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Q2 2023 REPORT

August 17, 2023

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Q2 Highlights

- In June we filed for full approval with the FDA based on the global NefIgArd Phase 3 trial, which successfully read out in March. It met its primary endpoint, kidney function, measured by estimated glomerular filtration rate (eGFR) with a p value of < 0.0001 and a benefit of ~3ml/min/year in total slope.
- The largest European renal conference was held on June 15-18th where we were able to share data from the trial in 2 oral presentations and 2 posters. It was very well received and marked the start of a dialogue with the nephrology community.
- The second quarter of 2023, saw a record level of 422 new enrolments for TARPEYO, reflecting the continued growth of the franchise.
- The number of prescribers also continues to grow, with Q2 seeing a total of over 1 100 prescribers of TARPEYO, compared to around 300 in Q2 2022.
- Total revenues of SEK 269 million (USD 25m), out of which TARPEYO net sales represented SEK 259, reflecting a 39% growth over Q1 and over 270% growth over Q2 2022. Based on our experience to date of the limited label, continued market access friction, and potential seasonality impact from the summer period, we revise our 2023 Outlook to USD 100-120 million of net sales for TARPEYO for 2023.

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Post period events and pipeline update

In early July we reported out data related to our Phase 2 study in Head and Neck cancer. The data supported the presumed anti- fibrotic action of setanaxib and showed promising progression free survival (PFS) data. Based on this, as well as other factors, including regulatory interactions, we have decided to revise our trial design in PBC (TRANSFORM) to allow us to read out Phase 2b data, which is targeted for 1H 2024.

This adjustment will allow us to explore potential alternative endpoints and indications in light of advances in the liver area, as well as entertain potential partnering discussions. This is expected to have a beneficial impact on OPEX spend in 2024 and 2025 by around USD 15 – 25m.

We are continuing the initiation of our Phase 2 study in Alport syndrome and we are on target to start the trial in 2H 2023. We are also exploring other renal indications which might benefit from the NOX platform mode of action.

In August we reported that the full data of the global Phase 3 NefIgArd trial was published in The Lancet.

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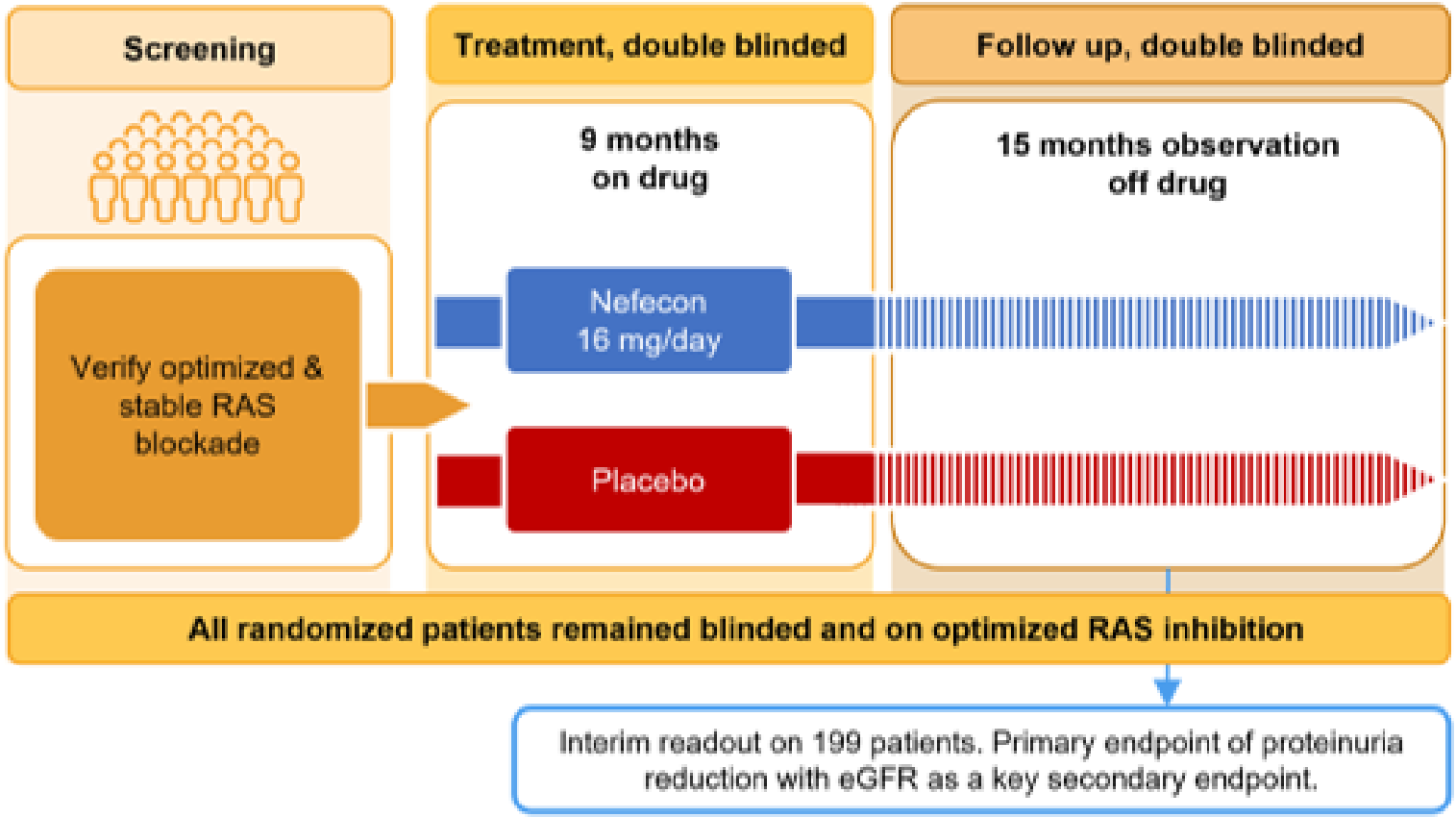
NefIgArd Trial – Final Analysis

