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Q1 2024 REPORT

May 23, 2024

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Q1 Highlights

Following the December 20th full approval by the FDA of TARPEYO we updated all relevant marketing materials and trained all field based executives to reflect the new label and indication to allow for a roll out to the market in February

Maria Törnsen started as President North America in January and brings over a decade of rare disease experience, and expertise in building profitable franchises and launching drugs in orphan space.

In February we announced that the US PTO had issued a new patent covering TARPEYO, with product protection expiring in 2043.

In March the FDA granted TARPEYO seven years of orphan protection based on the new indication related to the reduction of loss of kidney function. Orphan exclusivity thus expires in December of 2030.

Everest Medicines Announces Singapore Health Sciences Authority Approves NEFEGAN® for the Treatment of Primary IgA Nephropathy in Adult Patients

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Commercial Highlights

With 705 enrolments, Q1 was another quarter with record enrolments, reflecting a 27% increase over Q4 following the 51% increase over Q3, cementing the trend of strong demand for the product.

Typical seasonality observed in the quarter due to insurance reverifications. Unexpected cyberattack on Change Health negatively impacted the quarter by approximately $4.7m, reducing net product revenues booked in the quarter to 26.8 M due to delays.

Substantial number of P&T committee meetings completed with major plans indicating updates will take effect from next planned update slated for June / July.

Continued strong demand observed in Q2 with net product revenues of approximately $25.5 m to date, confirming the technical impact on revenues limited to Q1 with delayed revenues being captured over the next several months.

Expect EMA to review and make recommendation regarding full approval of Kinpeygo at upcoming meeting.

Commercial launch in China took place in mid May, regulatory reviews ongoing in South Korea and Taiwan

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Post period events

Positive Phase 2 POC Head and Neck data

PFS - statistically significant
OS – statistically significant

R&D Day scheduled for May 30th

Supportive Open Label Extension data
Several abstracts presented at ISN World Congress of Nephrology
Notice of Allowance received for Setanaxib in Cancer
Commercial launch in China by Everest Medicines

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Upcoming Events in 2024 – an exciting year ahead!

- ✓ Potential full approval of Kinpeygo in Europe
- ✓ Commercial build out in China with the potential for negotiations related to inclusion in national reimbursement
- ✓ Readout of setanaxib data from Phase 2 trial in PBC in Q3
- ✓ Readout from Phase 2 investigator led study in IPF in Q4 (ILS)
- ✓ Reimbursement decisions expected for additional countries in Europe
- ✓ Start of Phase 3 study in Japan with Nefecon
- ✓ Continued strong growth of TARPEYO in the US market

CATEGORY LEADER IN A GROWING MARKET!

