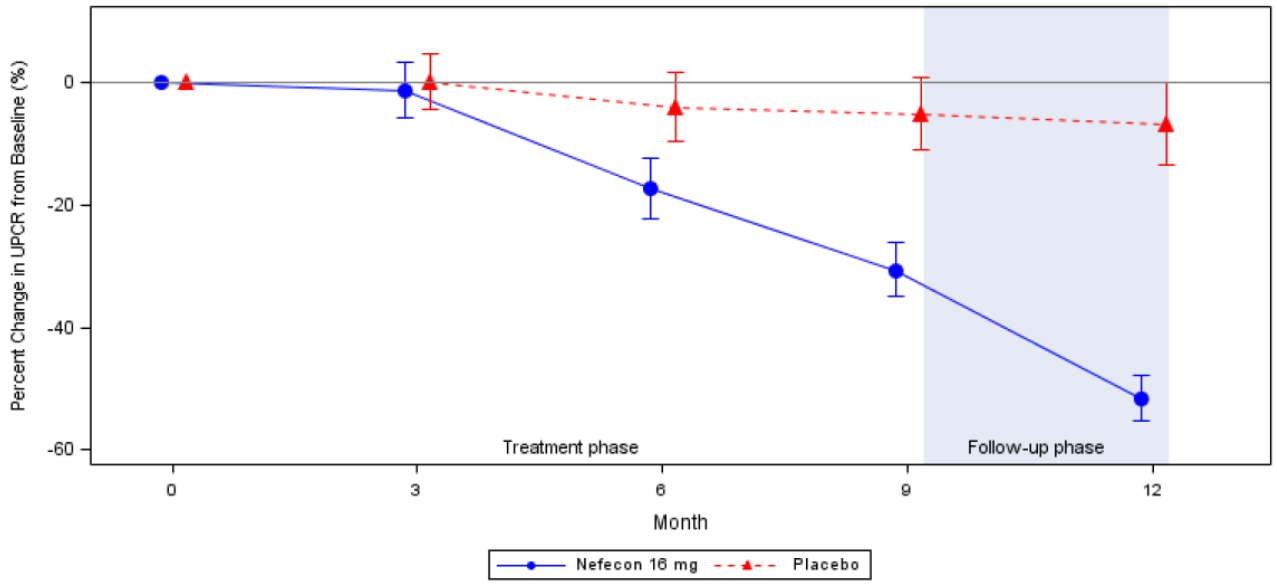
Effect of TARPEYO on Proteinuria During Treatment and Follow-Up

Overall study population

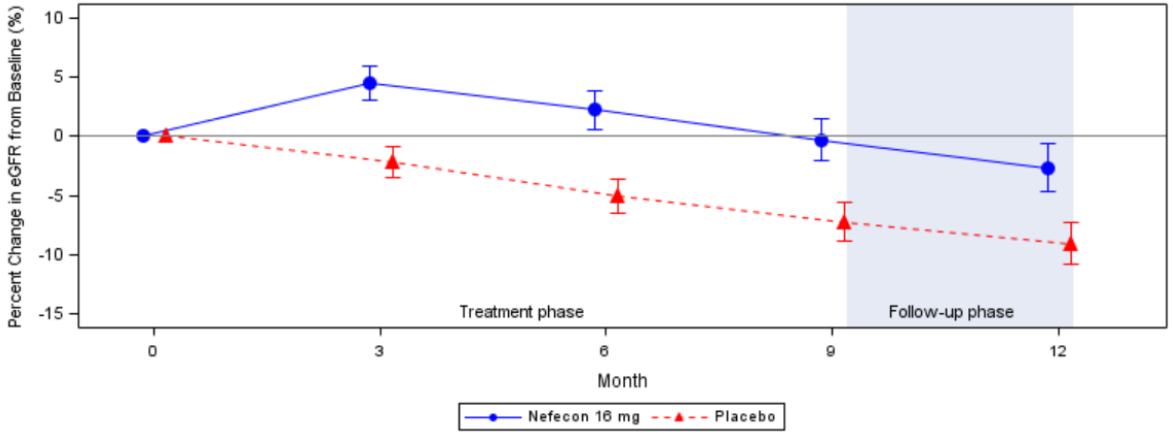
- The effect of TARPEYO on proteinuria is gradual, becoming clearly apparent after 6 months of treatment, with further accrued benefit at 9 months and 12 months
- At 12 months (off treatment for 3 months), there is a 52% reduction in proteinuria (UPCR) versus baseline (48% versus placebo)
- The effect of TARPEYO on proteinuria is consistent across all sub-groups evaluated (including baseline proteinuria and eGFR)