Dr Richard Philipson, Chief Medical Officer

NefIgArd study design



Interim Readout

- 199 patients
- Primary endpoint: proteinuria
- Read out positive data in November 2020
- Basis for accelerated/conditional approval in USA/Europe, respectively

Full Phase 3 trial

- Designed to confirm the long-term renal benefit of observed proteinuria reduction
- 364 patients
- Primary endpoint: eGFR
- Read out positive data in March 2023

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eGFR Outcomes

- The primary endpoint of eGFR averaged over 2 years, and the primary supportive 2-year eGFR slope analysis included in hierarchical testing, were both statistically significant ($p<0.0001$ and $p=0.0035$, respectively)

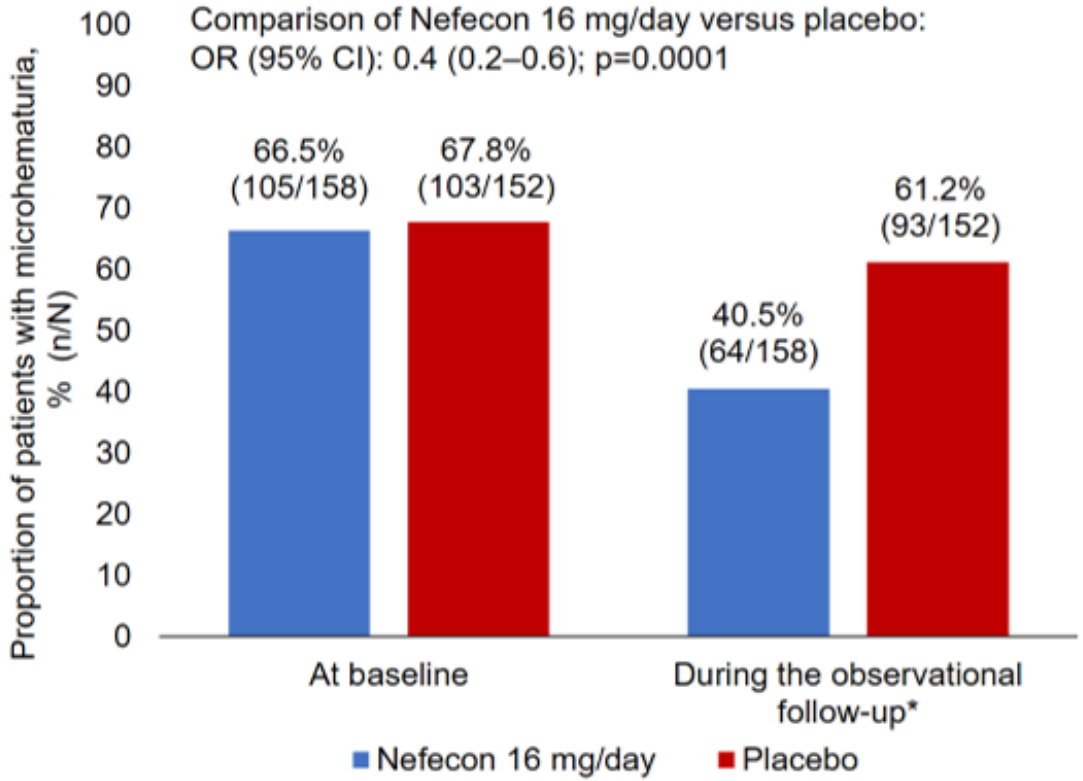
- Additional supportive analyses of eGFR 2-year slope were also statistically significant

