



# Corporate Presentation

November 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 **NeflgArd** 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
- July 2022, EC approval in Europe; Sept 2022, transfer of MA to partner STADA, who will launch in Germany in Q4 2022

■ **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**

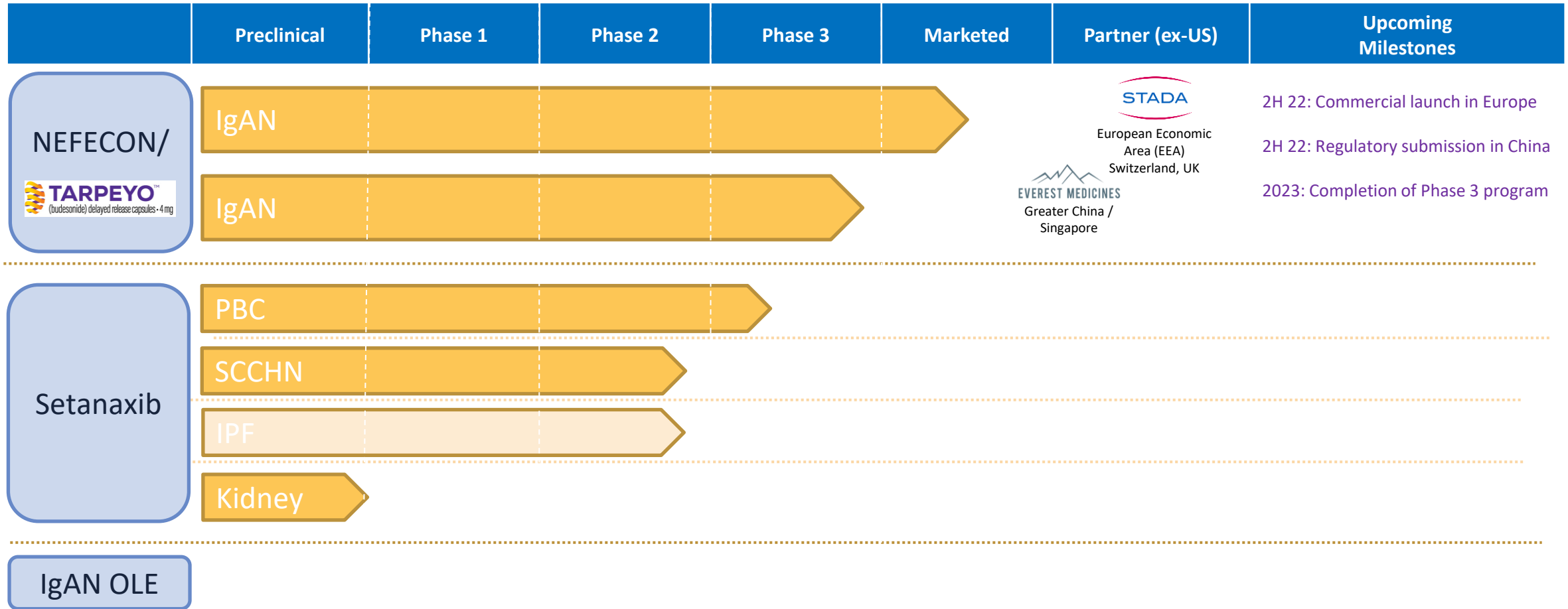
Exchange	OMX NASDAQ (CALTX)
	NASDAQ (CALT)

**Key Institutional Shareholders**

BVF Capital  
Industrifonden  
Linc  
Sofinnova Partners

**Cash (30/09/22): SEK 736.2m**

# Pipeline



Depicts ongoing/planned clinical trial stage:



Depicts Investigator Led Trial:



† Open Label Expansion, 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.

