calliditas
THERAPEUTICS

Company Presentation

September 2021

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calliditas THERAPEUTICS

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

- Lead candidate, Nefecon, is a **novel treatment for IgA nephropathy (IgAN), targeting the origin** of this progressive orphan **kidney disease.**

- Nefecon **positioned to become the first ever approved drug for IgAN.**
  All clinical trials **met primary and secondary endpoints** and demonstrated that Nefecon was well-tolerated.

- **Building integrated orphan / nephrology focused business** through in-licensing or acquisition of product candidates; recently acquired platform of first-in-class NOX Inhibitors. **Pipeline** in orphan liver and kidney indications. POC in head and neck cancer.

- Headquartered in Stockholm, Sweden; listed on **OMX NASDAQ in Sweden (ticker: CALTX)** and on **NASDAQ (ticker: CALT)**
  Key institutional shareholders include: BVF Capital, Industrifonden, Sofinnova Partners, Linc.

- **Cash balance** as of June 30, 2021: **SEK 709M** (US$80M).
  Subsequently in July, Calliditas signed a European commercial partnership of €97.5m with a €20m upfront, as well as a loan agreement of $75 million. In August the company raised $37m of equity.

Our lead indication: IgA Nephropathy – a significant unmet medical need

PROFILE

- Genetic predisposition is required but not sufficient; environmental, bacterial, dietary factors also play a role

- Patients are typically diagnosed between 20-30 years of age
- Up to 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 indicate disease progression and increased risk of ESRD

- Significant unmet medical need.
- There is no approved treatment – only recommended treatment (KDIGO) is blood pressure-lowering agents (ACEs and ARBs.)

ESTIMATED PREVALENCE

MAIN MARKETS

130,000-150,000

Based on market research and prevalence estimates; **target market of $4-5bn** in the U.S alone.

2,000,000[1]

Calliditas partnered with Everest Medicines to commercialize Nefecon in China in 2019.

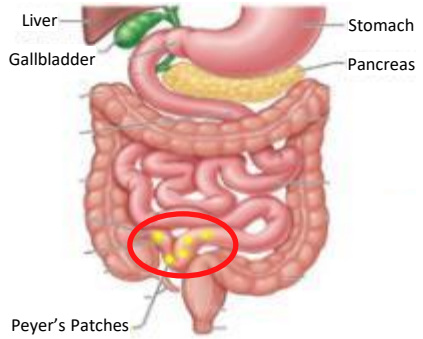
200,000

Calliditas partnered with STADA to commercialize Nefecon in EAA member states, United Kingdom and Switzerland in July 2021.

1) Estimates in Greater China based in part on published prevalence among ethnic patient populations in U.S., analyses of prevalence in Europe and published incidence rates in certain geographies.

Disease origin and progression – predominant theory

Peyer´s patches

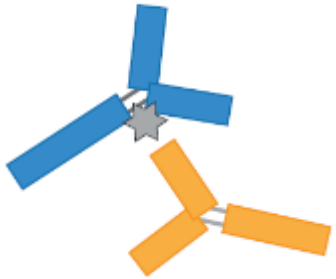


- Follicles of lymphatic tissue, known as Peyer's patches, in the distal part of the small intestine (ileum) produce secretory IgA antibodies

1 Galactose-deficient IgA

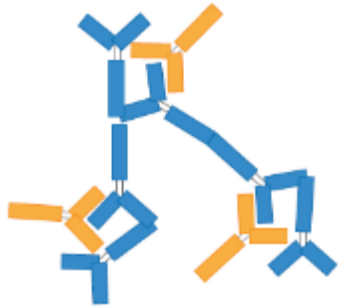
- Patients with IgAN have an increased appearance in the blood of secretory IgA antibodies that lack galactose units (galactose-deficient IgA) in the hinge region, which makes the antibody immunogenic

2 Immune recognition



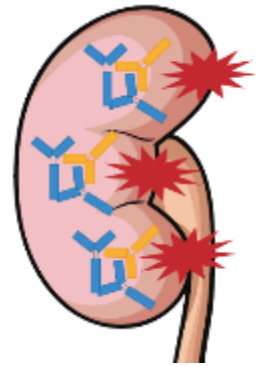
- These IgA antibodies trigger autoantigen production and form autoantibody complexes with autoantibodies directed against the IgA hinge region

3 IgA – dependent immune complex



- These aggregates form pathogenic immune complexes that deposit in the glomeruli, which are the filtration apparatus of the kidney

4 IgA Nephropathy



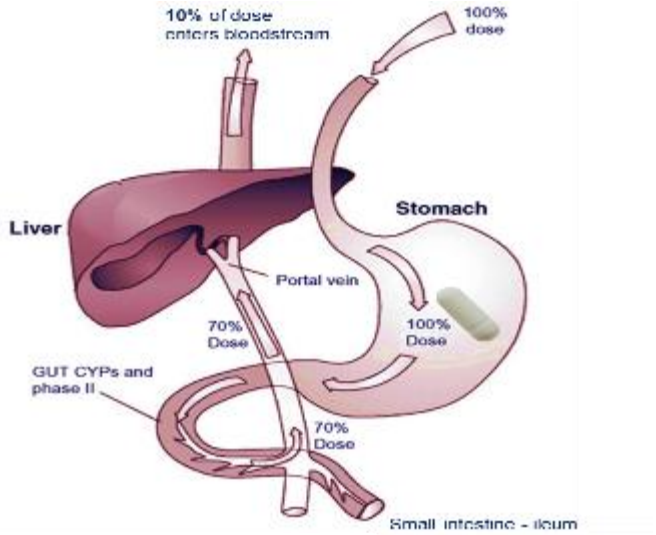
- The deposits of immune complexes in the glomeruli cause an inflammatory cascade that destroys the glomeruli, reducing the kidney's ability to remove waste products from the blood and eventually may result in ESRD

Sources: Suzuki et al, J Am Soc Nephrol 2011;22(10):1795-803; Novak et al, Curr Opin Nephrol Hypertens 2013; 22(3):287-94; Novak et al, Kidney Dis (Basel). 2015; 1(1):8-18.