Effect of TARPEYO on eGFR During Treatment and Follow-Up

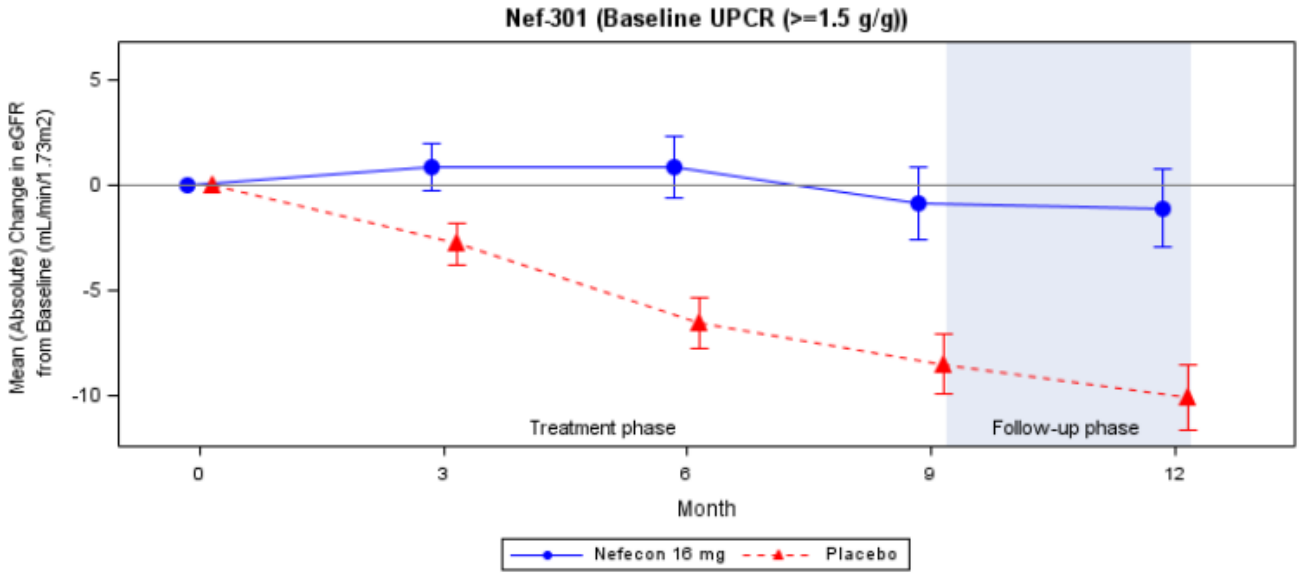
Overall study population

- Early separation of eGFR curves
- Separation maintained at 12 months (off treatment for 3 months)



Effect of TARPEYO on eGFR During Treatment and Follow-Up
Sub-group of patients with UPCR≥1.5 g/gram

- Early separation and divergence of eGFR trajectories
- At 9 months, there was an absolute reduction in eGFR of -0.88 mL/min/1.73 m^2 in patients treated with TARPEYO (n=31) vs -8.49 mL/min/1.73 m^2 in patients treated with placebo (n=33)
- Separation maintained at 12 months (off treatment for 3 months)