# 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**

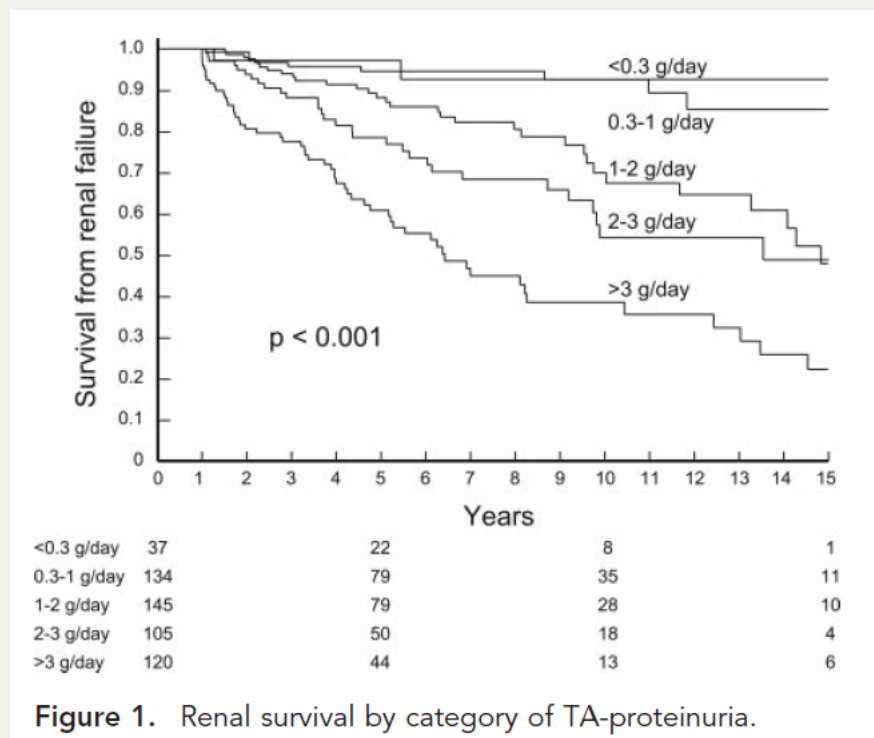
**The first and only EMA approved drug specifically designed for IgAN  
Positive CHMP Opinion in May 2022, European Commission approval in July 2022  
Commercial Partner, STADA, received MA in September 2022  
and will launch in Germany in Q4 2022**