Nefecon targets the presumed origin of disease

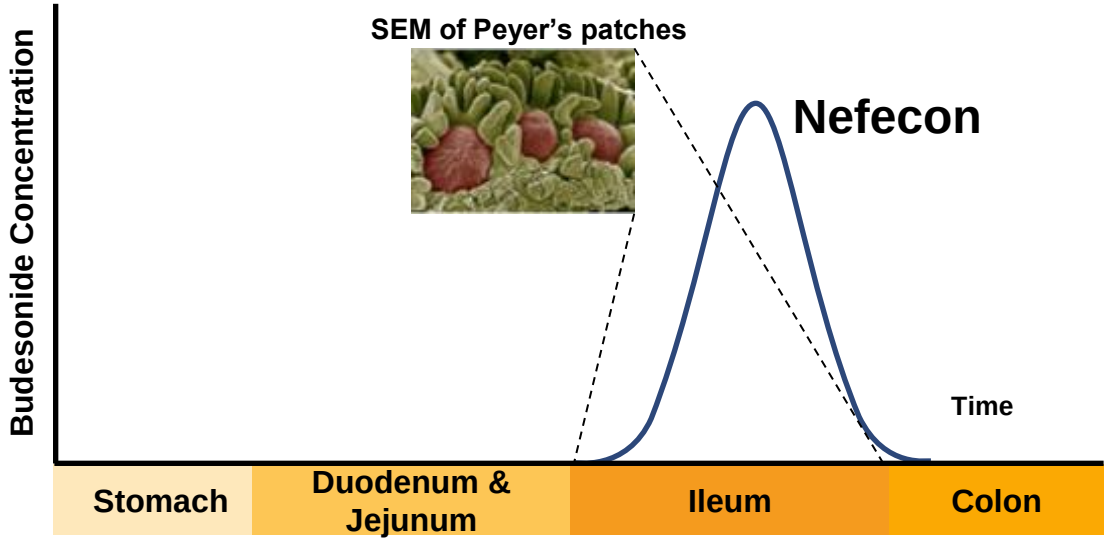
Drug product based on known active ingredient

- Active ingredient is budesonide – an established, highly potent, locally acting corticosteroid
- 90% cleared in first pass metabolism by liver → minimize systemic side effects
- Designed to deliver a targeted and highly concentrated dose directly to the Peyer's patches



Novel targeted release profile

- Designed for targeted local delivery of potent immunosuppressant 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



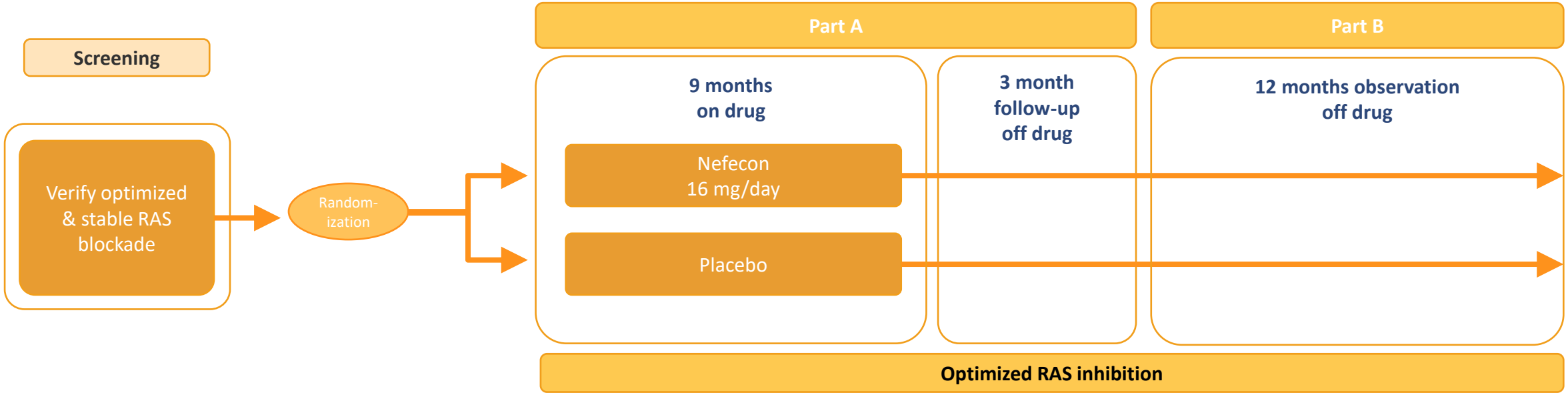
Pivotal Phase 3 clinical trial (NeflgArd)

Part A: Key highlights

- Designed to assess efficacy and safety
- Basis for approval
- 200 patients in 19 countries with over 145 sites
- Primary Endpoint: reduction of proteinuria
- Read out positive data in November 2020

Part B: Key highlights

- Post approval follow up trial design to confirm the long-term renal benefit of observed proteinuria reduction
- 360 patients, including 200 from Part A
- Primary endpoint: difference in kidney function as measured by eGFR over the 2-year period
- Fully enrolled in January 2021.
- Readout expected in early 2023.