eGFR Slope Analyses

Analysis	Difference between Nefecon 16 mg/day and placebo in 2-year eGFR total slope (mL/min/1·73 m^2 per year)	2-year eGFR total slope (mL/min/1·73 m^2 per year) Nefecon 16mg/day (n=182)	2-year eGFR total slope (mL/min/1·73 m^2 per year) Placebo (n=182)
Random coefficients analysis	1.82 (p=0.0035)	-3.55	-5.37
Robust regression analysis	2.95 (p<0.0001)	-3.06	-6.00
Linear spline mixed-effects analysis (“Vonesh”)	2.78 (p<0.0001)	-2.65	-5.44

Microhematuria

- The presence of microhematuria during observational follow-up was included as a secondary endpoint for the NefIgArd trial final analysis
  - (+)ve dipstick urine test result at ≥2 visits during observational follow-up (months 12 – 24)
- 310 patients contributed data to this secondary analysis (158/182 pts and 152/182 pts, Nefecon and pbo)
- At baseline, proportion of patients with microhematuria was 66.5% and 67.8% in Nefecon and placebo groups respectively
- During the observational follow-up, between months 12 – 24, the proportion of patients with microhematuria was:
  - 40.5% in patients previously treated with Nefecon
  - 61.2% in patients previously treated with placebo



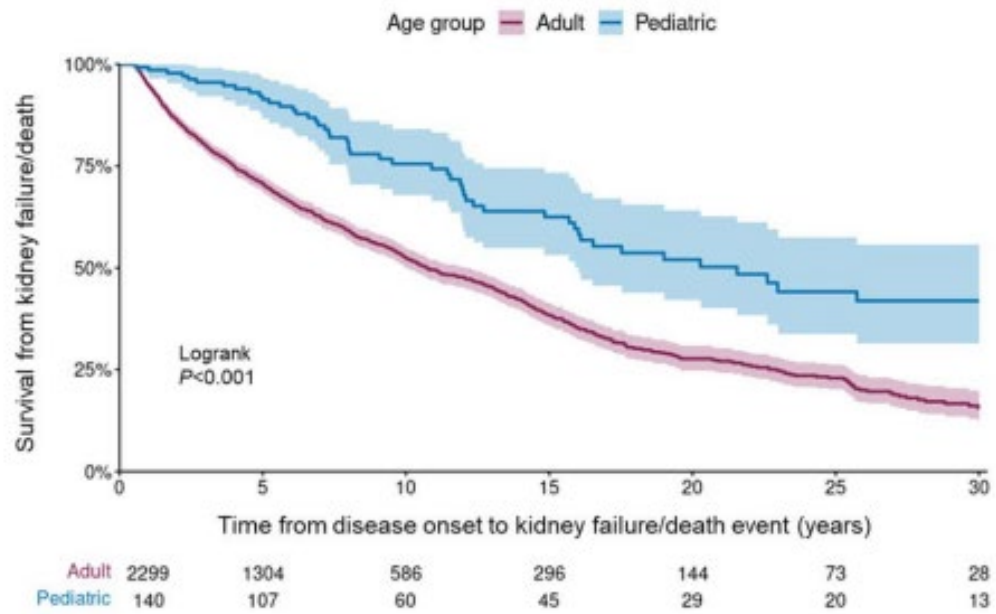
**Patients with a positive urine dipstick result in at least 2 of the following time points: 12, 18, and 24 months following the first dose of study drug.*

CI, confidence interval; OR, odds ratio.