**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)  $\geq 1.5$  g/g**

# 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



## Estimated Prevalence

### Market Opportunity



130,000  
- 150,000



200,000



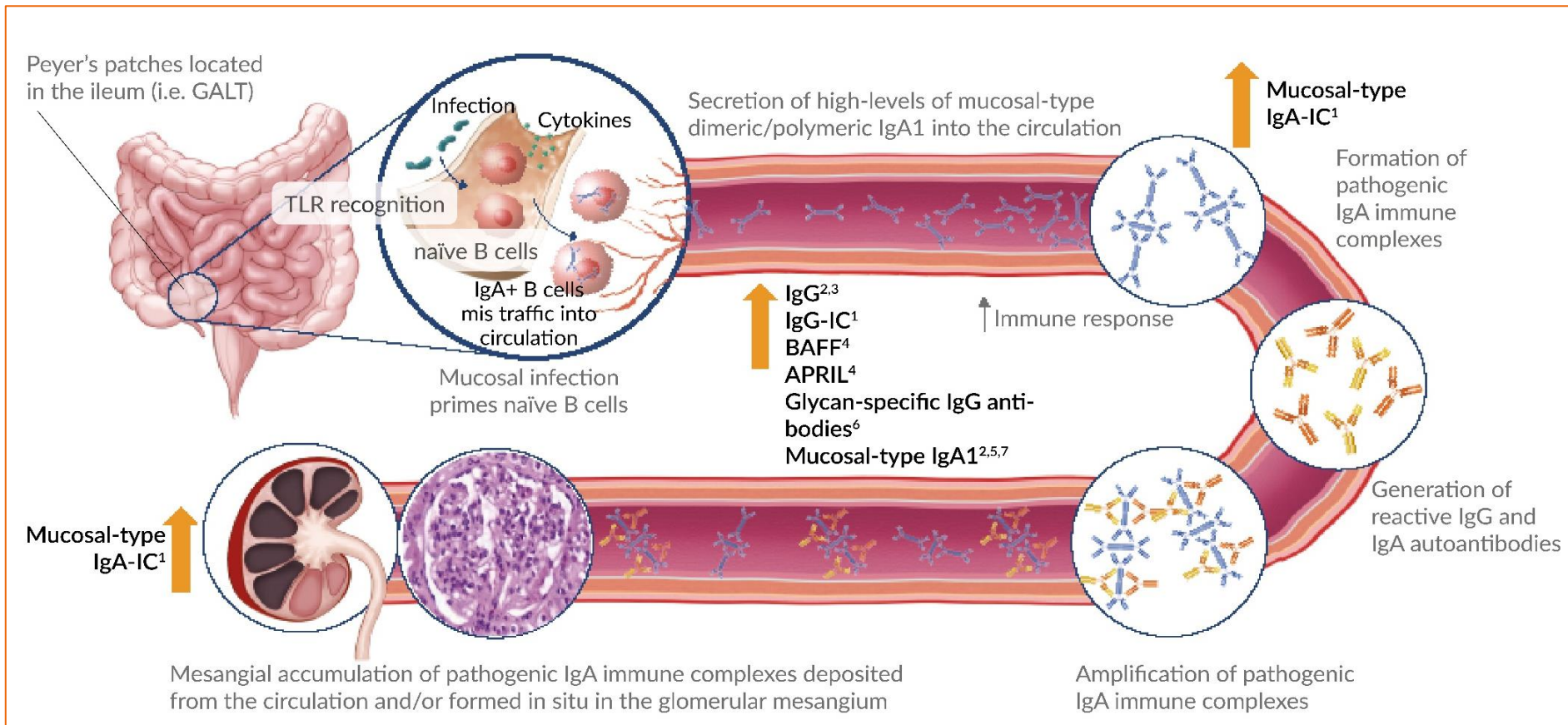
~5,000,000

# 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



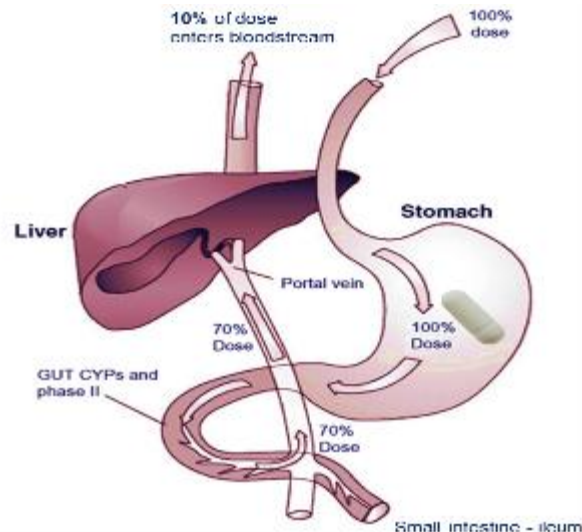
These immune complexes are deposited in the glomeruli of the kidney, causing an inflammatory cascade and destroying the glomeruli. This reduces the kidney's ability to remove waste products from the blood and eventually may result in ESRD



# Designed to target the presumed origin of the disease

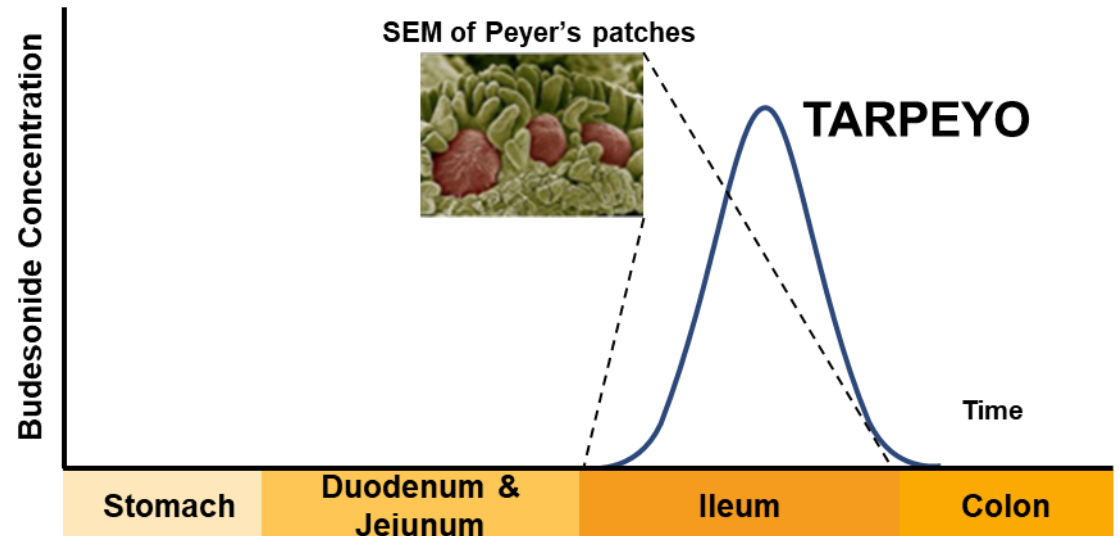
## Drug product based on known active ingredient

