calliditas
THERAPEUTICS

Corporate Presentation

September 2022

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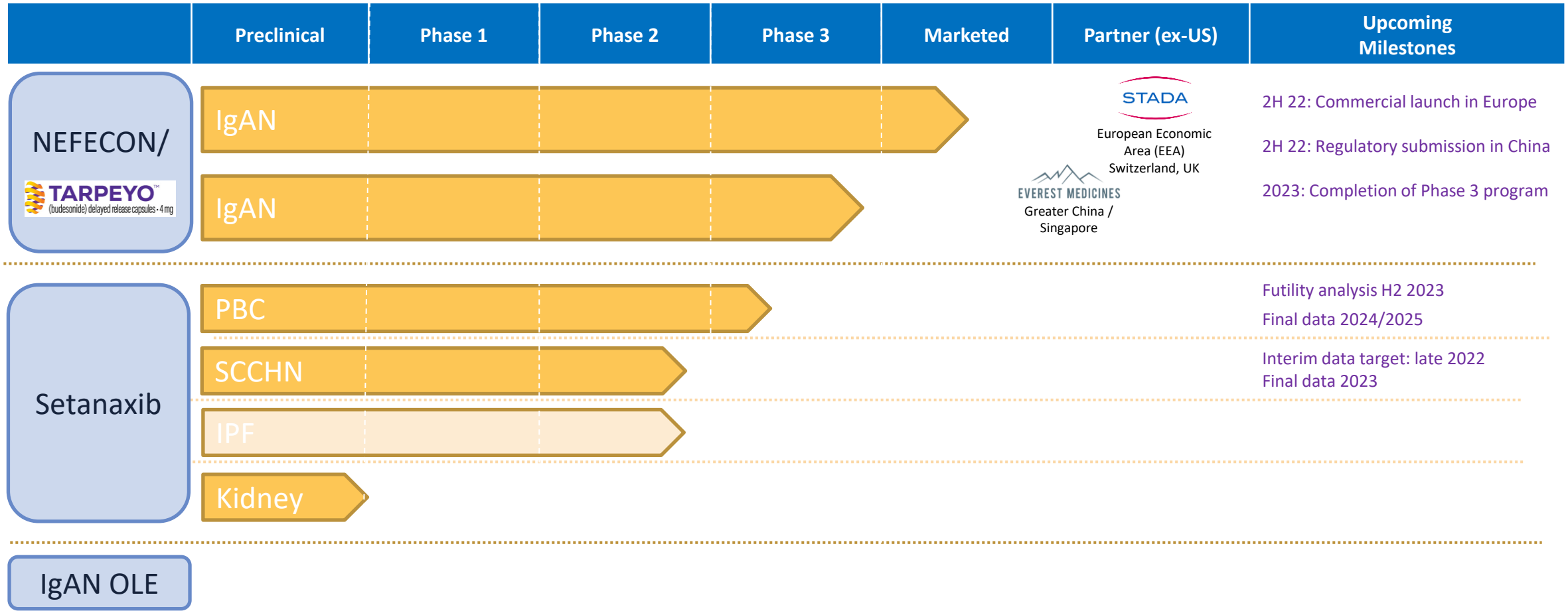
A commercial stage biopharma company focused on novel treatments in orphan indications, with an initial focus on renal and hepatic diseases with significant unmet needs.

- **Pioneers in immunoglobulin A nephropathy (IgAN);**
  - Positive Phase 2b results published in The Lancet
  - Successful top-line data read out from the ongoing Phase 3 **NefIgArd** trial in November 2020.
  - Both clinical trials met primary and key secondary endpoints.
  - December, 2021; the first and only FDA approved medication for this rare disease
  - May 2022; positive CHMP opinion in Europe; July 2022, EC approval

- **Strong pipeline in orphan liver and kidney indications; platform of first-in-class NOX Inhibitors.**
  - Actively expanding through in-licensing and/or acquisition of product candidates.

Headquartered: Stockholm	
Exchange	OMX NASDAQ (CALTX)
	NASDAQ (CALT)
Key Institutional Shareholders	
BVF Capital Industrifonden Sofinnova Partners Linc	
Cash (30/06/22): **SEK 846.8 M**	

Pipeline



Depicts ongoing/planned clinical trial stage: Depicts Investigator Led Trial:

† Open Label Expension, intended to primarily support treatment-related considerations

* 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.

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First and Only Approved Medication for IgAN in Europe & USA

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

The first and only EMA approved drug specifically designed for IgAN
Positive CHMP Opinion in May 2022, European Commission approval in July 2022
MAA being transferred to Commerical Partner, STADA;
Launch in Q3 2022

Launched under an accelerated approval 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

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IgA Nephropathy – a significant unmet medical need

Profile

- Genetic predisposition is required but not sufficient; environmental, bacterial, dietary factors may play a role
- More than 50% are at risk of developing ESRD within 10-20 years, which can only be treated via regular haemodialysis or kidney transplant
- High levels of proteinuria is connected to disease progression and worse outcomes for patients

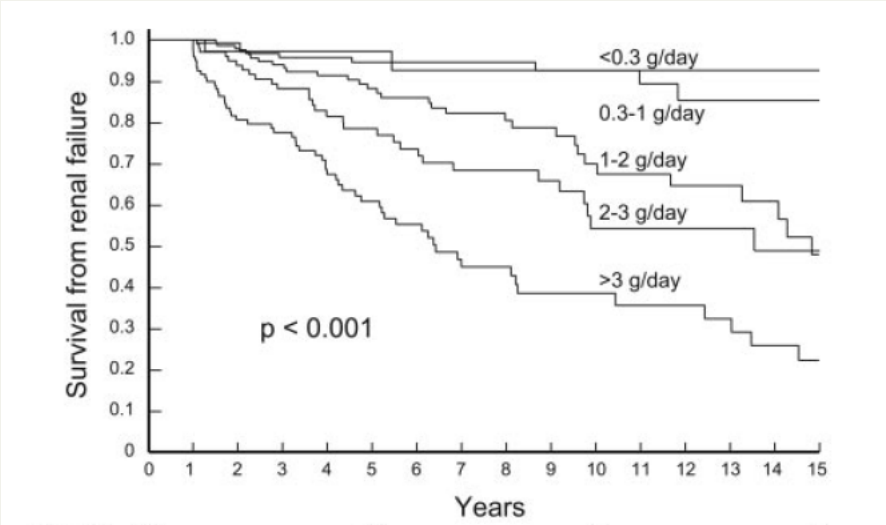


Figure 1. Renal survival by category of TA-proteinuria.