NefIgArd Part B

- 360 patients, including 200 from Part A
- Primary endpoint: difference in kidney function as measured by eGFR over the 2-year period
- Fully enrolled early 2021; final readout expected in H1 2023

NefIgArd Open Label Extension Study

As of end of Q3 approximately 180 patients have chosen to enter screening for the OLE trial[1]

106 Patients: Enrolled

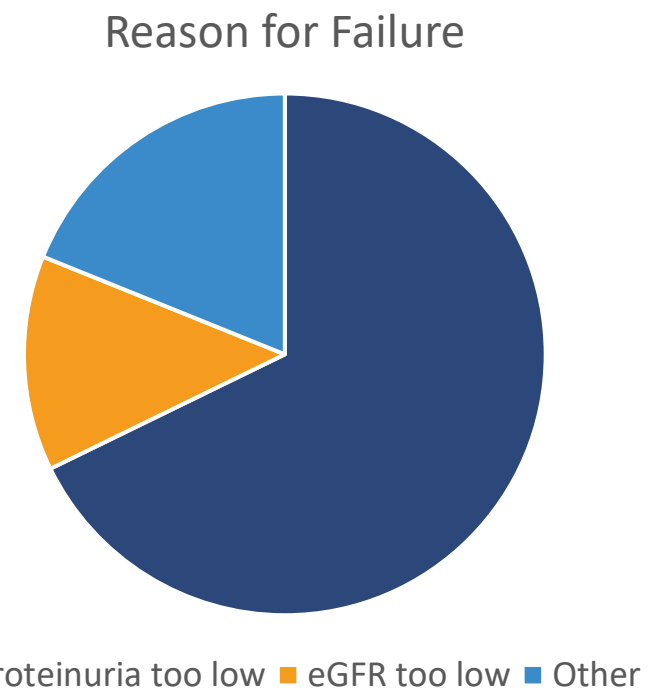
74 Patients: Failed Screening

Main inclusion criteria:

- Patients that completed the NefIgArd study
- Stable & optimised RAS inhibitor therapy (ACEIs and/or ARBs)
- Proteinuria ≥1g/24 hours or UPCR ≥0.8 g/gram
- eGFR: ≥30 mL/min/1.73 m^2

Main exclusion criteria:

- Patients with acute, chronic, or latent infectious disease
- Patients with liver cirrhosis
- Patients with poorly controlled type 1/2 diabetes
- Kidney transplant
- Patients with systemic diseases which may cause mesangial IgA deposits



1. Not all completed patients necessarily choose to enter screening for OLE

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Q3 Update

Commercial Overview

Growth and Expansion…

- $12.1 M in net sales from TARPEYO in Q3
- Added 20 sales representative for a total of 60
- 281 Q3 enrollments reflected a strong September after summer holiday months
- Additional 166 prescribers during the quarter – total of 480 since launch
- Market Access remains strong – reached goal of more than 90% of US lives covered
- Encouraging and consistent payer mix – less than 25% government insured with remainder either private insurance or cash
- Added resources at TARPEYO Touchpoints to maintain service levels of increased demand
- Awareness continues to grow to over 80%
- Advocacy and patient meetings and activities ongoing

What to look forward to in Q4 and beyond

- Nephrologist receptivity of publication of NefIgArd Part A in Kidney International
- American Society of Nephrology annual meeting
- Impact of expansion
- Part B results in 1H 2023