- 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

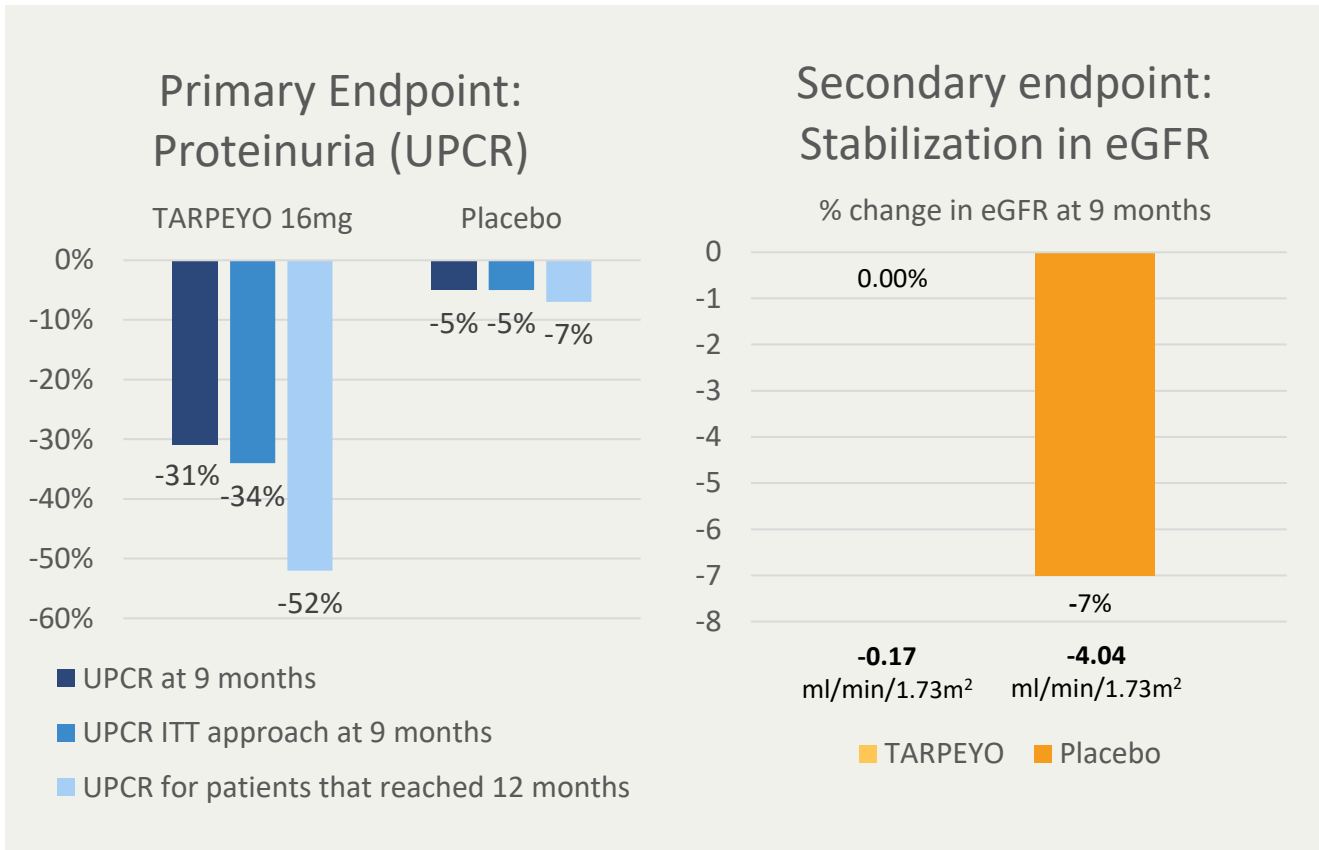




# Positive Phase 3 Data – Part A Efficacy Results

## 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<sup>2</sup>
  - eGFR decline for placebo = 4.04ml/min/1.73m<sup>2</sup>

## 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

# TARPEYO: A differentiated and targeted approach for IgAN

## Targeted immunomodulator down regulating IgA1 at the source

Proteinuria reduction vs SOC of physicians choice  
significant continued reduction off drug

Designed to locally target origin of disease with the  
potential of being disease modifying

Local action complemented by limited systemic exposure  
due to first pass metabolism of 90%

## Patient centric

Well characterized active ingredient  
and safety profile

Option of intermittent, rather  
than chronic treatment

Demonstrated impact not just on proteinuria but  
on eGFR in patients at risk of rapid progression



# 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)  $\geq 1.5$  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.

calliditas  
THERAPEUTICS

 **TARPEYO™**  
(budesonide) delayed release capsules

\*Please see full Prescribing Information, available at [TARPEYOHCP.com](https://www.tarpeyohcp.com).