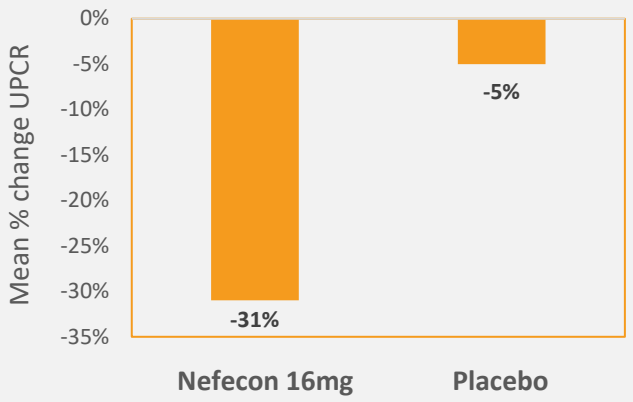
Positive Phase 3 Data

eGFR Stabilization: Basis for Disease Modification

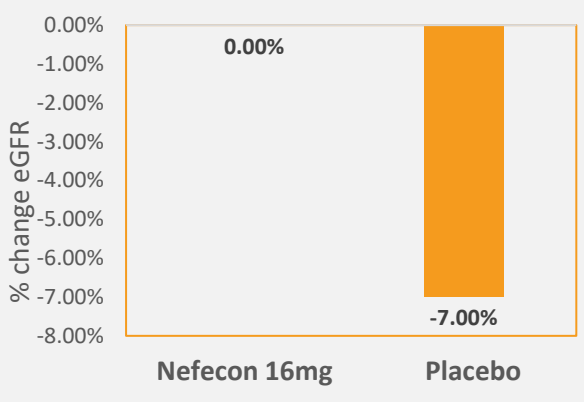
First successful readout of a Phase 3 trial in IgA nephropathy.

9 months of dosing with 16mg Nefecon in 199 patients demonstrated a statistically significant and clinically meaningful reduction in proteinuria and in eGFR stabilization.

Primary endpoint: reduction in proteinuria



Secondary endpoint: stabilization of eGFR



-0.17 ml/min/1.73m²

-4.04 ml/min/1.73m²

Efficacy findings

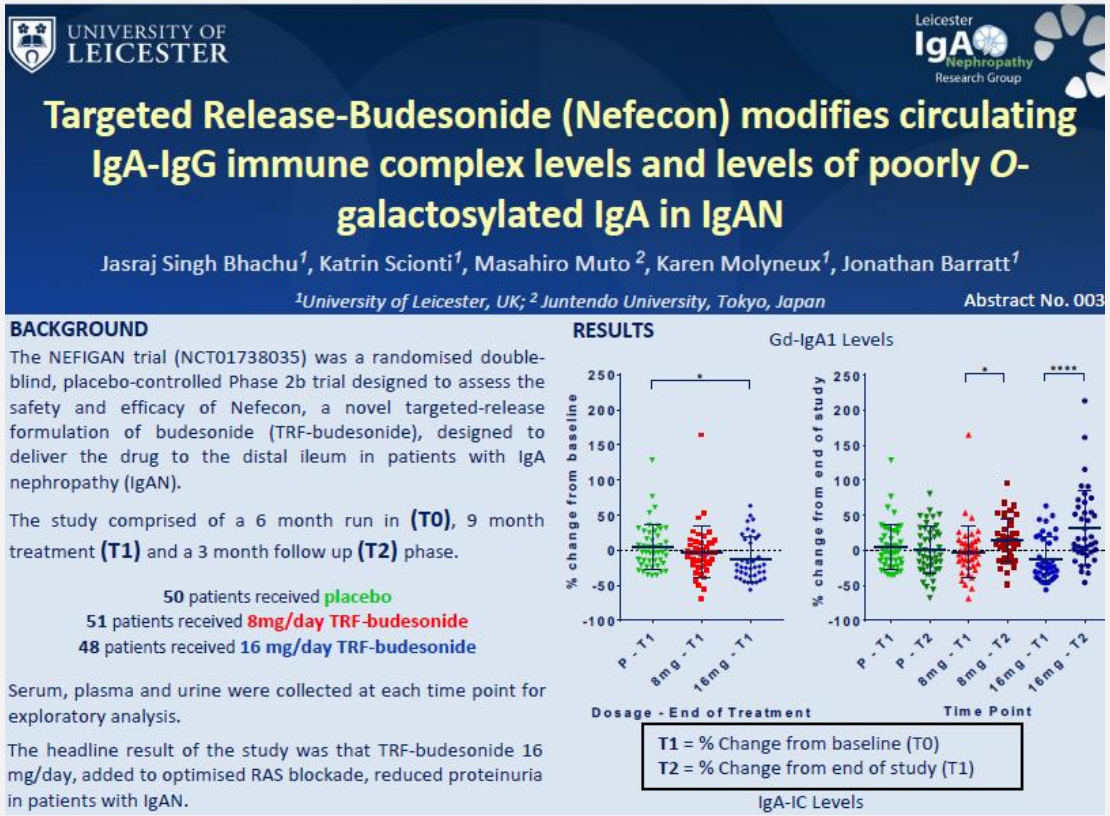
- ✓ Statistically significant 27% UPCR reduction with Nefecon (16 mg) compared to placebo – 9 months treatment (p=0.0005)
- ✓ Statistically significant eGFR stabilization with Nefecon (16 mg) compared to placebo – 9 months treatment (p=0.0029)
- ✓ Significant continued decline in proteinuria observed for patients having reached 12 months

Tolerability findings

- ✓ Generally well-tolerated, with a safety profile in keeping with the Phase 2b results
- ✓ No adverse clinical effects on the cardiovascular or metabolic system
- ✓ No severe infections