Estimated Prevalence

Market Opportunity

130,000 - 150,000

200,000

2,000,000

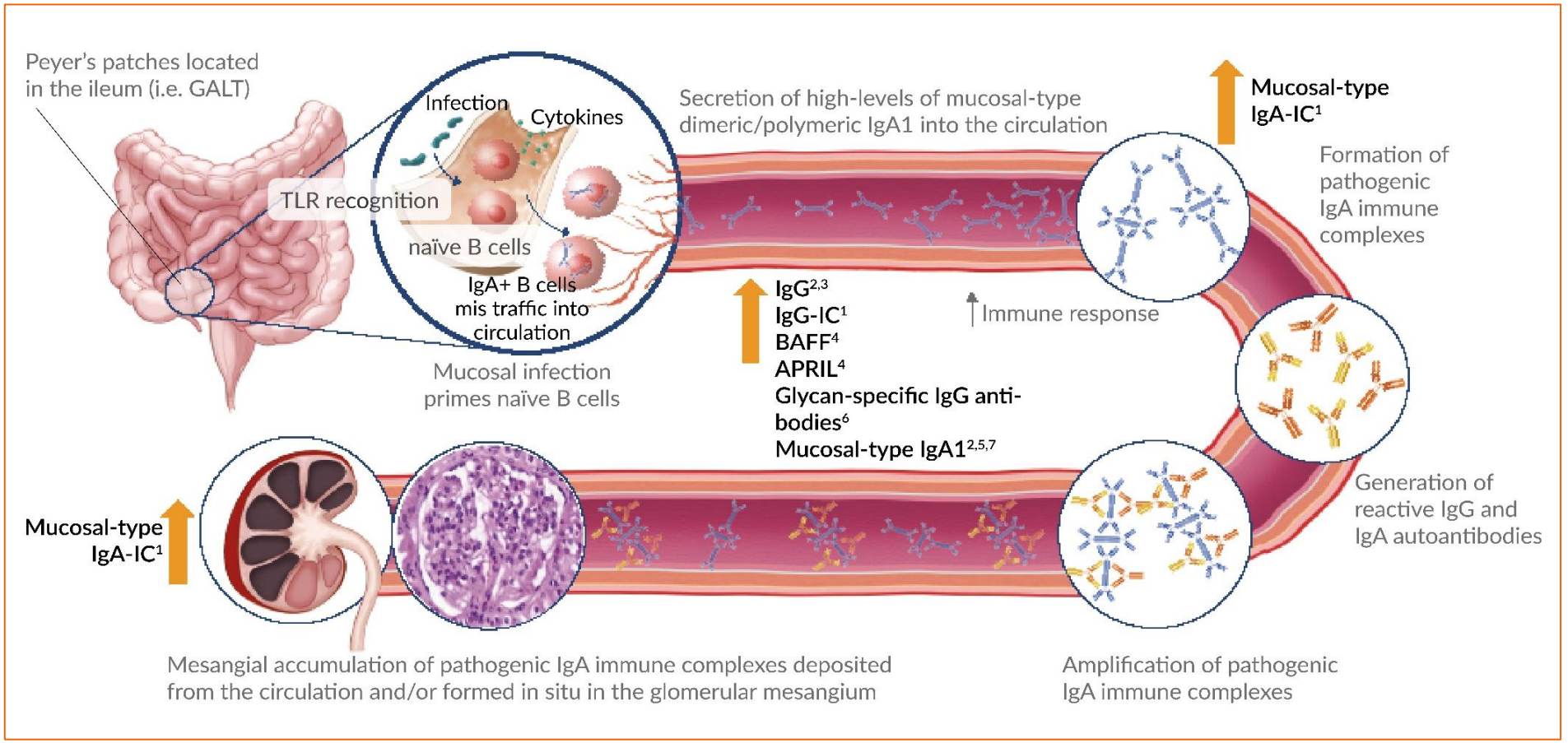
Pathophysiology of IgAN – predominant theory

Patients with IgAN have an increased appearance in the blood of secretory IgA antibodies, which are produced in the Peyer's patches, that lack galactose units in the hinge region

These galactose-deficient IgA antibodies are immunogenic, triggering IgA and IgG autoantibody production directed against the hinge region

The galactose-deficient secretory IgA antibodies form immune complexes with the IgA and IgG autoantibodies

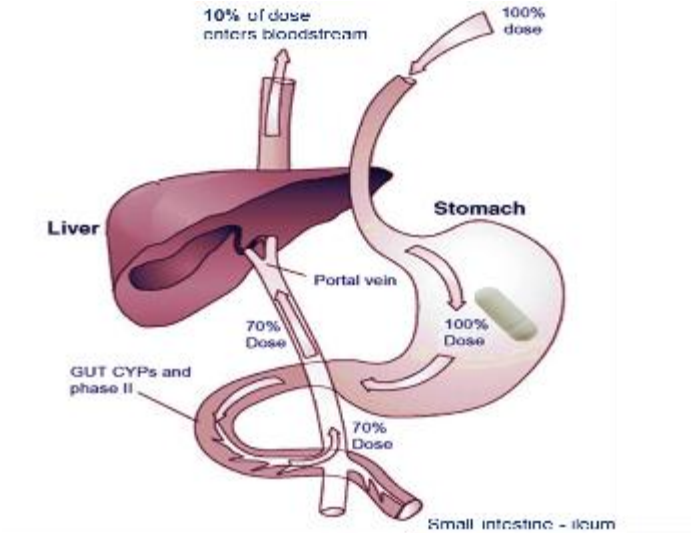
These immune complexes are deposited in the glomeruli of the kidney, causing an inflammatory cascade and destroying the glomeruli. This reduces the kidney's ability to remove waste products from the blood and eventually may result in ESRD