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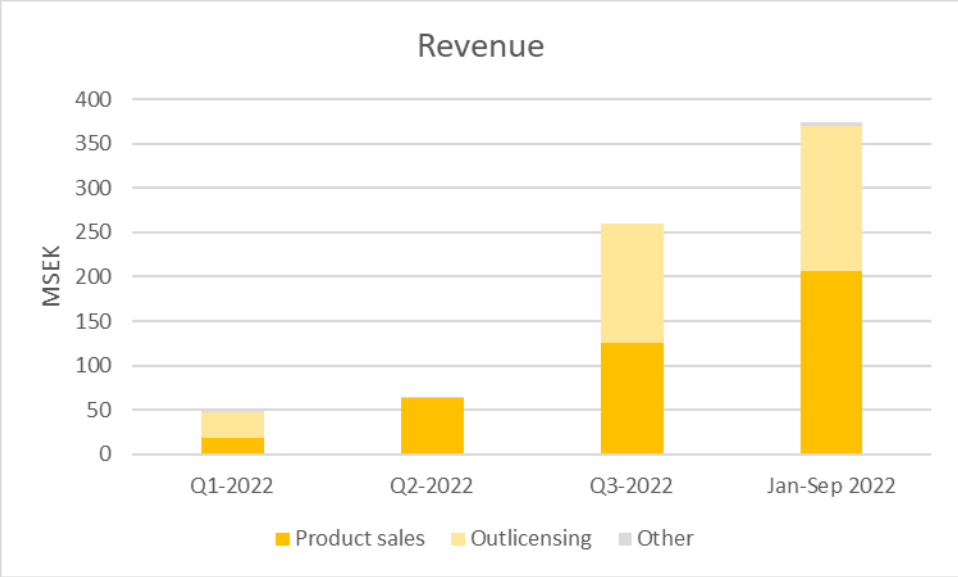
Financial Overview – Jan-Sep 2022



MSEK	Jan-Sep 2022	Jan-Sep 2021	Jan-Dec 2021
Net sales	373,8	198,2	229,3
Gross profit	366,5	198,2	229,3
Operating loss	-454,4	-302,3	-524,5
Loss for the period	-408,6	-290,9	-509,5
Cash Position	736,2	1 163,80	955,5

- Revenues Jan-Sep 2022 of SEK 373.8 M vs SEK 198.2 M for same period last year.
  - Whereof SEK 205.0 M in net sales from TARPEYO.
  - Whereof SEK 163.8 M from licensing activities.
- Operating expenses Jan-Sep 2022 amounted to SEK 821.0 M vs SEK 500.5 M for same period last year.
- Operating loss Jan-Sep amounted to SEK 454.4 M vs 302.3 M for same period last year.
- Cash used Jan – Sep 2022 in operating activities amounted to SEK 541.4 M (whereof SEK 124.7 M in Q3)
- The cash position per end of September 2022 was SEK 736.2 M vs SEK 1,163.8 M per end of September 2021.

Financial Overview – Key Takeaways from Q3

- Revenue
  - Tarpeyo net sales in Q3 amounted to SEK 123.4 M (USD 12.1 M), a growth of 94% from Q2.
  - Milestones of SEK 135 M from Stada recognized in Q3.
- The 20 M increase in operating expense from Q2 to Q3 was mainly FX-driven due to a weak SEK.
- Cash used in operating expenses significantly improved from SEK 225.2 M in Q2 to SEK 124.7 M in Q3.
- Calliditas are well funded with a cash position of SEK 736.2 M as of end of September.
  - Appr. SEK 110 M of Stada milestones recognized as revenue in Q3 are due for payment in Q4 and was not included in the end of September cash position.
  - As of September 30, Calliditas had USD 25 M unused in the Kreos loan facility

Key takeaways

- Conditional approval achieved in Europe for Kinpeygo – the first and only treatment approved for IgA nephropathy. Conditional approval for patients with risk of rapid progression, UPCR ≥ 1.5g/g
- Revenues of SEK 260.1m (appr. $24.8m) of which net revenues of product sales of $12.1m in the US for the quarter
- Continued penetration into nephrology prescriber base
- Perceived broad interest from US based physicians following publication of Part A data, broad and supportive interactions at ASN
- Expanded sales force in place as of early November, ensuring that reach and frequency metrics are achieved
- Significantly lower net cash burn in Q3, supporting cash flow target in 1H 2023