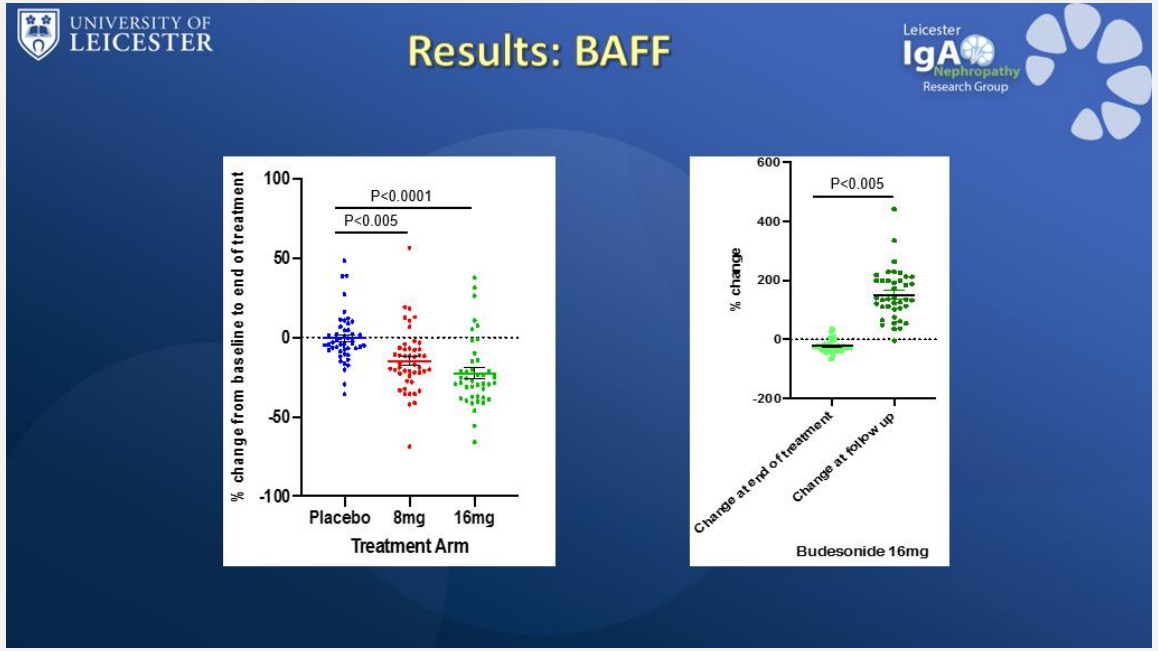
Biomarker Data

2018 IIGAN Poster from Professor Barratt at the Mayer IgA Nephropathy Laboratories at the University of Leicester

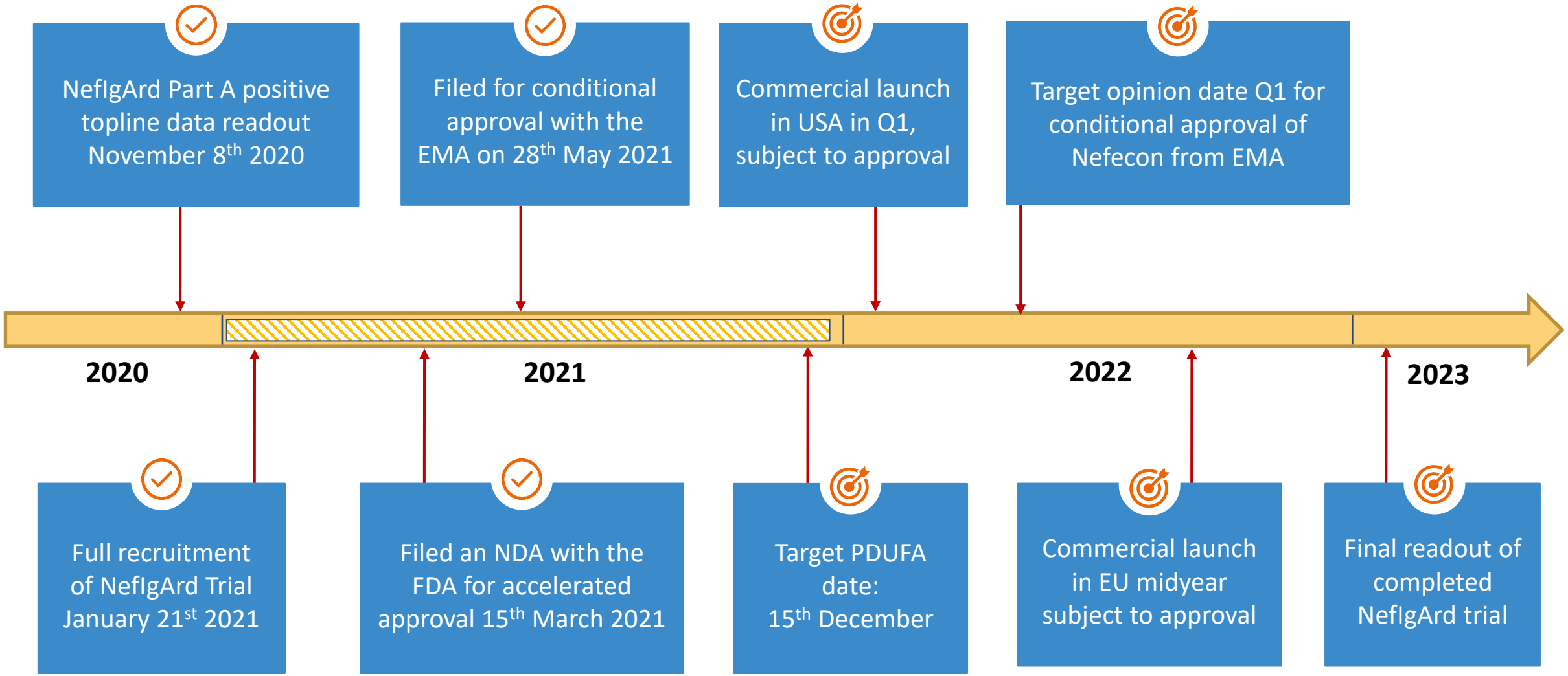


Presentation at ASN Digital Kidney Week 2020 at the oral abstract session “Glomerular Diseases: Charting New Territory” from Dr. Molyneux at the Mayer IgA Nephropathy Laboratories

Showed that Nefecon had **a demonstrated impact** on circulating pathogenic biomarkers in IgAN



Nefecon – Positioned to be first approved treatment for IgAN



2019 Market Landscape Research:

- 2019 IQVIA research, based on the Phase 2b data
- Qualitative interviews with 12 Nephrologist KOLs
- Quantitative research/survey with **102 Nephrologists** that, on average, treat 14 IgAN patients per month

Nephrologist summary

68% would prescribe Nefecon within the first year - positioning Nefecon as the first agent after, or in conjunction with supportive care (ACEs/ARBs)