Designed to target the presumed origin of the disease

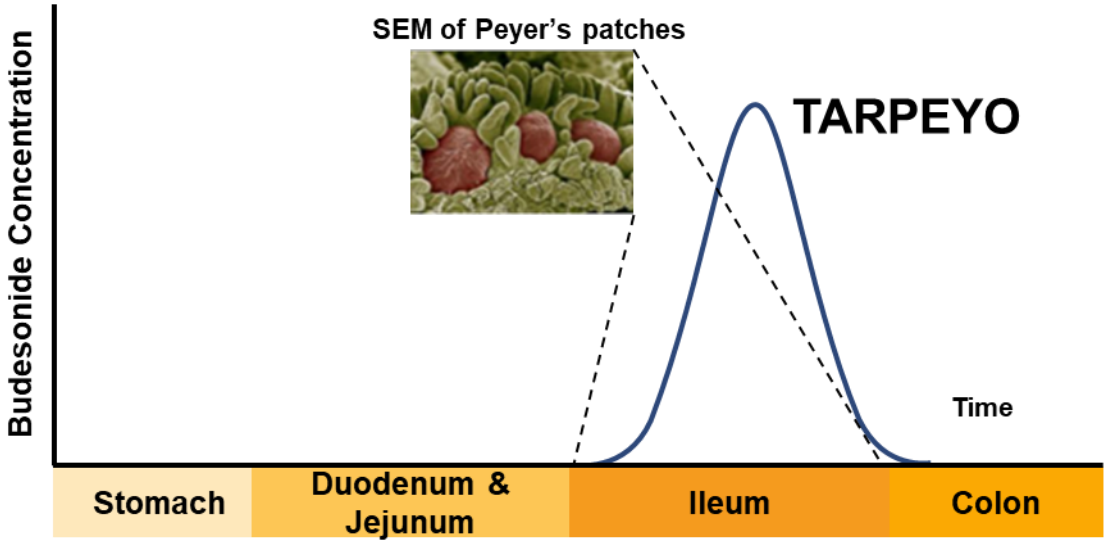
Drug product based on known active ingredient

- Active ingredient is budesonide – a highly potent, locally acting corticosteroid
- 90% cleared in first pass metabolism by liver, with the view of minimizing systemic side effects
- Safety profile as expected for oral administration; predominantly mild to moderate AEs, reversible upon discontinuation



Novel targeted release profile

- Designed to deliver a targeted and highly potent dose directly to Peyer's patches in the ileum
- Differentiated release profile
  - pH-governed delayed disintegration of the capsule until it reaches the ileum
  - Potent, sustained exposure throughout the ileum



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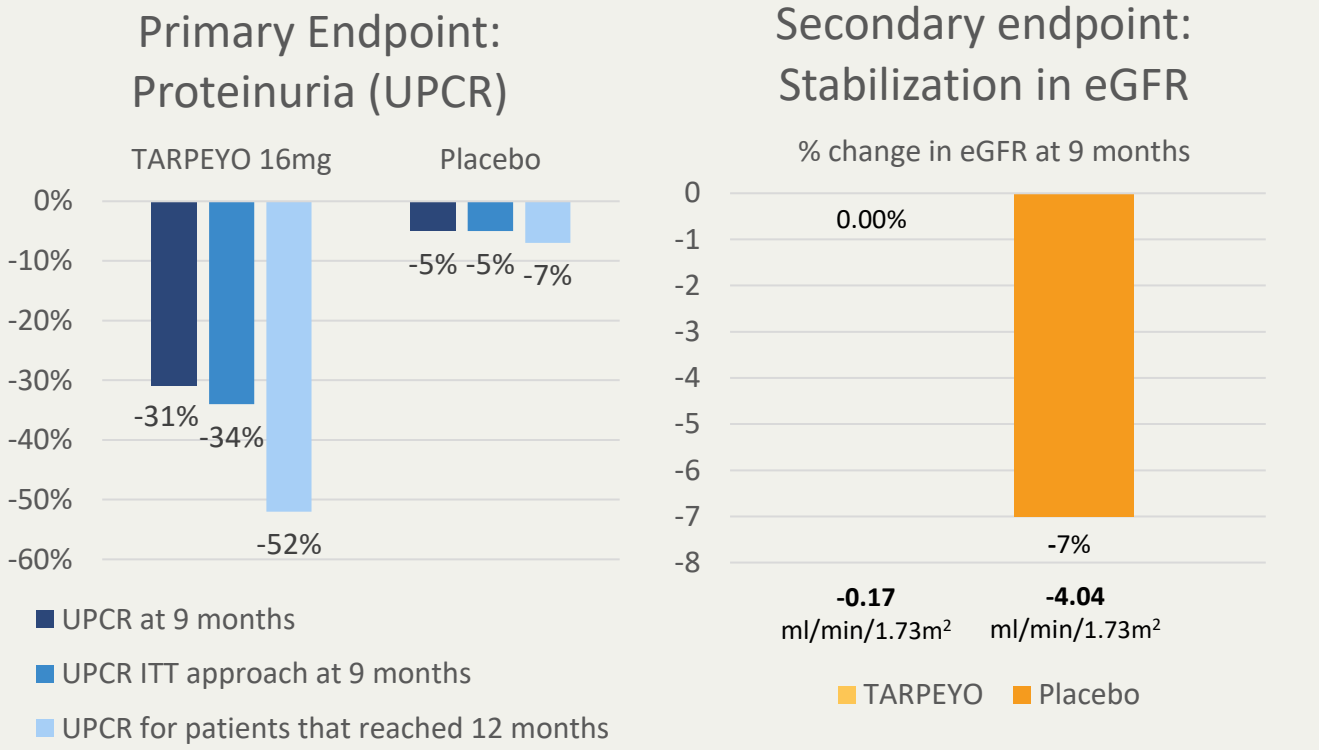
Positive Phase 3 Data – Part A Efficacy Results

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.