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CMO Richard Philipson

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Nefecon Update

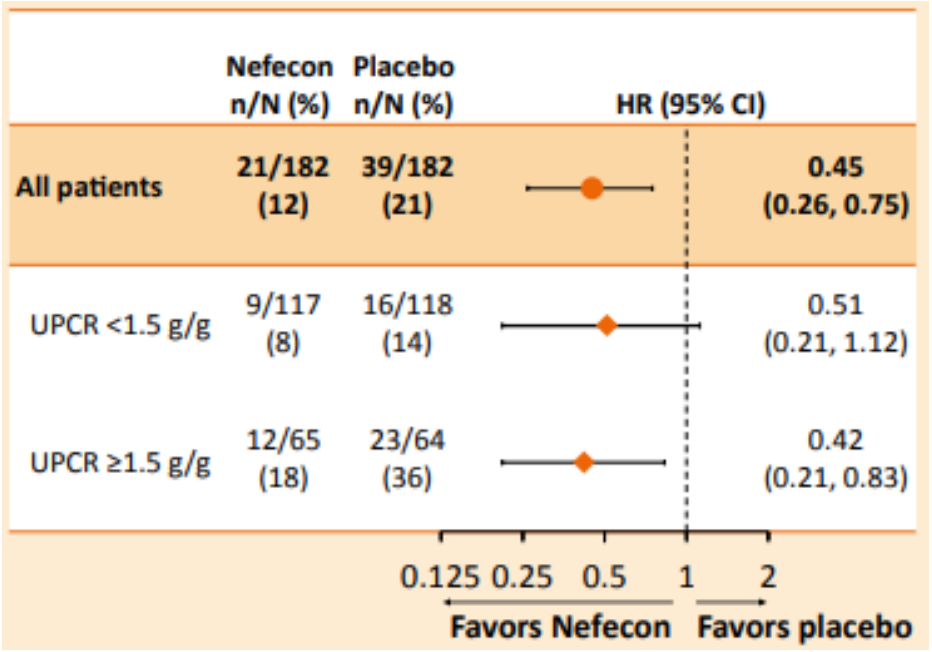
Scientific Communications

Calliditas Recent Scientific Communications

- Calliditas had a strong presence at the World Congress of Nephrology (WCN), a conference organised by the International Society of Nephrology, 13 – 16 April 2024:
  - 4 posters
  - Sponsored Symposium – Evolving Landscape of eGFR and Proteinuria Surrogate Markers in IgA Nephropathy

Data Presented at WCN

- Time to confirmed 30% eGFR reduction or kidney failure was significantly delayed with Nefecon versus placebo
  - treatment effect was consistent irrespective of baseline UPCR category
- Subgroup race analysis
  - Nefecon was efficacious and well tolerated, irrespective of White or Asian race
- Beneficial effects of Nefecon on eGFR slope observed in patients with UPCR <0.8 g/g
- Quality of life outcomes



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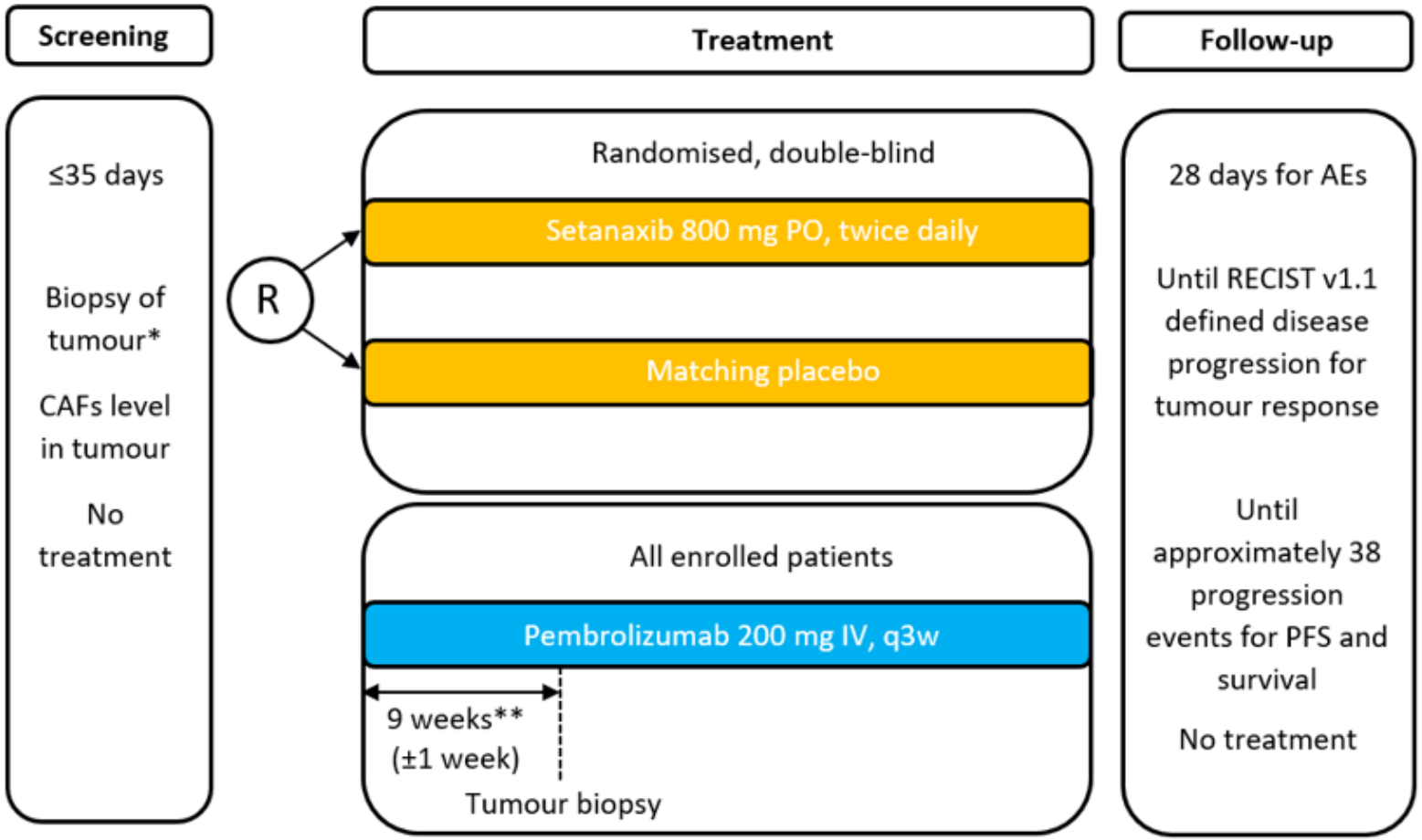
Setanaxib Update