90% of the nephrologists familiar with budesonide had a neutral or favorable opinion when learning the active ingredient in Nefecon was budesonide

Assuming no tolerability issues, **half** of nephrologists indicated an interest in potentially continue the use of Nefecon past its initial 9-month course

US Commercial Opportunity

OUTPUT CONFIRMED MARKET POTENTIAL

- Encouragement on progress made so far
- Receptivity of our target HCP audience

PATIENT CHART AUDIT

468 IgAN patient records submitted by **188** Nephrologists

- Fieldwork conducted December 2020 – February 2021

spherix GLOBAL INSIGHTS

RealWorld Dynamix
Exploring the Patient Journey

An Unsatisfied HCP Market Craving Advancement

46% Rate IgAN as “Extremely challenging” to manage in non-dialysis patients

52% Believe there are few/no effective treatment options currently available

65% Anticipation of IgAN patients who will progress to dialysis

53% Would like to replace systemic steroids as a treatment option

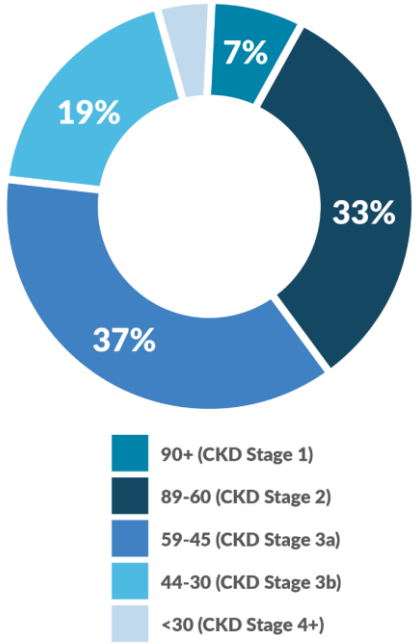
80% Believe early intervention is critical to successful outcome

Patient Population at Nephrology Offices

IgAN patients, on average:

70%

Arrive upon referral in CKD stage 2 or 3a



And at most recent visit, the majority have progressed to CKD stage 3a or 3b

3.1

Physician visits / year (during pandemic)

99.8%

Receive at least one lab test annually (eGFR and urinalysis)

4.9

Medications prescribed

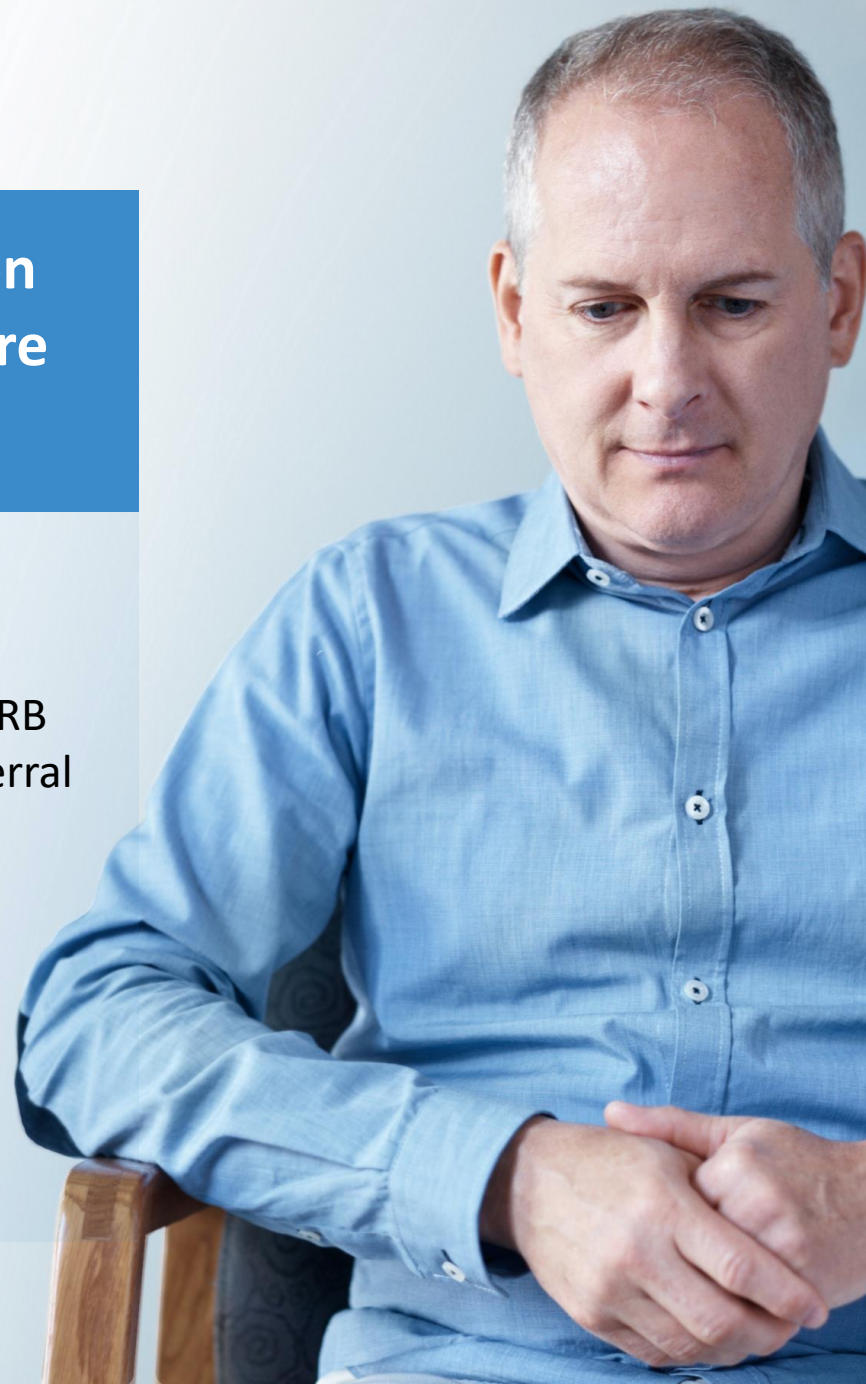
Majority are on Supportive Care (ACE / ARB):