Efficacy Findings

- Statistically significant UPCR reduction with TARPEYO (16 mg) compared to placebo following 9 months treatment (p=0.0001)
- After 9 months
  - Reduction in UPCR for TARPEYO treated patients = 31%
    In ITT population, this reduction was 34%
  - Reduction in UPCR for placebo = 5%
- After 12 months
  - Reduction in UPCR for TARPEYO treated patients = 52%
  - Reduction in UPCR for placebo = 7%
- Statistically significant eGFR stabilisation
  After 9 months:
  - eGFR decline for TARPEYO treated patients = 0.17ml/min/1.73m^2
  - eGFR decline for placebo = 4.04ml/min/1.73m^2

Safety Findings

- Generally well-tolerated; majority of AR mild/moderate in severity
- No adverse clinical effects on the cardiovascular or metabolic system
  No severe infections

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TARPEYO: Defining the market with the first and only FDA approved drug in IgAN

TARPEYO™ (budesonide) delayed release capsules is a corticosteroid indicated to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) ≥1.5 g/g. This indication is approved under accelerated approval based on a reduction in proteinuria. It has not been established whether TARPEYO slows kidney function decline in patients with IgAN. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory clinical trial.

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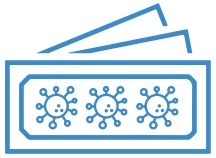
TARPEYO™ (budesonide) delayed release capsules

*Please see full Prescribing Information, available at TARPEYOHCP.com.

The US IgAN market: Substantial unmet need

High disease prevalence

- US prevalence: between 130,000 and 150,000
- ~50% of patients are at risk of progressing to end-stage renal disease
- 65% of patients with IgAN likely to progress to dialysis according to treating physicians



Costs associated with disease progression are high

- Costs of dialysis can be significant, at >$200,000 a year (commercial payers)
- Kidney transplants can cost >$400,000 and do not always prevent disease recurrence*

Source: Spherix Global Insights, RealWorld Dynamix IgA Nephropathy 2021 with 188 nephrologists (note 'Nefecon' was the product name used in the research)

*Cost of dialysis: Childers CP, Dworsky JQ, Kominski G, Maggard-Gibbons M. A Comparison of Payments to a For-profit Dialysis Firm From Government and Commercial Insurers. JAMA Intern Med. 2019;179(8):1136–1138. doi:10.1001/jamainternmed.2019.0431. Cost of transplant: https://www.statista.com/statistics/808471/organ-transplantation-costs-us/).

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Established highly successful support service for frictionless access

- TARPEYO Touchpoints™: full-service patient and provider support program. Fully operational on day 1 of TARPEYO approval
- Utilizes Biologics by McKesson's PharmacyElite™ model; integrated HUB* and exclusive Specialty Pharmacy
- Staffed by Care Navigators: dedicated case managers + designated Rare Pod Team (nurses, pharmacists, fulfillment and distribution team)
- Integrated with a financial assistance (commercial co-pay) program provided by CoverMyMeds® from McKesson

*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.

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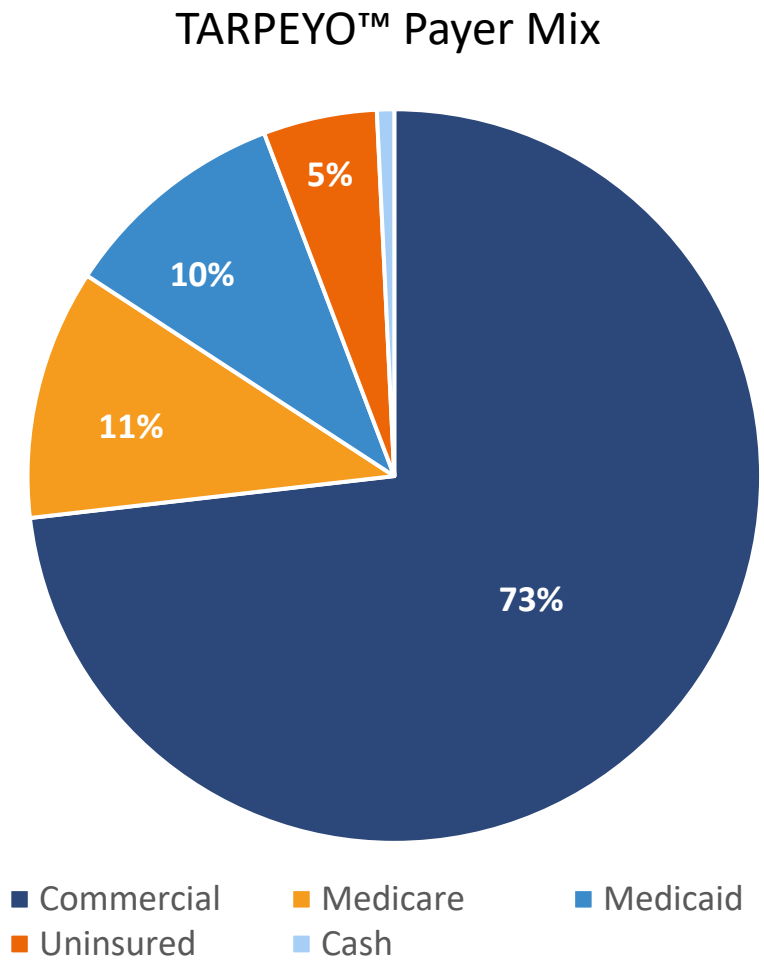
Pivotal progress made with market access