Long-Term Outcomes in IgA Nephropathy

- Most patients progress to kidney failure within 10–15 years, irrespective of age at diagnosis
  - Median kidney survival was 10.8 years and mean age at kidney failure of only 49 years in adults
  - Higher time-averaged proteinuria was associated with a greater likelihood of progressing to kidney failure more quickly

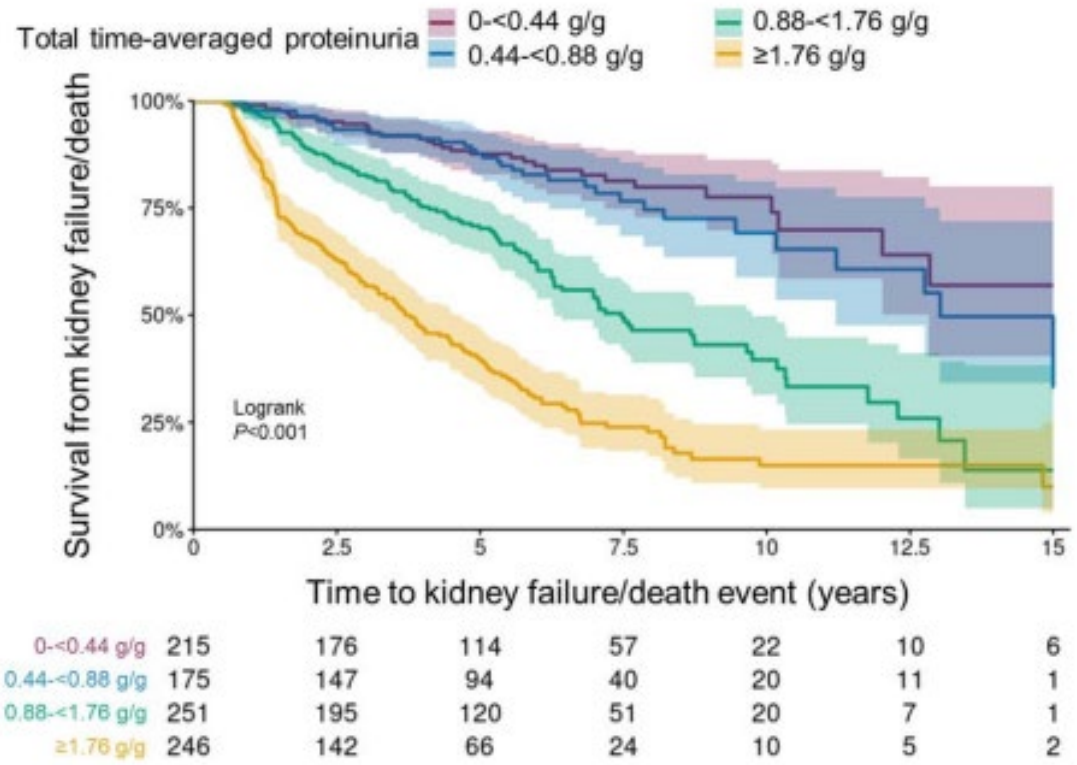
- Almost all patients are at risk of kidney failure within their expected lifetime unless a rate of eGFR loss ≤1 ml/min/ 1.73 m^2 per year is maintained from diagnosis
  - A decline of 3 ml/min per 1.73 m^2 per year would result in 100% of patients diagnosed before 40 years of age reaching kidney failure
  - a decline of 1 ml/min per 1.73 m^2 per year would result in approximately 40% of adult patients younger than 50 years at diagnosis reaching kidney failure within their expected lifetime



CJASN 18: 727–738, 2023

Long-Term Outcomes in IgA Nephropathy

- Higher time-averaged proteinuria was associated with a greater likelihood of progressing to kidney failure more quickly
- 30% of patients with time-averaged proteinuria of 0.44 to <0.88 g/g and approximately 20% of patients with time-averaged proteinuria <0.44 g/g develop kidney failure within 10 years
- Disease-modifying therapies that specifically target the immune system are more likely to be effective early in the natural history of IgA nephropathy, before the kidneys accumulate significant irreversible fibrosis



