calliditas
THERAPEUTICS

Corporate Presentation

November 2023

Disclaimers

Important information

This presentation contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, statements regarding Calliditas' strategy, commercialization efforts, business plans, regulatory submissions, clinical development plans and focus. The words "may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "project," "potential," "continue," "target," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements in this presentation are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties, and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this presentation, including, without limitation, any related to Calliditas' business, operations, continued and additional regulatory approvals for TARPEYO and Kinpeygo▼, market acceptance of TARPEYO and Kinpeygo, clinical trials, supply chain, strategy, goals and anticipated timelines, competition from other biopharmaceutical companies, revenue and product sales projections and forecasts and other risks identified in the section entitled "Risk Factors" in Calliditas' reports filed with the Securities and Exchange Commission. Calliditas cautions you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. Calliditas disclaims any obligation to publicly update or revise any such statements to reflect any change in expectations or in events, conditions, or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements. Any forward-looking statements contained in this presentation represent Calliditas' views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date.

calliditas THERAPEUTICS

Calliditas is a biotech company developing and commercializing novel treatments in rare diseases with significant unmet medical needs

Commercial asset TARPEYO (U.S.) / KINPEYGO (Europe, UK), is the first therapy approved to treat Immunoglobulin A nephropathy (IgAN), an autoimmune disease of the kidney

First-in-class NOX inhibition platform with late-stage pipeline in rare diseases

Strategy to continue to build the company through in-licensing and/or acquisition of products or product candidates

OMX NASDAQ (CALTX)
NASDAQ (CALT)

HEADQUARTERS: Stockholm

Cash (30/09/23): SEK 787m
(~$73m)

calliditas THERAPEUTICS

Pipeline Designed to Develop Novel Treatments in Rare Diseases

	Phase 1	Phase 2	Phase 3	Marketed	Rights	Commercial Region	Milestones
NEFECON (indication)							
TARPEYO (budesonide) delayed release capsules - 4 mg / KINPEYGO 4 mg Modified-release hard capsules budesonide Immunoglobulin A nephropathy (IgAN)					calliditas THERAPEUTICS	+ ROW	*Filed for full approval in the US in June 2023, PDUFA date Dec 20**
					STADA		*STADA filed for full approval with EMA in September 2023*
					EVEREST MEDICINES		*NDA accepted and FTD received in China. Decision expected in Q4 2023*
					VIATRIS		*Discussions with regulators initiated regarding approval requirements*
SETANAXIB (indication)							
Primary Biliary Cholangitis							*Phase 2 readout mid 2024*
Squamous Cell Carcinoma of Head and Neck					calliditas THERAPEUTICS		*Phase 2 readout 1H 2024*
Idiopathic Pulmonary Fibrosis							*Phase 2 readout 2H 2024*
Alport Syndrome							*Trial initiation targeted for Q4 2023*

* Approved under accelerated approval in the USA under the tradename TARPEYO®. TARPEYO (budesonide) delayed release capsules is a prescription medicine used to reduce levels of protein in the urine (proteinuria) in adults with a kidney disease called primary immunoglobulin A nephropathy (IgAN) who are at high risk of rapid disease progression, generally UPCR ≥ 1.5g/g

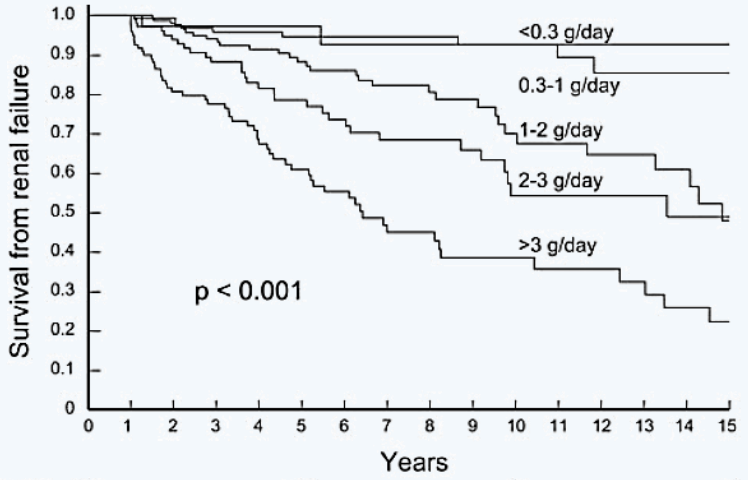
Commercial
Ongoing Trial
Planned Trial
Investigator Led Trial

calliditas THERAPEUTICS

IgA Nephropathy – A Large Market Opportunity

Patient Profile

- Genetic predisposition is required but not sufficient; most patients diagnosed in their 20s and 30s
- More than 50% are at risk of developing ESRD within 10-20 years, leading to haemodialysis or kidney transplant
- Treatment goal is to preserve eGFR / kidney function
- Proteinuria levels of > 1g/24h indicate a risk of disease progression and worse outlook



<0.3 g/day	37	22	8	1
0.3-1 g/day	134	79	35	11
1-2 g/day	145	79	28	10
2-3 g/day	105	50	18	4
>3 g/day	120	44	13	6

Figure 1. Renal survival by category of TA-proteinuria.