# Established highly successful support service for frictionless access

**TARPEYO™**  
(budesonide) delayed release capsules - 4 mg

**Touchpoints™**  
Support beyond the script

I am a healthcare provider | I am a patient or caregiver

Enroll Now | Your Team | Access Support | Financial Support | Ordering & Delivery | Resources

**TARPEYO Touchpoints™ is available at every step of the journey**

We offer services, assistance, and resources to help your patients easily access treatment.

Please use the links below to learn more about:

- Access Support
- Financial Support Programs
- Ordering & Delivery

- 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.

# Our US Commercial Launch leadership team of industry experts



Extensive launch expertise: commercial experience at top-tier pharma (eg, Pfizer, Bayer, BMS, Regeneron)



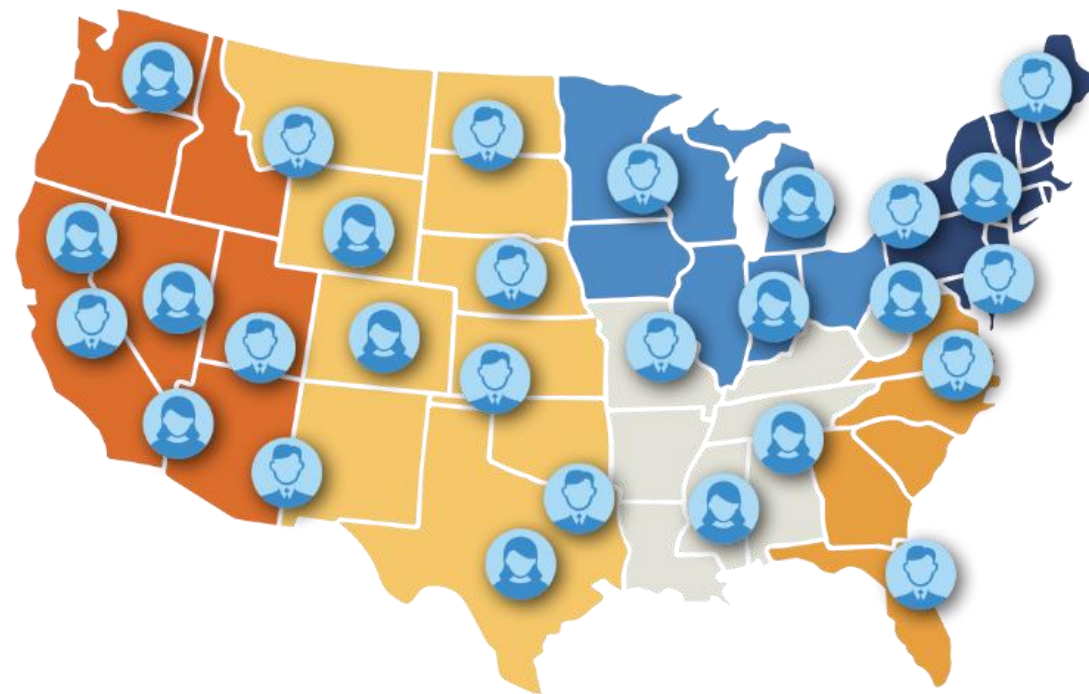
Experienced sales force: 60 sales reps with core background in rare disease, specialty products and nephrology market