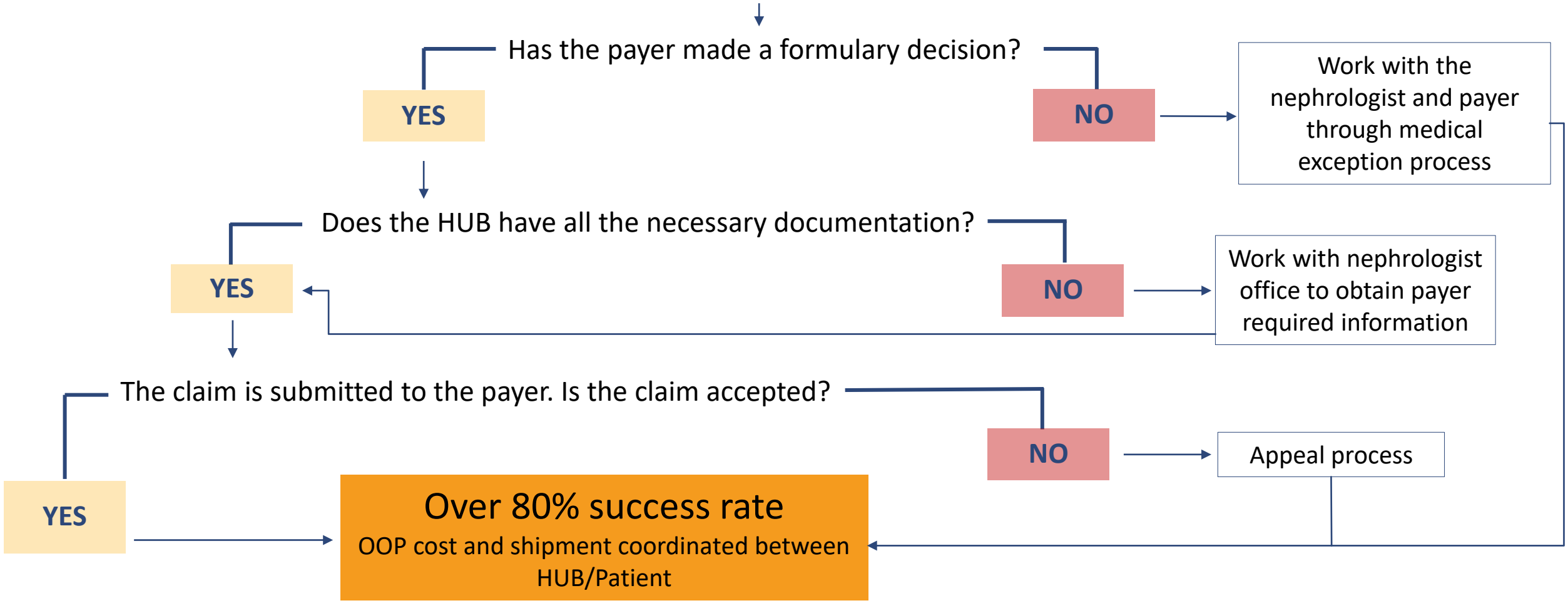
- All specialty products are reviewed by insurance companies' Pharmacy and Therapeutics (P&T) Committees prior to coverage decisions being made
  - The majority of plans take 6 – 9 months to go through this process
- Well over 80% of US lives (322 million people) are covered for TARPEYO®* based on publicly available reports
- Commercially insured lives are the vast majority (73%) of patients



*Source: Breakaway Partners, a Komodo Health Company

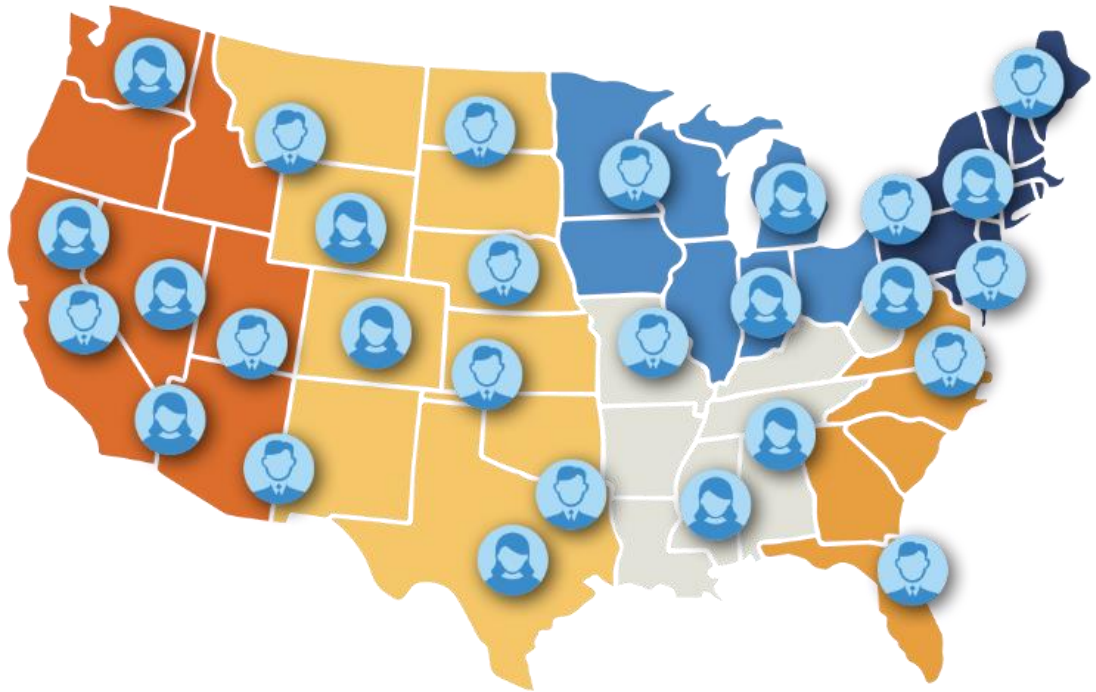
The prescription process

Nephrologist prescribes TARPEYO and an enrollment form is submitted to the HUB / Specialty Pharmacy.
The HUB confirms and investigates benefits, working with the Patient, Nephrologist and Payer.