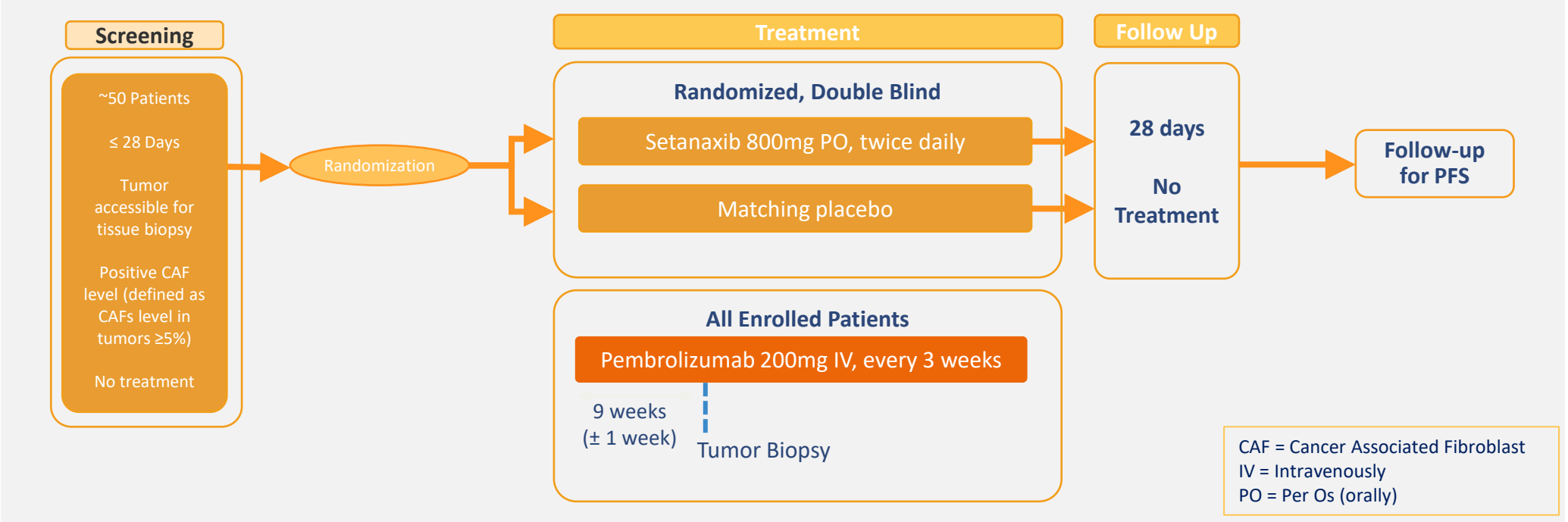
CJASN 18: 727–738, 2023

GSN000400: Interim Data Review

Dr Richard Philipson, Chief Medical Officer

Study Overview

- Investigate the administration of setanaxib in conjunction with pembrolizumab
- The study involves ~50 patients and investigates the change in tumor size and progression free survival (PFS) in patients with recurrent/metastatic cancer treated with either setanaxib + pembrolizumab, or placebo + pembrolizumab (NCT05323656)



Interim Data Review

- Planned interim review of clinical and biomarker data after 12 patients with paired biopsies had completed at least 9 weeks of treatment
- Included patients randomized up to 28-Feb-2023 with data cut-off 26-May-2023
  - 20 patients included at the time of the data cut, and contribute information on clinical outcomes
  - 12/20 patients had paired biopsies and were included in the biomarker analyses
- Evaluation comprised:
  - Change from baseline in biomarkers in tumour tissue
  - Transcriptomic analysis of changes in gene expression in tumour tissue
  - Clinical (change in tumour size, progression events)
- Safety not included – safety reviewed by IDMC on 10 Mar 2023, with next planned meeting in September 2023

Clinical Outcomes

- 7 (6 setanaxib, 1 placebo) out of the 16 evaluable patients were progression-free with either stable disease or partial response
- 6 of the 7 patients were still on the study drug at the time of the data readout; the longest period on drug was 21 weeks, related to a patient in the setanaxib arm

Biomarker Outcomes

- Transcriptomic analysis indicated that down-regulation of gene expression in the idiopathic lung fibrosis and hepatic fibrosis pathways was more significant in the patients receiving setanaxib (+pembrolizumab) compared to patients receiving placebo (+pembrolizumab)

- Potential favourable effect of setanaxib treatment on the immunological activity of the tumour observed (Foxp3 and CPS)

Summary

- Numerical difference in progression events and patients remaining on randomised treatment in favour of setanaxib

- Preliminary signal suggests greater down-regulation of importants genes in the idiopathic lung fibrosis and hepatic fibrosis pathways in patients treated with setanaxib versus placebo, consistent with MoA

- Potential favourable effect of setanaxib treatment in increasing the immunological activity of the tumour (FOXP3 and CPS); no evidence of favourable effects of setanaxib on CAFs, but α-SMA levels at baseline were not balanced between the groups, and tumour biopsy samples were generally small

Q2 Update: TARPEYO

Andrew Udell, President North America

Continued growth and improved metrics

- $25M net revenues from TARPEYO sales in the quarter – 39% growth from Q1 2023
- Record quarter of 422 new patient enrollments
- 232 new prescribers in Q2 2023
- Over 90% of patients enrolled in TARPEYO Touchpoints during Q2 received TARPEYO*
- Reduced average time-to-fill