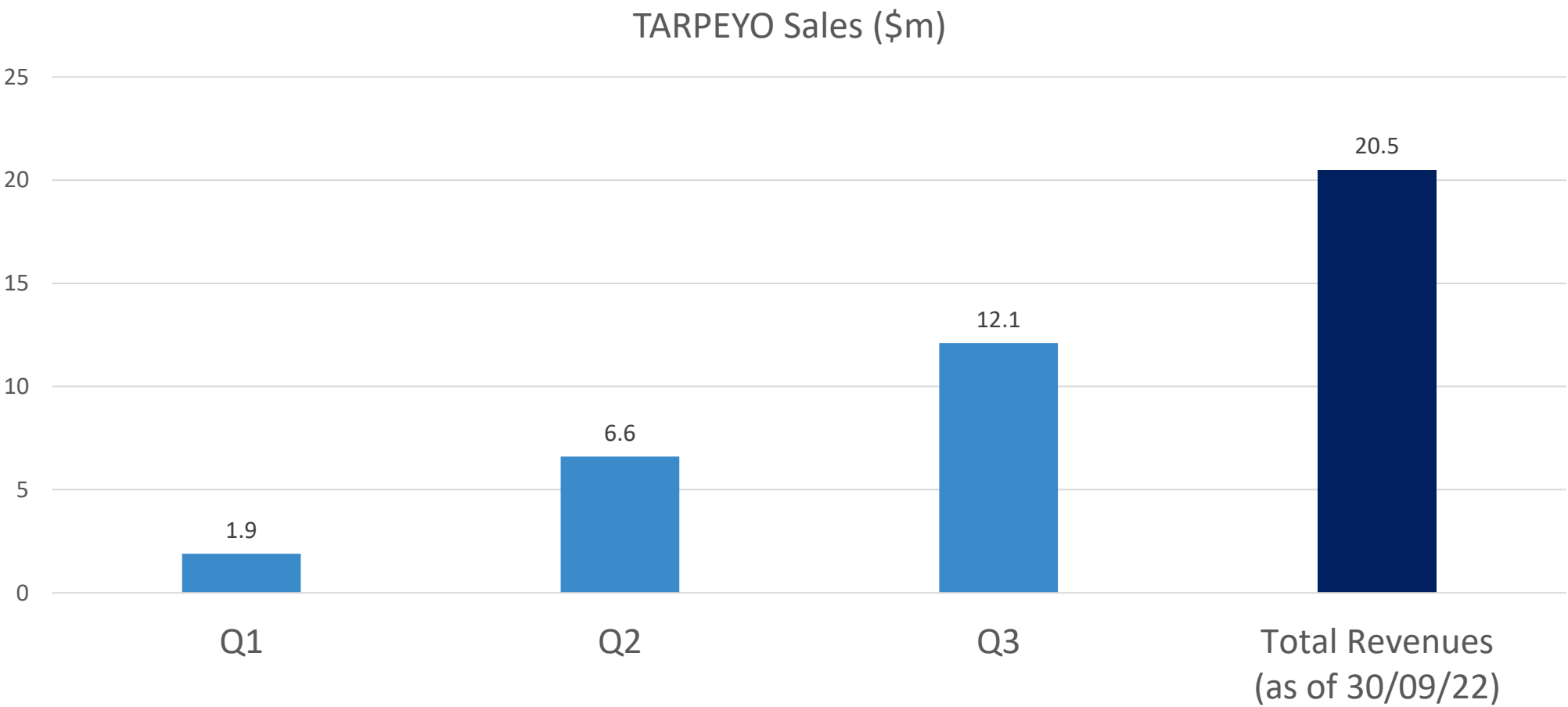
Hands-on managers: 6 national account managers in the field and engaging targeted payers



Expert partners: AmerisourceBergen (ICS), McKesson (Biologics), CDM and LifeSci Communications



# TARPEYO Launch Metrics



Total Unique Prescribers: **480**

Total Enrolments: **730**

# Continued growth through Q3 2022

- Strong net sales
- Continued penetration of prescriber base
- Encouraging and broad interest from nephrology community
- Market Access reached goal of more than 90% of US lives covered
- Payer mix – less than 25% government insured with **remainder either private insurance or cash**
- Awareness continues to grow - now over 80%
- Advocacy and patient meetings and activities ongoing
- Clinical data recently published in peer reviewed journal





# Ex-US Commercial Partnerships



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 (1952.HK)