Our US Commercial Launch leadership team of industry experts

- Extensive launch expertise: commercial experience at top-tier pharma (eg, Pfizer, Bayer, BMS, Regeneron)
- Experienced sales force: 60 sales reps with core background in rare disease, specialty products and nephrology market
- Hands-on managers: 6 national account managers in the field and engaging targeted payers
- Expert partners: AmerisourceBergen (ICS), McKesson (Biologics), and CDM and LifeSci (healthcare communications)



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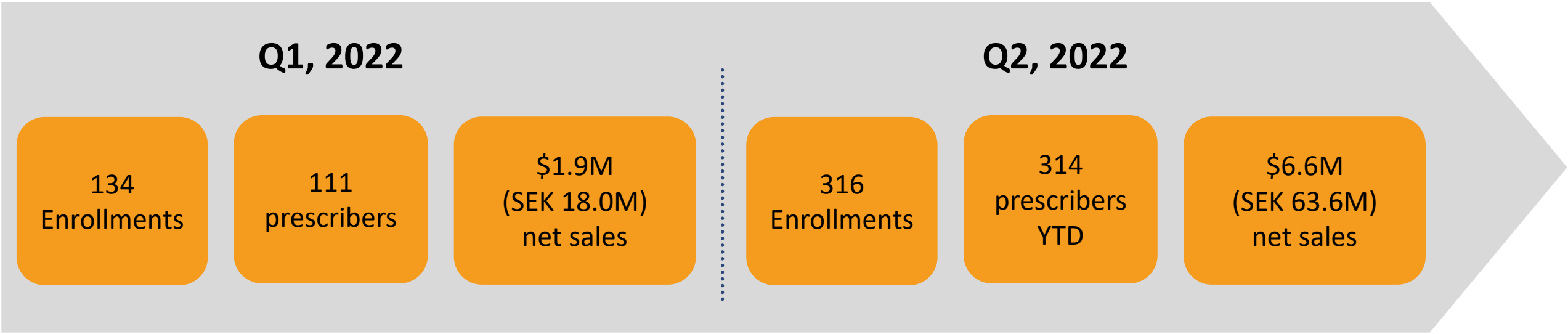
Successful launch reflecting receptivity and growth

- First sale and shipment of product took place January 28th, 2022



- Receptivity from Nephrologists and IgAN community remains strong
- Nephrologist awareness of TARPEYO® has grown to 70% unaided and 80% aided
- Strong initial prescriber base reflecting strong clinical data, incl treatment effect on eGFR

Ex-US Commercial Partnerships

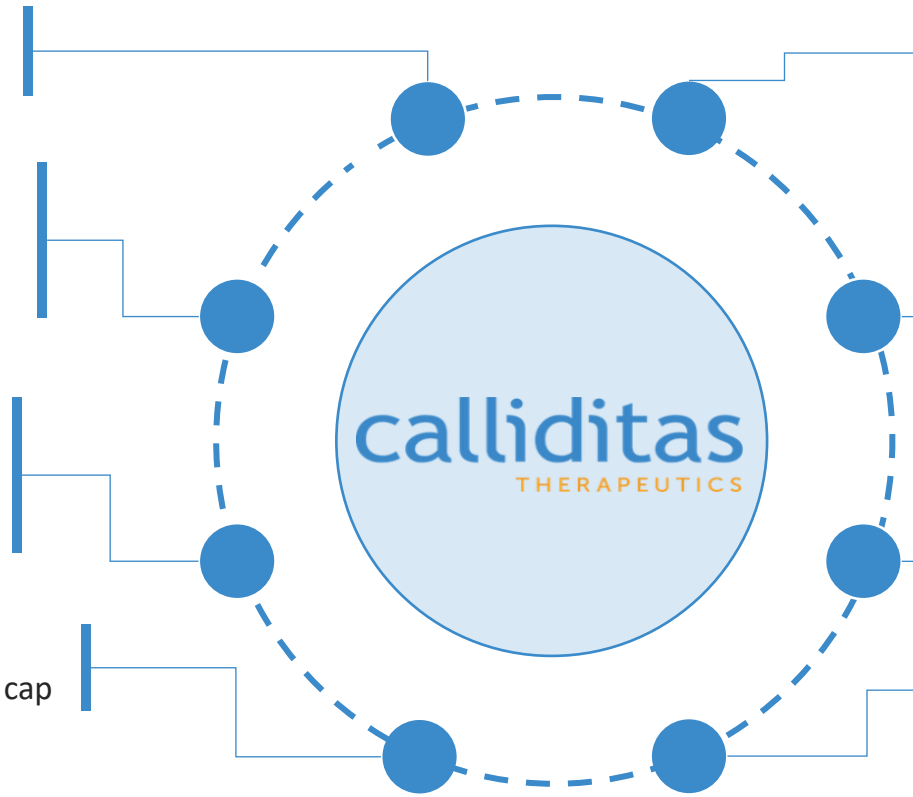
EVEREST MEDICINES

2019: Partnered with Everest Medicines in Greater China and Singapore

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

Strong expertise in clinical development and regulatory arena with an innovative biopharm approach.
Nine other products in the pipeline, 3 others FDA-approved

Public company listed on the Hong Kong exchange (ticker: 1952.HK) with a market cap of 8,36B USD



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.
$13M EUR ($13M) milestone payment following European Commission approval in July 2022

Extensive marketing and sales platform across Europe; large team with over 12,400 FTE

Private company with reported revenue in 2021 of 3,249.5M EUR ($3,256M), EBITDA of EUR 776.5M EUR ($778.1M)

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NOX Inhibitor Development Program

A first-in-class platform

NOX Inhibitors

- Calliditas' development programs are based on **a first in class, novel NOX inhibitor platform** that includes lead compound setanaxib, the **first NOX inhibitor to reach the clinical trial stage.**

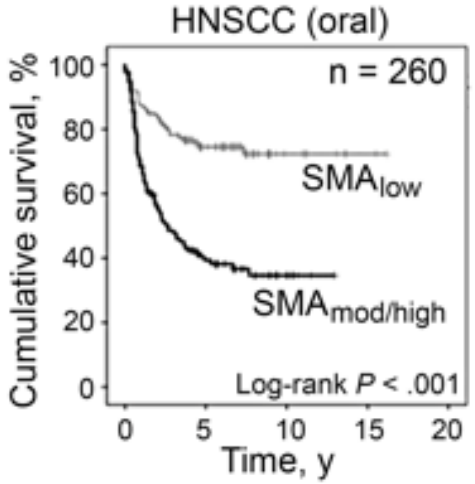
- NOX enzymes are solely dedicated to producing reactive oxygen species (ROS) as their primary and sole function. There are seven NOX members, each differing in composition, modes of activation and the ROS type they produce.
  NOX1, NOX2, NOX3, and NOX5 transfer electrons from NADPH to molecular oxygen, producing superoxide anion ($O_2^{\cdot -}$). NOX4, DUOX1 and DUOX2, meanwhile, mainly produce hydrogen peroxide (H_2O_2).