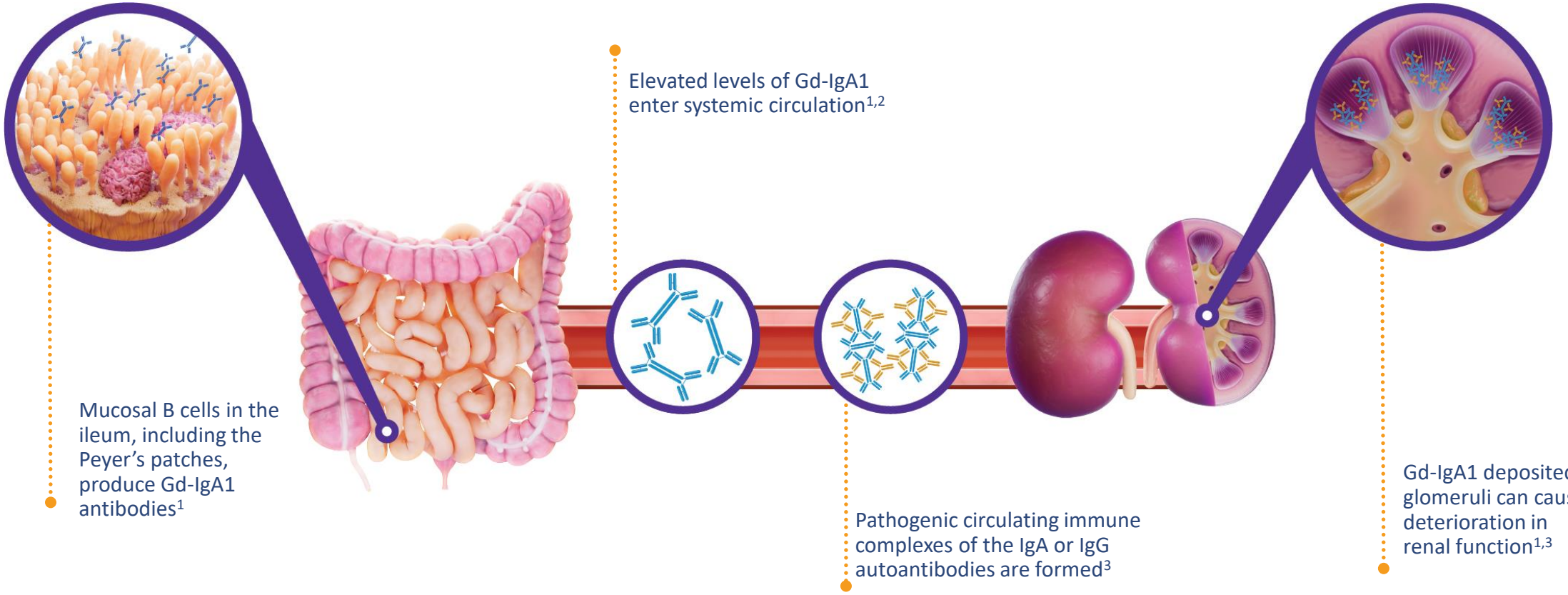
Estimated Prevalence

130,000 - 150,000	
200,000	
c.5,000,000	

Multi billion dollar global addressable Market

calliditas THERAPEUTICS

Understanding the pathophysiology of IgAN is essential for developing effective treatment approaches



Gd-IgA1, galactose-deficient immunoglobulin A1; IgA, immunoglobulin A; IgG, immunoglobulin G.

1. Barratt J, et al. Kidney Rep. 2020;5(10):1620-1624. 2. Kiryluk K, et al. J Clin Invest. 2014;124(6):2325-2332. 3. Canetta PA, et al. Clin J Am Soc Nephrol. 2014;9(3):617-625.