Results of GSN000400 – setanaxib in recurrent or metastatic squamous cell carcinoma of the head & neck

Study Design



Topline Results

Results announced on 6th May

- Study conducted at 37 sites in 7 countries (UK, US, France, Germany, Spain, Italy, Poland)
- LPI 25-Oct-2023 with data collected until 19-Feb-2024 when all randomized patients had at least 15 weeks of follow-up
- Primary Analysis of 55 randomized patients, including 38 progression events
- Treatment groups well-balanced at baseline
  - No exclusions from analysis sets, no important deviations were considered to impact efficacy

Topline Results

Results announced on 6th May

- Statistically significant improvements[1] in progression-free survival (PFS) and overall survival (OS) were observed
  - Median PFS was 5 months versus 2.9 months, setanaxib versus placebo (Hazard ratio= 0.58)
  - OS was 92% vs 68% at 6 months and 88% vs 58% at 9 months, setanaxib versus placebo (Hazard ratio=0.45)
- 70% of setanaxib-treated patients showed a best response of at least stable disease compared to 52% in placebo-treated patients
  - Responses appeared to be more durable in setanaxib-treated patients
- Increase in CD-8+ T-cells in tumour tissue (transcriptomic analysis)
- No significant difference in the primary endpoint of best percentage change from baseline in tumor size was observed
- Tolerability of setanaxib when given with pembrolizumab was generally good, with no new safety signals identified

*Met the pre-defined threshold for statistical significance of p<0.2

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Summary

- Statistically significant improvements[1] in progression-free survival (PFS) and overall survival (OS), with more durable responses in setanaxib-treated patients
- Increase in intra-tumoral CD-8+ T-cells in setanaxib-treated patients
- No new safety signals

*Met the pre-defined threshold for statistical significance of p<0.2

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President, North America Maria Törnsén

Q1 2024 US Financial Metrics

705
New Patients enrolled in Q1
27% QoQ growth

354
New Prescribers in Q1
LTD Prescribers: 1,993
17% QoQ growth

$26.8M
Net sales of TARPEYO in Q1 2024

$25.5M
Preliminary Net sales of TARPEYO Q2 QTD

- Strong underlying demand for Tarpeyo, 27% QoQ, following a 51% growth from the prior quarter
- Strongest quarterly gain of new prescribers with 354 prescribers added in Q1