>50%

Already on ACE/ARB at the time of referral

88%

Are on an optimal dose, per nephs



High recognition and receptivity to Nefecon

Of Nephrologists:

~1/2 Are ***very familiar*** with Nefecon and the phase 3 results (unaided awareness), and awareness is growing

These HCPs are ***extremely likely*** to prescribe Nefecon for

~70% of their patients

Health Economic Burden

IgA progression to ESRD comes at a high cost

Dialysis severely restricts patients' lives (requires three 3-5 hour sessions every week) and significantly impacts patients' quality of life

Kidney transplantation is a major surgery requiring lifetime follow-up and treatment.
Up to 30% may experience organ rejection
30% experience recurrence of IgAN

USA

MEAN ANNUAL COST FOR PATIENTS WITH ESRD

$121,948 Commercial

$87,339 Medicare

EUROPE

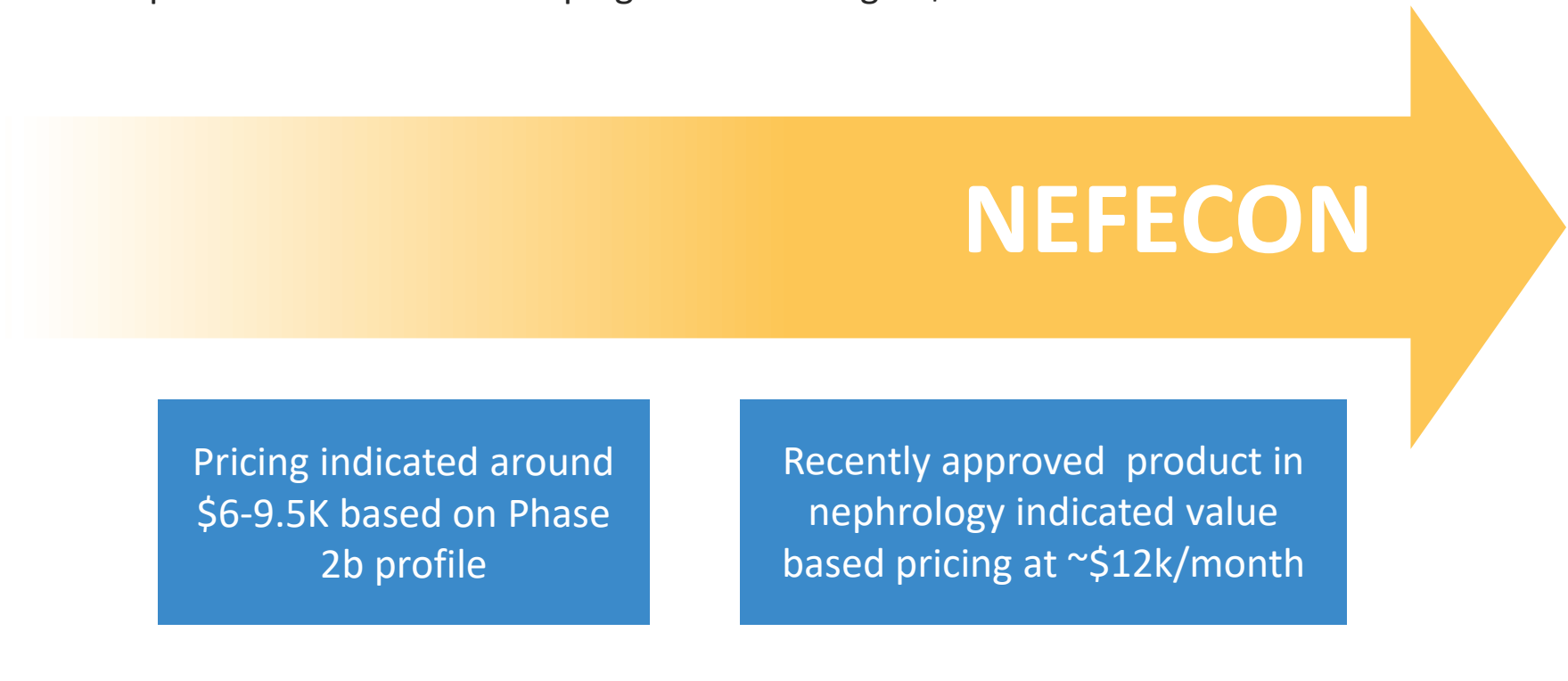
£504 million total annual cost of transplants in UK

€35,744-€62,610 typical cost of dialysis patient / annum within Europe

Value-Based Pricing Strategy

MARKET OPPORTUNITY IN THE USA

- 130 – 150k prevalence estimate for IgA nephropathy
- Core target market: up to 50% at risk of developing ESRD resulting in $4.5 – 5bn in the U.S. alone