calliditas THERAPEUTICS

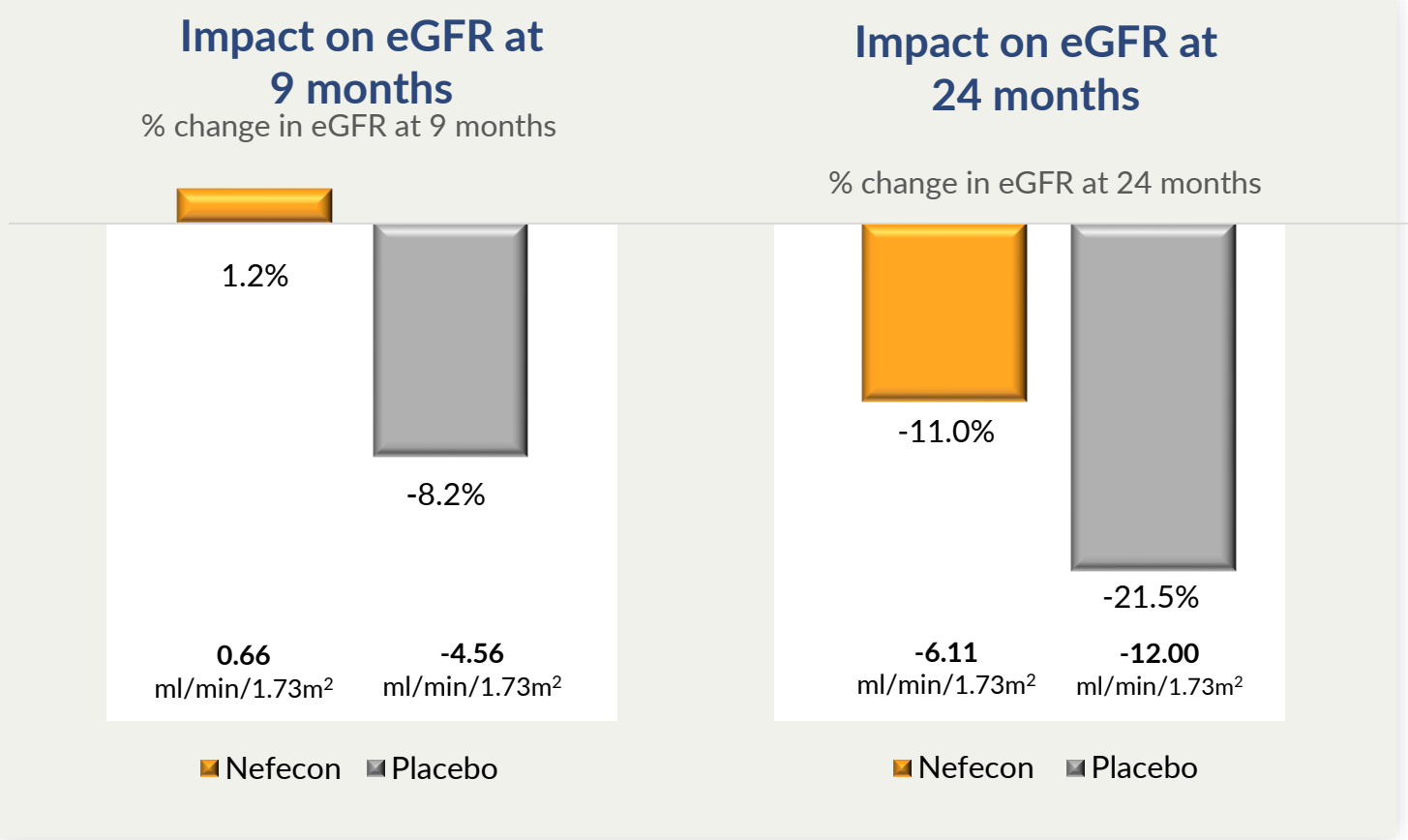
calliditas
THERAPEUTICS

Pioneering New Treatment in IgA Nephropathy

eGFR Phase 3 Data – effects supporting disease modification

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

eGFR stabilization with Nefecon (16 mg) compared to placebo during 9 months treatment, showing durability over 15 months of observation ($p < 0.0001$)

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:

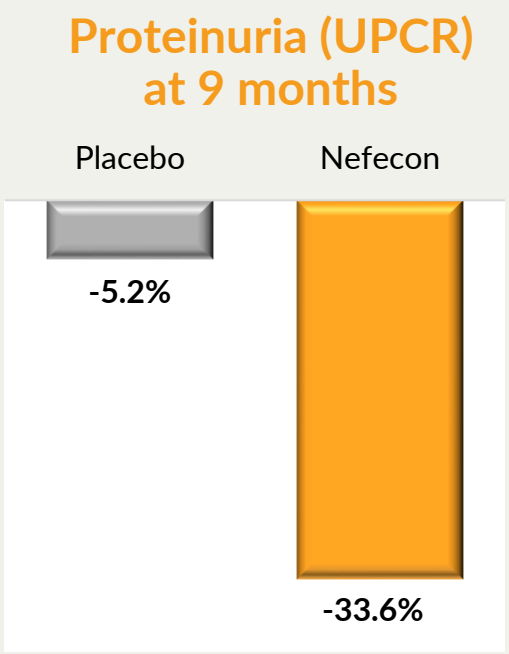
- eGFR decline for Nefecon treated patients: 6ml/min/1.73m^2 vs 12ml/min/1.73m^2 for placebo
- Total 2-year slope improvement with Nefecon ~3ml/min per year