*Does not include patients that are still waiting final insurance decision

Scientific Exchange and Patient Advocacy at Key Meetings

- Scientific Exchange at:
  - NKF Spring Clinical Meetings
  - European Renal Association (ERA/EDTA Congress)

- IgA Nephropathy Foundation's SPARK 2023

NATIONAL KIDNEY FOUNDATION SCOM23 SPRING CLINICAL MEETINGS

60TH ERA CONGRESS MILAN & VIRTUAL JUNE 15-18, 2023

SPARK IGA NEPHROPATHY FOUNDATION

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Market experience during the accelerated approval

- Accelerated approval with label focus only on proteinuria reduction
- Existing label reflects proteinuria levels equivalent to a UPCR of 1.5g/g
- At the end of the period about 15-20% of enrolments are still in process.
- Market access friction results in 5-15% of enrolments not resulting in conversion
- Average duration of treatment observed is around 8 months
- Lack of experience / frustration with specialty product process among physicians

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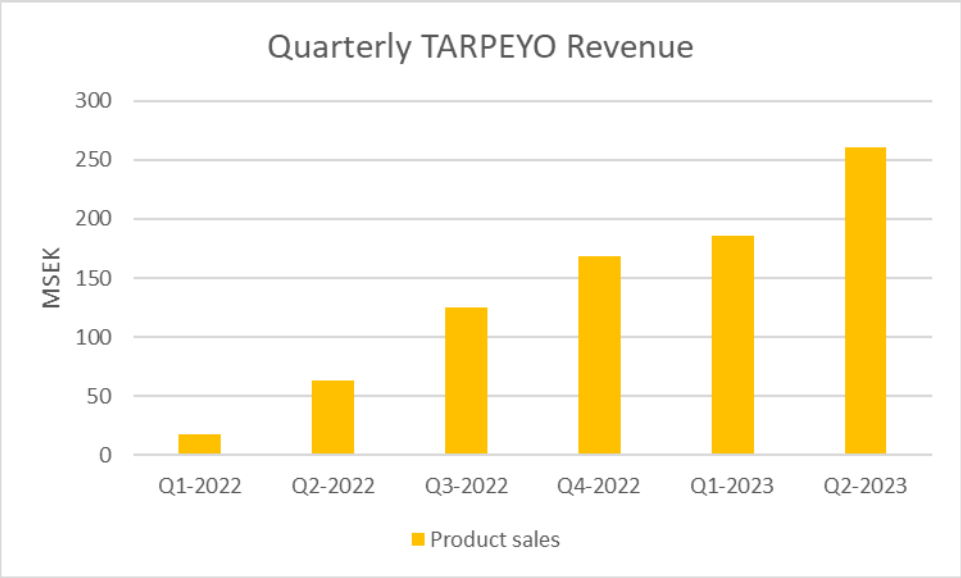
Addressing market access friction

- Full approval in broader population - significant impact
- Additional resources in place to assist with insurance process
- Publication of full results in peer reviewed journal
- Education around mode of action, treatment profile and clinical results to nephrology community
- Results from OLE study
- Presentations at conferences
- Physician experience and success stories

Q2 Update: Financial Overview

Fredrik Johansson, Chief Financial Officer

Financial Overview – Second Quarter 2023



MSEK	Apr-Jun 2023	Apr-Jun 2022
Net sales	269,4	64
Gross profit	255,2	61,7
Operating loss	75,2	209,8
Loss for the period	91,9	192,4
	June 2023	**June 2022**
Cash Position	866,2	846,8

- Revenues for Q2 2023 of SEK 269.4 M vs SEK 64.0 M for Q2 2022.
  - Whereof SEK 259.2 M in net sales from TARPEYO vs SEK 63.6 M for Q2 2022.
  - Whereof SEK 10.1 M from partners vs SEK 0.4 M for Q2 2022.
- Operating expenses Q2 2023 amounted to SEK 330.3 M vs SEK 271.5 M for Q2 2022.
- Operating loss Q2 2023 amounted to SEK 75.2 M vs SEK 209.8 M for Q2 2022.
- Cash used in operating activities for Q2 2023 amounted to SEK 163.0 M vs SEK 225.2 for Q2 2022.
- The cash position per end of June 2023 was SEK 866.2 M vs SEK 846.8 M per end of June 2022