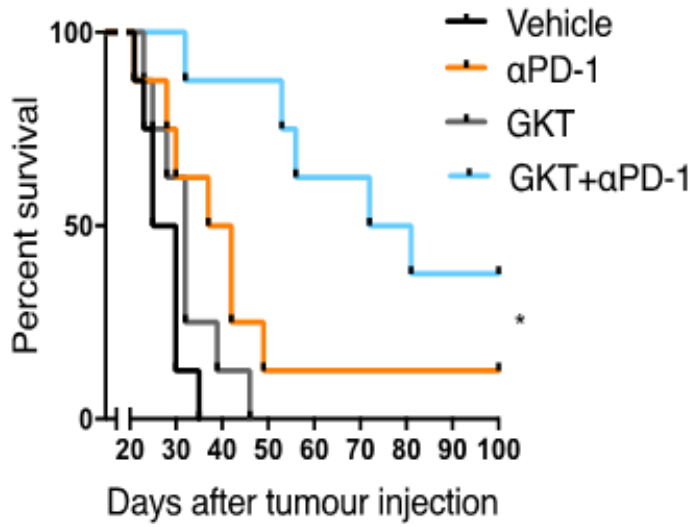
- At appropriate concentrations, ROS have essential functions in cellular signalling processes, helping to regulate cell proliferation, differentiation and migration, as well as modulating the innate immune response, inflammation and fibrosis. However, disruption of redox homeostasis has been implicated in multiple disease pathways.

Setanaxib in Squamous Cell Carcinoma of the Head & Neck

Scientific rationale

- The response to immuno-oncology therapies can be affected by the tumour microenvironment, in particular by the numbers of tumour-infiltrating lymphocytes (TILs) and cancer-associated fibroblasts (CAFs) in the tumour.
- A relationship between cancer associated fibroblasts (CAFs) and prognosis in squamous cell carcinoma of the head & neck (SCCHN) has been established.
- NOX4 is highly over-expressed in CAFs and drives myofibroblastic activation within tumours, shielding them from CD8+ TILs. Targeting CAFs with setanaxib could improve patients' responses to immunotherapies, and function as an adjunctive.
- There is increasing use of pembrolizumab as 1st line monotherapy in patients with relapsed or metastatic SCCHN, although response rates are low (ORR approx. 20%).





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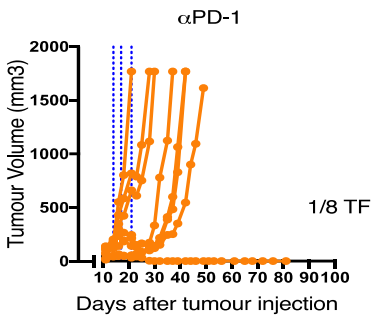
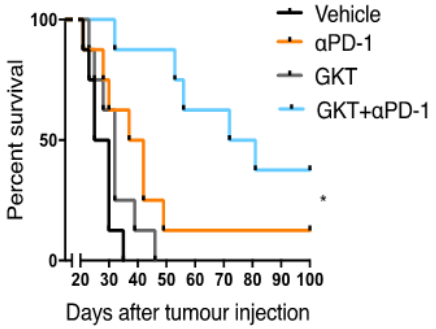
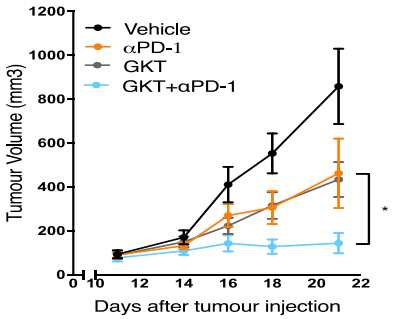
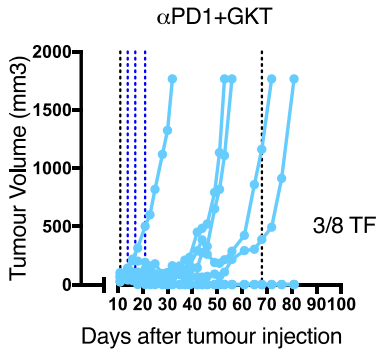
Preclinical work:
Combining GKT137831 with aPD-1 in CAF-rich tumours (TC1)

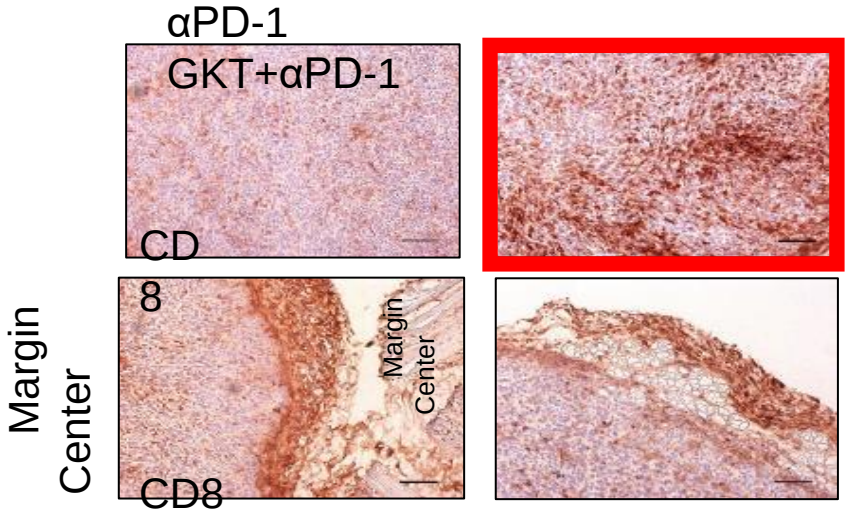
- Using a CAF-rich tumour model in mice, administration of setanaxib + pembrolizumab (versus either treatment alone) resulted in:
  - Improved penetration of TILs into the centre of the tumour
  - Slowing of tumour growth
  - Improved survival