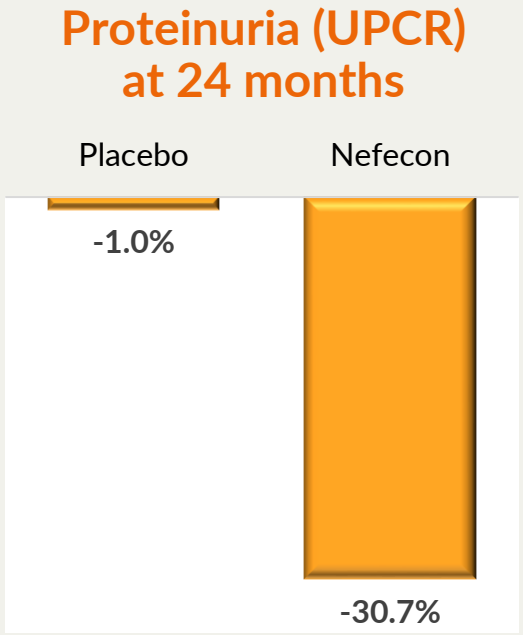
calliditas THERAPEUTICS

Phase 3 NefIgArd Study Results: UPCR & Safety

Effect on UPCR Maintained at 9 Month Level, or Lower, from the End of Treatment Through 15 Months Off Drug

Patients treated wit Nefecon maintained more than 30% proteinuria reduction from the end of treatment (9 months) through the follow-up period, with over 50% reduction observed at 12 months





Nefecon was generally well tolerated

The adverse event profile was similar to that reported in the interim readout

- Objective measures of mean weight and BP showed non-clinically relevant, fully reversible changes
- The most commonly reported TEAEs observed with an increased frequency compared to placebo were peripheral oedema, 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.

calliditas THERAPEUTICS

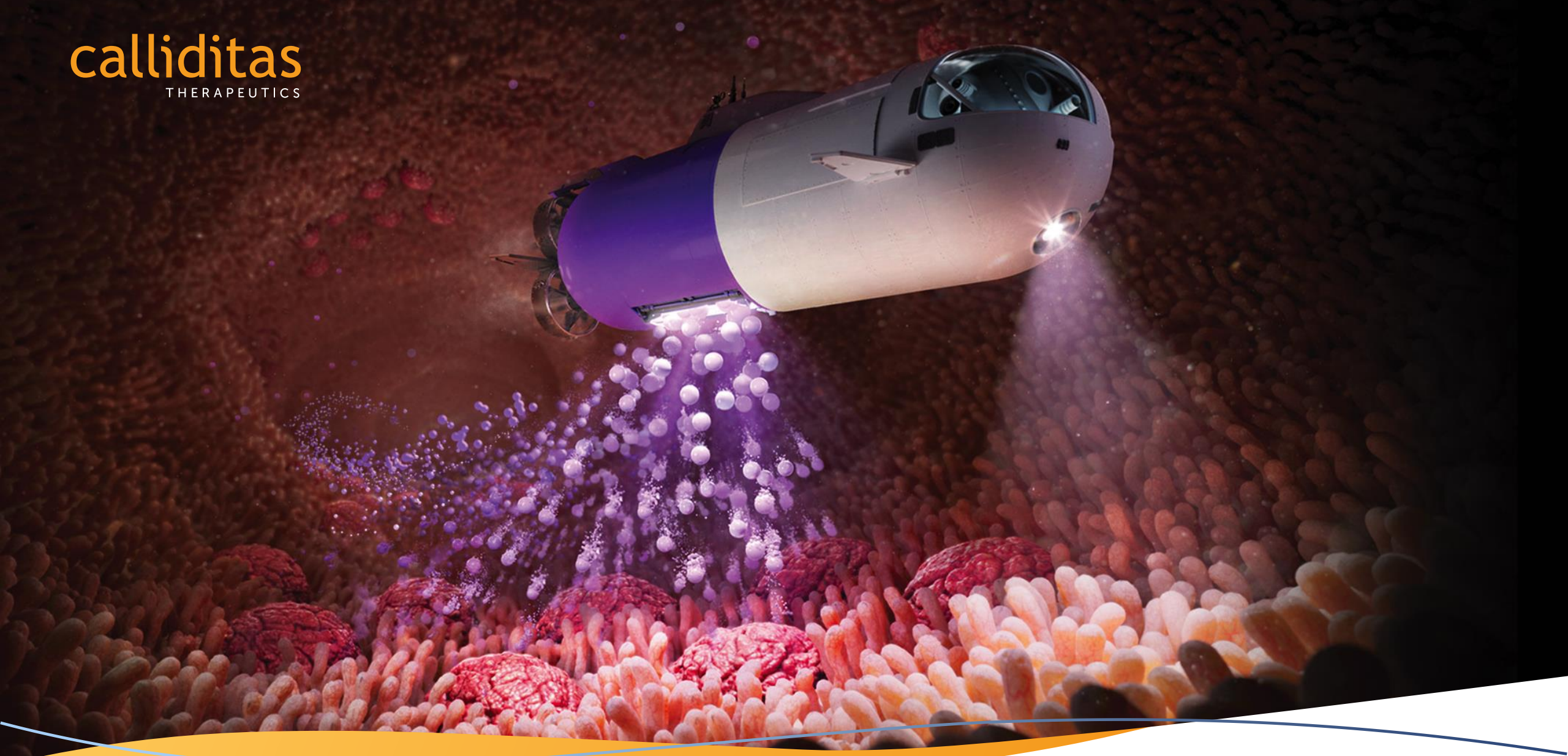
Nefecon Has the Potential to Establish New Standard of Care in IgAN