Market Preparations

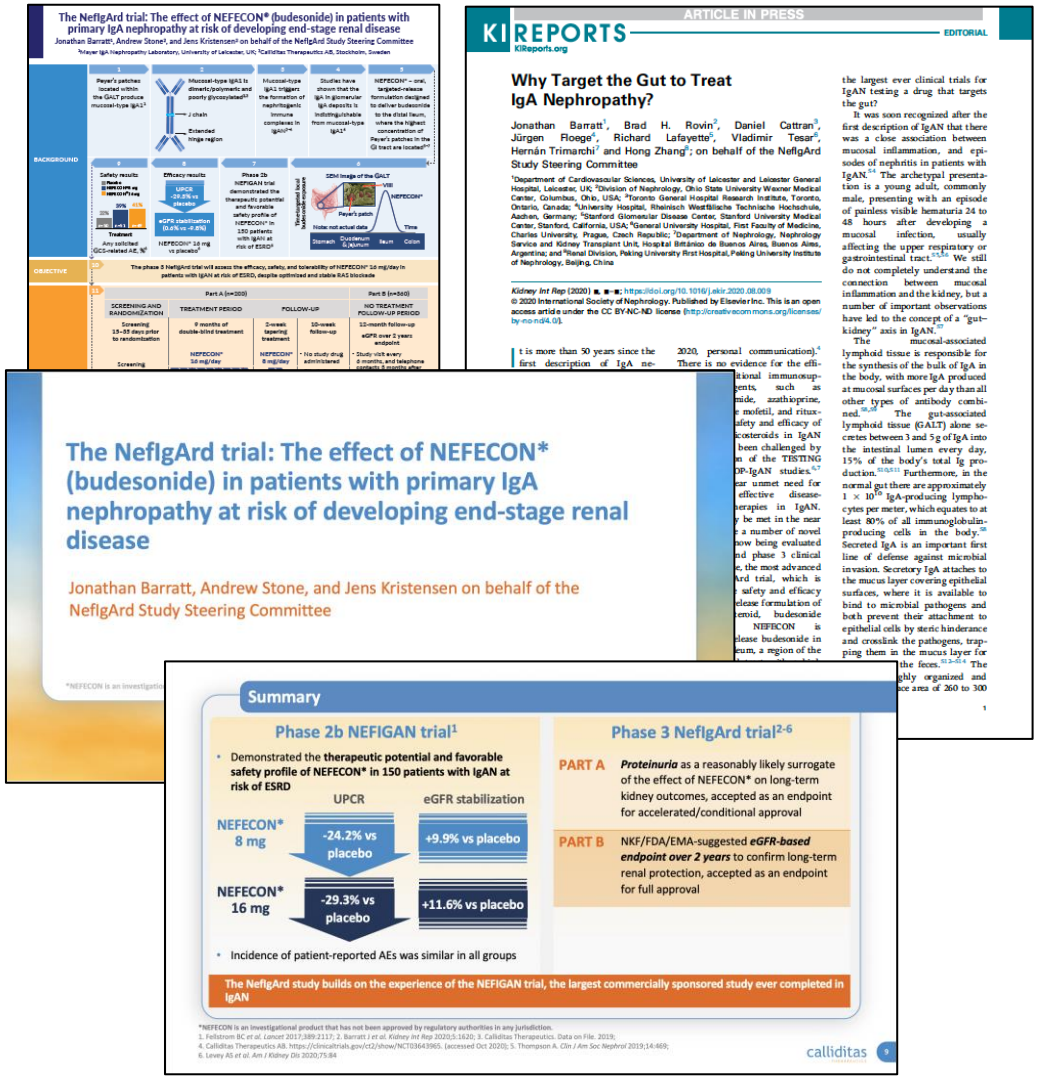
Present Day → PDUFA Date

MEDICAL AFFAIRS TO EDUCATE HCPs

- **Published articles & posters**
- **Advisory boards and work with KOLs**
- **Congress Presence**
  - 11 abstracts at major congresses
  - Activities at 25 International, National, and regional congresses
- **Solidifying key relationships with KOLs**
  - Targeting 1,000 1:1 interactions with top 8-10% of experts in IgAN
- **New 2021 publications**
  - 4 manuscripts (including HEOR)

MINIMIZING BARRIERS TO MARKET ACCESS

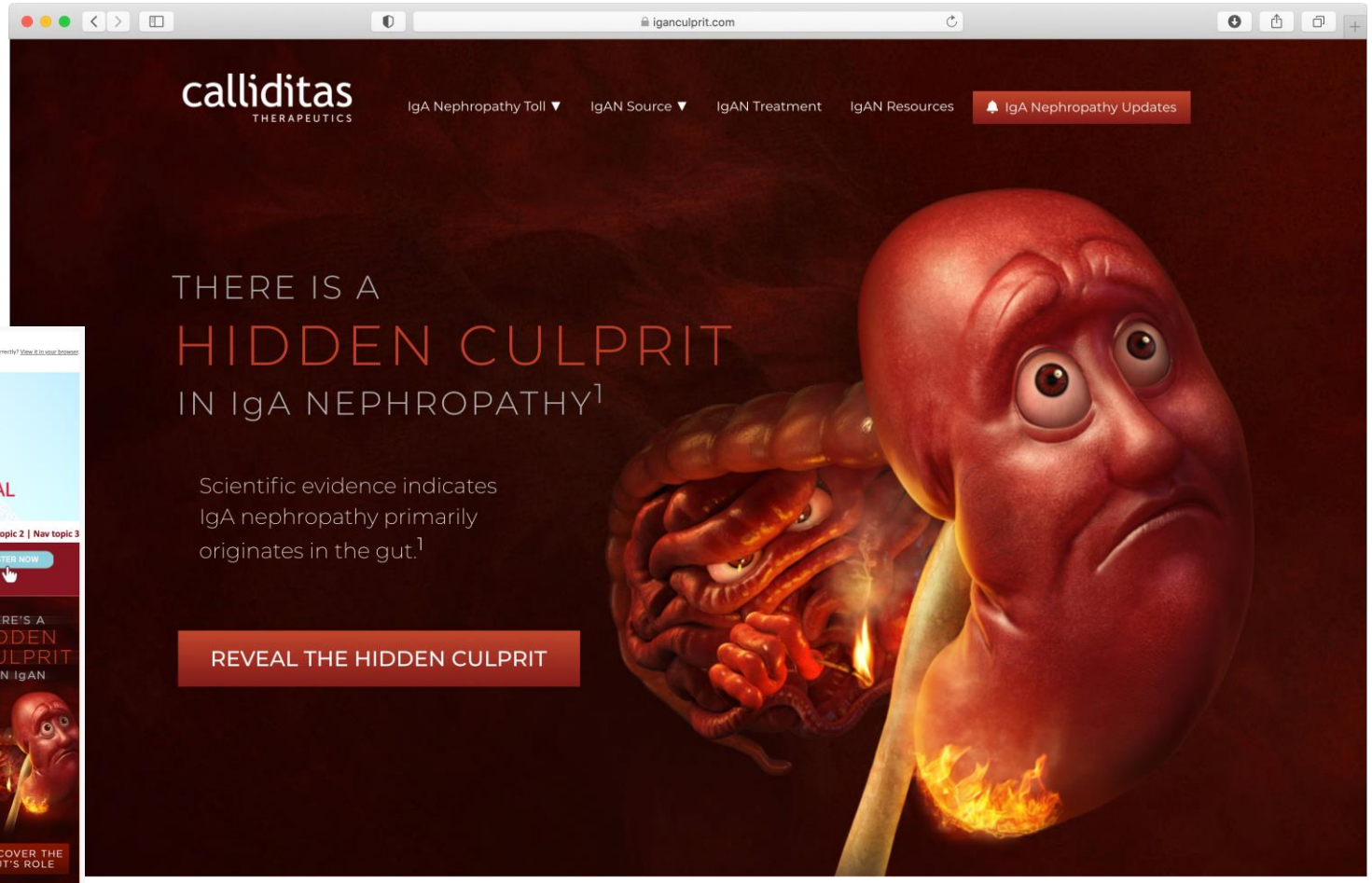
- **Trade/distribution partners are established**
- **National Account Managers will begin calling on payers**