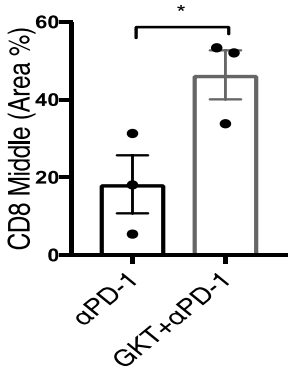


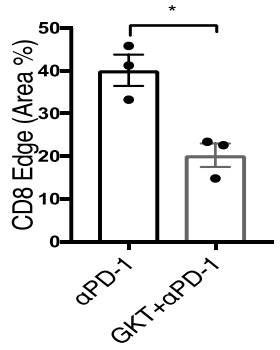












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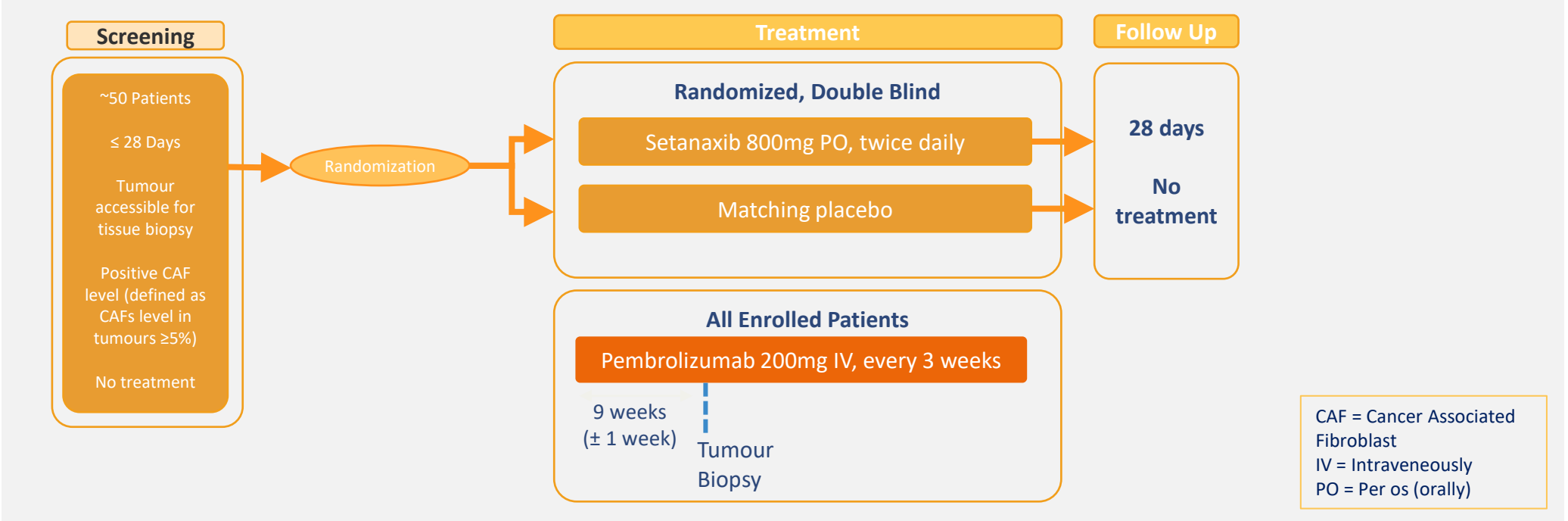
Phase 2 proof-of-concept study in patients with SCCHN

- Investigate the administration of setanaxib in conjunction with immunotherapy targeting CAFs.
- The study will likely involve around 50 patients; the first patient was randomized in May, 2022
  - Biomarker readout targeted for late 2022, subject to recruitment rate
  - final data readout expected in 2023



Setanaxib Phase 2b/3 (TRANSFORM) Trial in Primary Biliary Cholangitis (PBC)

- Double-blind, randomized, placebo-controlled, adaptive study design
  - Primary endpoint: ALP <1.67x ULN, and ALP reduction >15%, and total bilirubin <ULN
- ~318 Patients with PBC, elevated liver stiffness, and inadequate biochemical response/ intolerance to UDCA
  - 52 weeks of treatment with setanaxib 1200mg daily, setanaxib 1600mg daily, or placebo
  - Interim/ futility analysis after 99th patient has completed 24 weeks of treatment; will determine what dose of setanaxib to select for Phase 3
  - A 52 week extension phase, where all patients will receive blinded treatment with setanaxib
- Futility analysis targeted for 2H 2023 and the final data readout expected in late 2024/early 2025
- Calliditas received FDA fast track designation for setanaxib in PBC in August 2021

Anticipated Milestones

Anticipated milestones regarding Calliditas' clinical, regulatory and commercial plans

2H 2021

- European commercial partnership ☑
- FDA target PDUFA date accelerated approval for TARPEYO in IgAN ☑
- Initiate pivotal Phase 2/3 TRANSFORM trial in PBC ☑

2022

- Commercial launch of TARPEYO in the US ☑
- Initiate proof-of-concept Phase 2 trial in head and neck cancer ☑
- Positive EMA opinion for conditional approval for Kinpeygo (Nefecon) and European Commission Approval ☑
- Commercial launch in Europe
- Regulatory filing in China
- Commercial ramp in US
- Interim analysis in proof-of-concept head and neck cancer trial, subject to recruitment rate

2023

- Futility analysis of TRANSFORM trial in PBC
- Final readout of head and neck cancer trial
- Readout of NeflgArd study Part B; completion of Phase 3 program
- Filing for full approval in primary IgAN
- Potential approval in China
- Commercial ramp in EU, subject to approval

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