Mechanism of Action	Targeted B cell immunomodulator designed to locally target origin of disease – disease modifying potential
Patient focus	In combination with the optimized RASi therapy; option of intermittent, rather than chronic treatment
Efficacy	Durable eGFR benefit and sustained proteinuria reduction validate disease-modifying effects in IgAN
Safety	Well characterized active ingredient and safety profile

Filed for full approval in June 2023 with the FDA, September 2023 with EMA and October 2023 with MHRA based on the Phase 3 trial

calliditas THERAPEUTICS

calliditas
THERAPEUTICS



TARPEYO®
(budesonide) delayed release capsules • 4 mg

First Approved Medication for IgAN in Europe & USA

TARPEYO®
(budesonide) delayed release capsules · 4 mg

The first FDA approved drug specifically targeting Immunoglobulin A Nephropathy (IgAN)
Approved by FDA in December 2021; Launched in Jan 2022

The first and only EMA approved drug specifically targeting IgAN
European Commission approval in July 2022
Commercial Partner, STADA launched in Germany in September 2022

KINPEYGO 4 mg
Modified-release hard capsules
budesonide

Accelerated approval in the US to reduce proteinuria in adults with IgAN at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) ≥ 1.5 g/g

Phase 3 long term data shows durable proteinuria response and sustained eGFR effect in study population off drug, supporting disease modification

calliditas THERAPEUTICS

Recent Company Highlights – YTD Q3 2023

Continued Growth and Progress Executing on Our Strategy

Financial Highlights

TARPEYO net sales for 9 Months 2023	**SEK 729 M (USD 69 M)**
TARPEYO net sales for 9 Months 2022	**SEK 205 M**
Cashflow used in operating activities Q3 2023	SEK 62.5 M
Cash position end of Q3 2023	SEK 787 M

256% growth
year over year

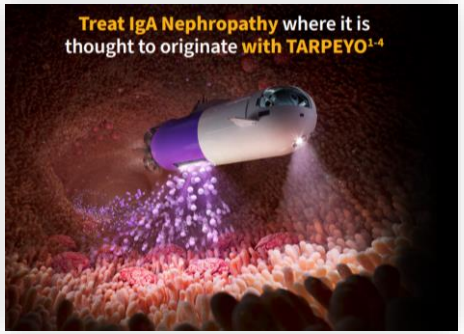
50% reduction
year over year

Calliditas is a category leader driving growth in a large market

calliditas THERAPEUTICS

Continue to Build upon Success with A Focused Strategic Approach

HCP Education & Engagement

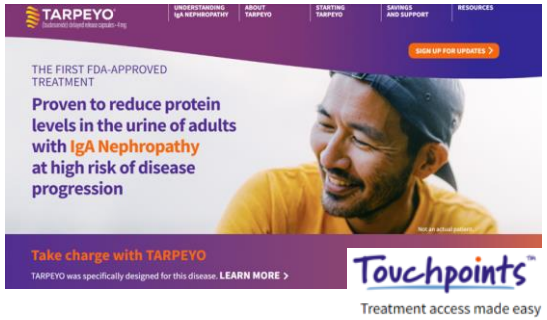


IgAN & TARPEYO education, targeting underlying pathology, Peer-to-Peer Engagements

Ensuring Access & Reimbursement

Integrated HUB* and exclusive specialty pharmacy, integrated with financial assistance program provided by CoverMyMeds