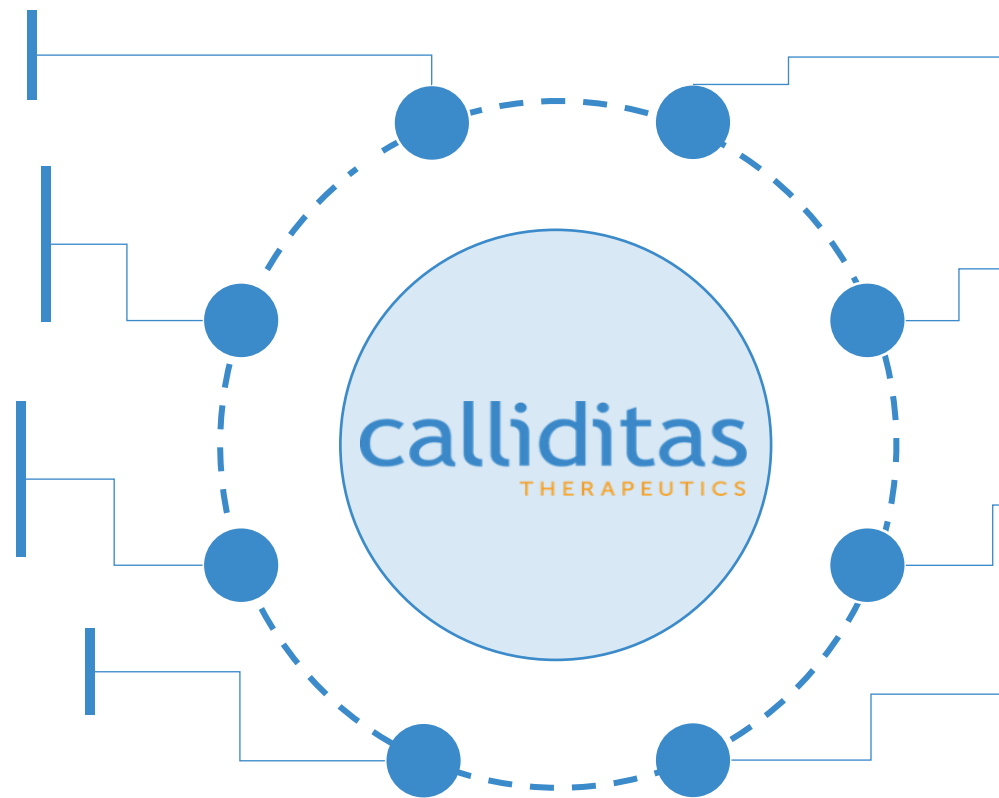


2021: Partnered with STADA in the European Economic Area (EEA) member states, Switzerland, and the UK

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)



# 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 ( $H_2O_2$ ).

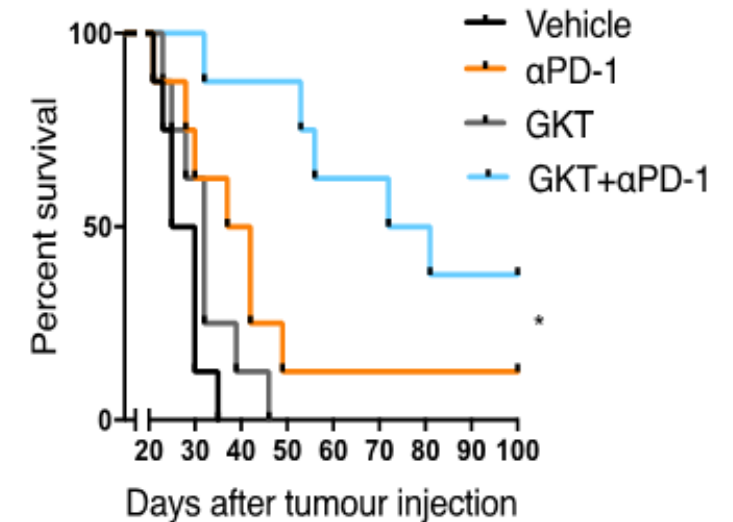
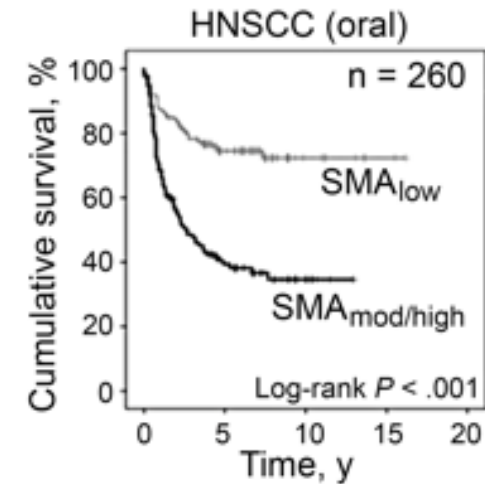


- At appropriate concentrations, ROS have essential functions in cellular signalling processes, helping to regulate cell proliferation, differentiation and migration, as well as modulating the innate immune response, inflammation and fibrosis. However, disruption of redox homeostasis has been implicated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