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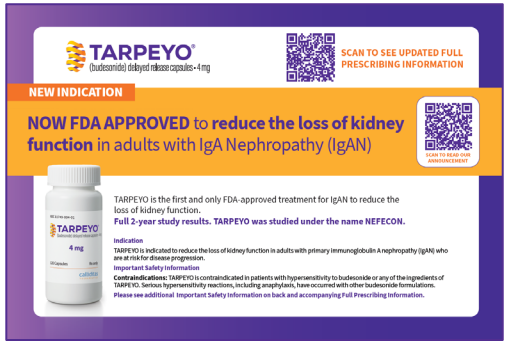
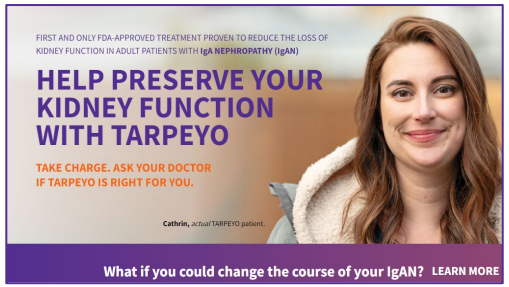
Q1 Achievements

- **Full Approval Launch – The expanded field teams were equipped and ready to promote the new label**
  - First and only product FDA-approved to reduce the loss of kidney function for patients at risk of progression
  - TARPEYO is the only approved immunomodulating, disease-modifying therapy designed to target the production of pathogenic Gd-IgA1, yielding significant eGFR benefits



- **Patient Education – Launched new patient education materials & programs to drive patient education**
  - Patients like that TARPEYO is a once-daily treatment with a defined 9-month treatment course and a significant impact on kidney function. This affords them the freedom to complete a course and see lasting results beyond the treatment course
  - Patients are aware of the lack of monitoring needed for TARPEYO and no REMS



- **Scientific Exchange & Data Generation – Drove peer-to-peer engagements**
  - Presentations at WCN highlighted eGFR results found in patients on Nefecon, sub-analysis evaluating benefits of Nefecon for patients with lower levels of UPCR, and the data on quality of life during the trial

- **Payer Education – Accelerated engagements with payers to update coverage policies**

Exciting Journey Ahead

Continue US promotional efforts to drive TARPEYO's positioning as a disease-modifying backbone therapy in IgAN

Drive scientific exchange and data dissemination at major scientific congresses & programs (e.g. ERA, NKF, ASN)

Leverage KDIGO guidelines

expected in 2024

Educate and inform US payors on the full approval to ensure TARPEYO payor policies are reflecting new label

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CFO Fredrik Johansson

Financial Overview – First Quarter 2024

MSEK	Jan-Mar 2024	Jan-Mar 2023
Net sales	295,5	191,4
Gross profit	281,5	182,3
Operating loss	203,8	180,1
Loss for the period	246,2	187,5
	Mar 31 2024	**Mar 31 2023**
Cash Position	810,3	1013,6

- Total revenues for Q1 2024 of SEK 295.5 M vs SEK 191.4 M for Q1 2023.
  - Whereof SEK 278.3 M (USD 26.8 M) in Q1 2024 in net sales from TARPEYO vs SEK 185.7 M (USD 17.8 M) for Q1 2023, a growth of 50%.
  - Whereof SEK 13.0 M from partners for Q1 2024 vs SEK 4.4 M for Q1 2023.
- Operating expenses in Q1 2024 amounted to SEK 485.3 M vs SEK 362.4 M for Q1 2023.
- Operating loss in Q1 2024 amounted to SEK 203.8 M vs SEK 180.1 M for Q1 2023.
- Cash used in operating activities for Q1 2024 amounted to SEK 198.2 M vs SEK 231.9 for Q1 2023.
- The cash position per end of March 2024 was SEK 810.3 M vs SEK 1,013.6 M per end of March 2023.

Key Takeaways for the quarter

- Record quarter in terms of enrolments and new prescribers
- New patent issued covering TARPEYO with expiry in 2043
- Orphan exclusivity in the US for new indication with expiry in December 2030
- Continued strong demand for TARPEYO
- Validating clinical data for setanaxib anti fibrotic effect
- Total revenue guidance for 2024 unchanged, reflecting strong growth expectations of USD 150 – 180M

- **Category leader – Disease modification**