Patients Education & Support

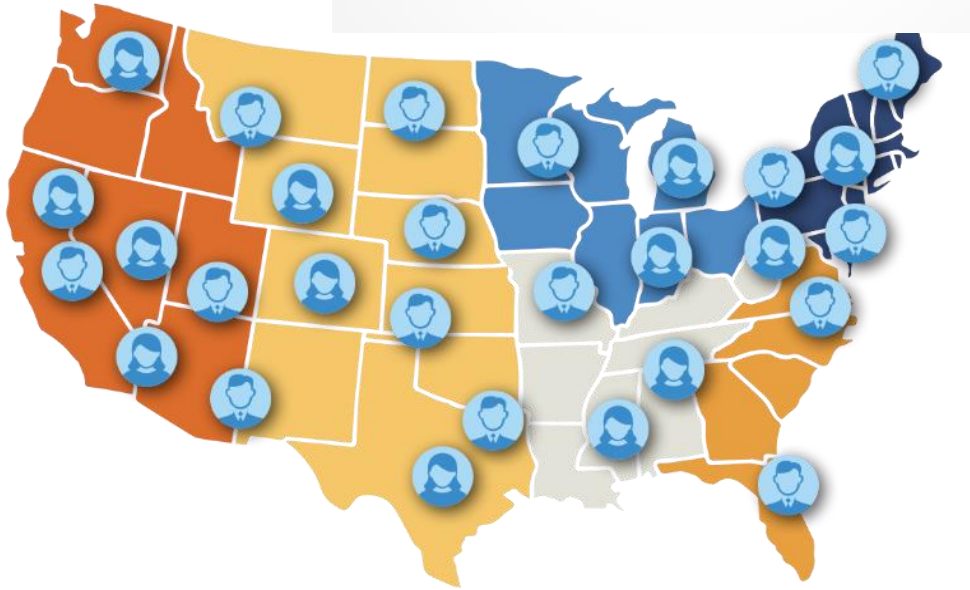


Dedicated case managers and designated Rare Pod Team (nurses, pharmacists, fulfilment and distribution team) to support patients and prescribers to ensure adherence and outcomes

*HUB: Allows a manufacturer to have a singular point of contact with patients. Services generally entail benefits investigation, prior authorization processing, drug delivery and administration support, financial and co-pay assistance, education, compliance with risk evaluation and mitigation strategies (REMS), data reporting, bridge supplies, and prescription triaging.

Strong US Commercial leadership team generating results

- Nephrologist awareness, now over 90%, peer to peer recommendations building
- Experienced sales force: 70 sales reps with core background in nephrology, rare disease, specialty products
- Market access: Over 90% coverage of US lives achieved
- Increasing clinical evidence available and positive outcomes for a growing number of patients taking TARPEYO



calliditas THERAPEUTICS

Commercial Experience - Key Takeaways

- Over 1200 unique subscribers to date, and growing
- Majority of patients that have received 9 months of treatment remain on therapy beyond 9 months; too early to assess retreatment paradigm
- The channel mix of patients on therapy to date is primarily commercial ~70%
- Nephrology research continues to support their view and goal of eGFR stabilization when treating IgAN
- Increasing evidence of faster progression than assumed among patients at risk, as well as a broader, less severe patient population requiring dialysis in their lifetime
- Lack of experience of specialty product processes / not an acute disease; urgency to treat not always present, recent published data (clinical / longitudinal), education and guideline update will drive revised approach to disease management

calliditas THERAPEUTICS

Full approval – potential impact

Based on Phase 3 data achieving primary endpoint with high statistical significance and reflecting eGFR effect across entire study population

Reduced market access friction

Significantly larger addressable market

Revised label reflecting impact on kidney function

Updated KDIGO guidelines during 2024 supporting use of approved drugs / potentially broadening definition of population at risk

Ex-US Commercial Partnerships

STADA

2021: Partnered with STADA in the European Economic Area (EEA) member states, Switzerland, and the UK

Initial upfront payment of 20M EUR ($20M) and up to an additional 77.5M EUR ($77.6M) in future milestone payments, as well as tiered royalties on net sales at a low 20s to low 30s percentage.

EVEREST MEDICINES

2019: Partnered with Everest Medicines in Greater China, Taiwan, Singapore and South Korea (2022)

Initial upfront payment of 15M USD
Up to an additional 106M USD in future milestone payments, as well as royalties on annual net sales at a low- to mid-teens percentage

VIATRIS™

2022: Partnered with Viatris in Japan.

Initial upfront payment of US$20M upon signing and up to an additional US$80M in pre-defined development and commercialization milestones. Viatris will also pay mid-teens percentage royalties on net sales.