# Setanaxib in Squamous Cell Carcinoma of the Head & Neck

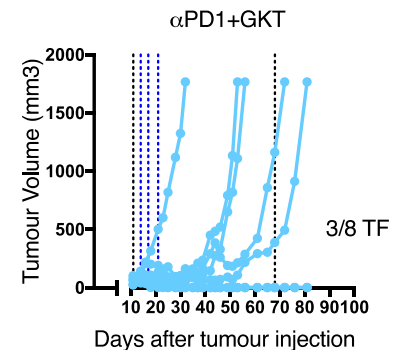
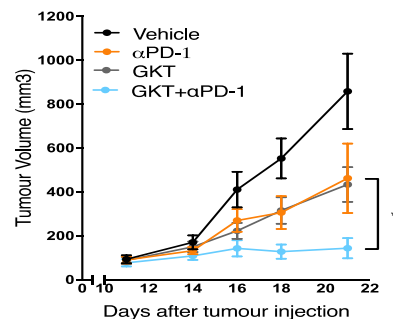
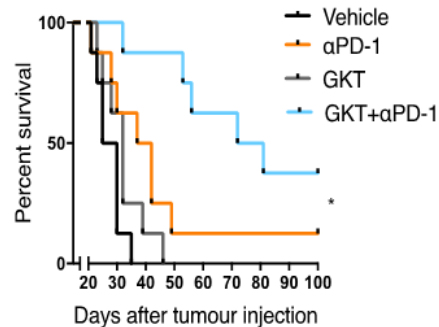
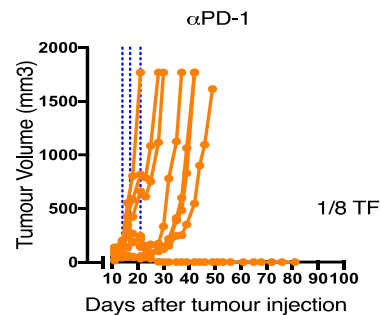
## Scientific rationale

- 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<sup>+</sup> 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%).

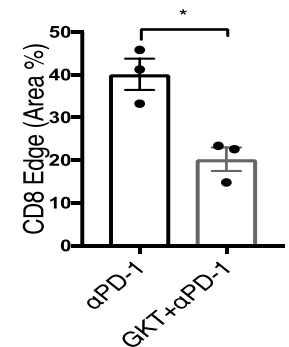
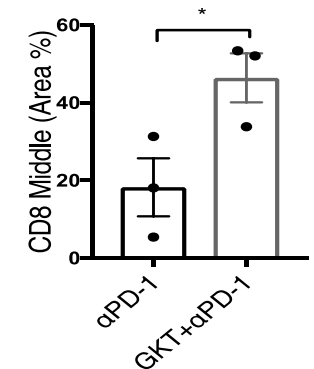
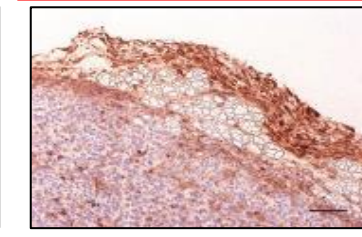
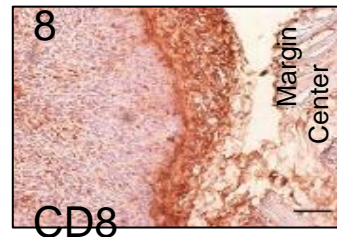
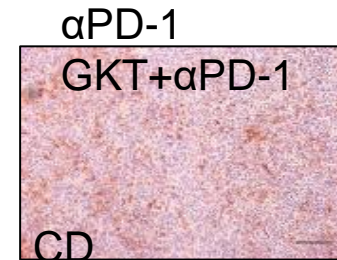


# Preclinical work: Combining GKT137831 with aPD-1 in CAF-rich tumours (TC1)

- 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



Margin  
Center



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

- Double-blind, randomized, placebo-controlled, adaptive study design
  - Primary endpoint: ALP  $<1.67 \times$  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
- Interim analysis targeted for 1H 2024, subject to recruitment
- 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	2022	2023
<ul style="list-style-type: none"> <li>➤ European commercial partnership <input checked="" type="checkbox"/></li> <li>➤ FDA target PDUFA date accelerated approval for TARPEYO in IgAN <input checked="" type="checkbox"/></li> <li>➤ Initiate pivotal Phase 2/3 TRANSFORM trial in PBC <input checked="" type="checkbox"/></li> </ul>	<ul style="list-style-type: none"> <li>➤ Commercial launch of TARPEYO in the US <input checked="" type="checkbox"/></li> <li>➤ Initiate proof-of-concept Phase 2 trial in head and neck cancer <input checked="" type="checkbox"/></li> <li>➤ Positive EMA opinion for conditional approval for Kinpeygo (Nefecon) and European Commission Approval <input checked="" type="checkbox"/></li> <li>➤ Commercial launch in Europe (Q4) <input checked="" type="checkbox"/></li> <li>➤ Regulatory filing in China (Q4) <input checked="" type="checkbox"/></li> <li>➤ Commercial ramp in US</li> </ul>	<ul style="list-style-type: none"> <li>➤ Readout of NeflgArd study Part B; completion of Phase 3 program</li> <li>➤ Filing for full approval in primary IgAN</li> <li>➤ Data from head and neck cancer trial, subject to recruitment</li> <li>➤ Potential approval in China</li> <li>➤ Commercial ramp in EU</li> </ul>