calliditas THERAPEUTICS

calliditas
THERAPEUTICS

NOX Inhibitor Development Program

A first-in-class platform

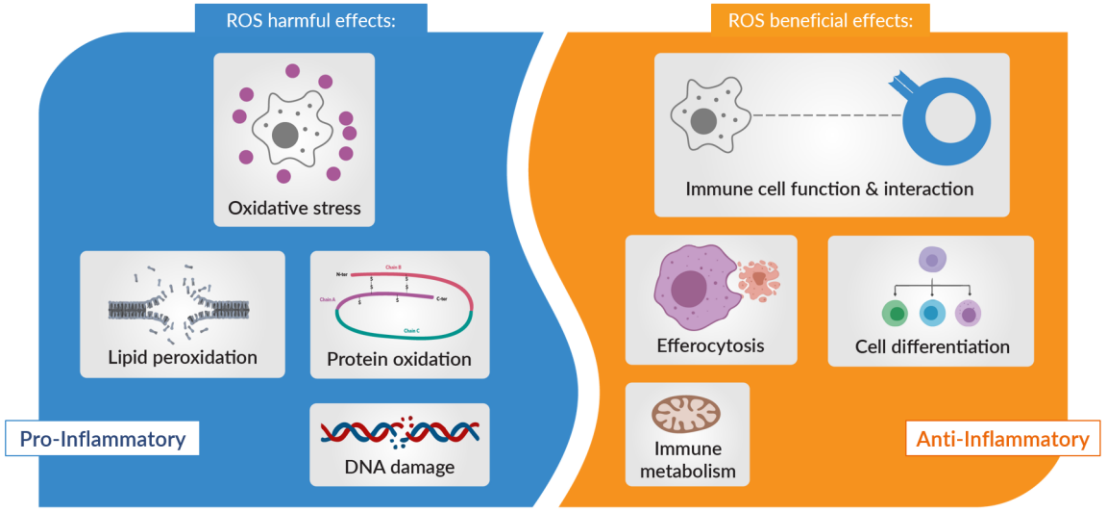
NOX1/4 are Important Targets for Therapeutic Inflammatory and Fibrotic Diseases Agents

NOX (NADPH oxidase) enzymes are dedicated to producing reactive oxygen species (ROS) which have a central role in cell signalling at appropriate concentrations

When a cell is injured, **excess NOX activity** is triggered and redox homeostasis becomes unbalanced, leading to **fibrogenesis**

Cancer cells also induce NOX enzymes in the microtumor environment, to create a favourable tumor growth and metastases

NOX1 and NOX4 enzymes are implicated in **inflammation and fibrosis pathways** and **represent a high potential therapeutic target**



Sullivan, L.B., Chandel, N.S. Mitochondrial reactive oxygen species and cancer. Cancer Metab. 2014; 2 (17) https://doi.org/10.1186/2049-3002-2-17

Meitzler J.L., Makhlouf H. R., Antony S., Wu Y., Butcher D., Jiang G., Juhasz A., Lu J., Dahan I., Jansen-Dürr P., Pircher H., Shah A. M., Roy K., Doroshow J.H. Decoding NADPH oxidase 4 expression in human tumors. Redox Biology, 2017 (13): 182-195. https://doi.org/10.1016/j.redox.2017.05.016 *Front Immunol.* 2021;12:635021 Frontiers | Reactive Oxygen Species in Autoimmune Cells: Function, Differentiation, and Metabolism (frontiersin.org)

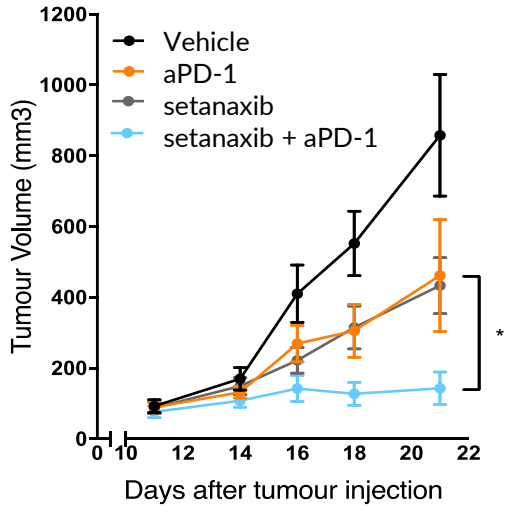
calliditas THERAPEUTICS

Preclinical Efficacy of Setanaxib + Anti-PD1 in CAF-Rich Solid Tumors

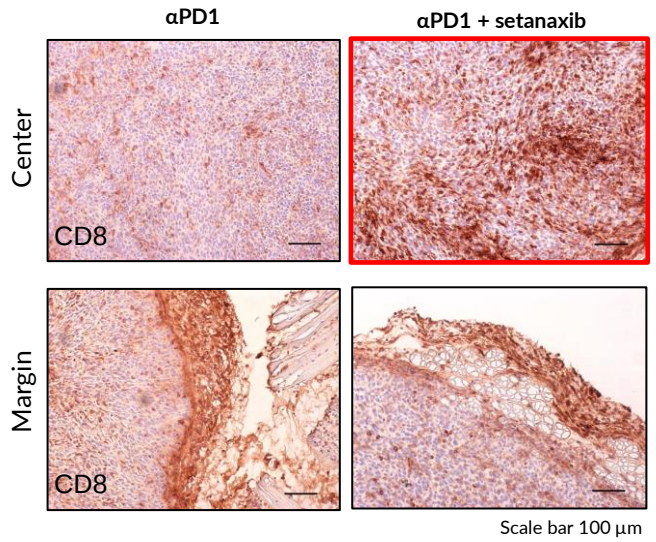
Setanaxib + anti-PD1 administration in murine CAF-rich solid tumor models resulted in **statistically significant**:

- Reduction in tumor volume
- Improvement in survival
- Improvement in immune cell penetration to the tumor center

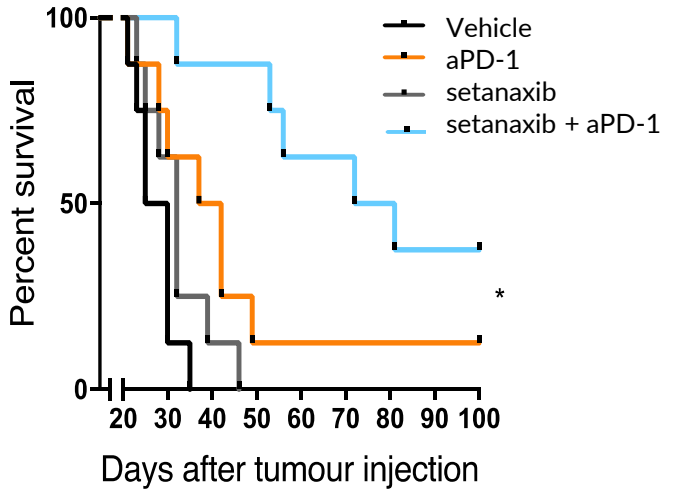
Tumor Growth



TIL Tumor Penetration



Survival



*p<0.05, CAF: Cancer-Associated Fibroblast, TIL: Tumor Infiltrating Lymphocytes, αPD-1: Anti-Programmed Death-Ligand 1 antibody

Ford K. et al. NOX4 Inhibition Potentiates Immunotherapy by Overcoming Cancer-Associated Fibroblast-Mediated CD8 T-cell Exclusion from Tumors. Cancer Res. 2020 May 1;80(9):1846-1860. https://doi.org/10.1158/0008-5472.CAN-19-3158

Ph2 Positive Interim Readout in SCCHN in July 2023

Data reflected encouraging early clinical PFS results and supports hypothesised anti-fibrotic MoA

16 evaluable patients after 9 weeks of treatment for tumor size and PFS results; in terms of PFS, 7 of the 16 patients were progression-free with either stable disease or partial response (6 setanaxib arm: 1 placebo arm).

A subset of 12 evaluable patients for biomarker analysis having had tumor biopsies before and after treatment; the transcriptomic analysis showed that the 2 top pathways impacted by the treatment were fibrosis-related signaling pathways (the IPF signaling pathway and hepatic fibrosis/stellate cell activation pathway) indication setanaxib's modulatory effect on activated myofibroblasts

Pathology analysis showed increased immunological activity within tumors of patients treated with setanaxib, with favorable changes in pathology markers Foxp3 and PDL-1 CPS

Full data readout expected 1H 2024 – basis for partnering discussions

PFS: Progression Free Survival, MoA: Mechanism of Action, IPF: Idiopathic Pulmonary Fibrosis, Foxp3: Forkhead Box Protein 3, PDL-1 CPS: Programmed Death-Ligand 1 Combined Positive Score

Press Release: Calliditas announces supportive interim data from Phase 2 head and neck cancer trial with lead NOX inhibitor candidate, setanaxib

calliditas THERAPEUTICS

Lead Compound Setanaxib, First NOX Inhibitor to Reach Clinical Stage, with Milestones Expected within 12 Months

Phase 2 study in H&N Cancer

Proof of concept study in SCCHN cancer with positive CAF level

50-patient study with setanaxib + pembrolizumab or placebo + pembrolizumab

Supportive interim readout

Final Phase 2 data expected in H1 2024

TRANSFORM trial in PBC

Ongoing Phase 2b Primary Biliary Cholangitis (PBC) trial

Protocol to be amended to enable data readout after Phase 2b portion

Data readout expected mid-2024

FDA Fast Track designation

Additional indications

Setanaxib evaluated in a **Phase 2 trial in IPF** (Investigator-led trial). Data expected in 2H 2024

Phase 2 **trial initiation** in Alport Syndrome in **H2 2023**

calliditas THERAPEUTICS

Exciting Journey Ahead in 2023

Opportunity for P2P education and Scientific Data presentations at key Nephrology conferences (ERA/EDTA, IIGANN, ASN)

Filed for full approval of TARPEYO in IgA Nephropathy; Priority review granted - PDUFA goal date: December 20, 2023

Regulatory decision in China expected in Q4 2023

Filed for full approval of Kinpeyo in IgAN with EMA; Decision expected in 1H 2024

Supportive interim biomarker readout in July from Head and Neck cancer – full data read out in 1H 2024

Initiation of Alport syndrome clinical trial in Q4 2023

calliditas THERAPEUTICS