Disease Awareness Campaign Launch

Present Day → PDUFA Date

IgANCulprit.com

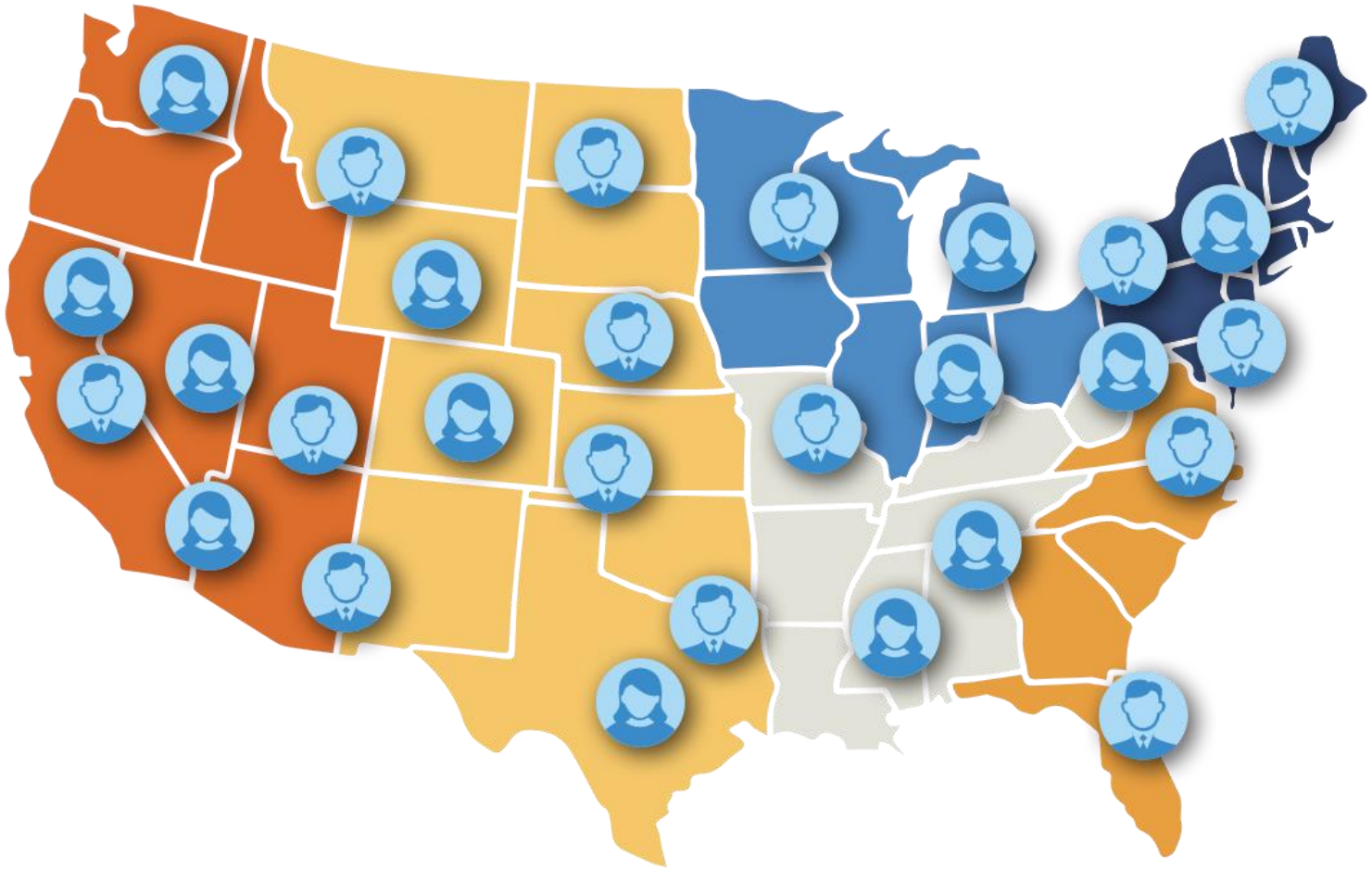


Sales Force Readiness

Present Day → PDUFA Date

SALES

- Targeted Nephrology audience of ~3,700
- 40 sales territories to provide appropriate reach and frequency



Clinical Activities

Clinical Candidate	Indication / Trial	Research/ Preclinical	Phase 1	Phase 2	Phase 3	Phase 4 / Marketed[1]
Nefecon	IgAN/ NefIgArd					
Setanaxib	PBC					
Setanaxib	Oncology					
	Kidney					
Setanaxib (ILS)	IPF					
	DKD					
Nefecon	IgAN Open Label Extension[1]					

Depicts ongoing/planned clinical trial stage: Depicts ongoing/planned clinical trial stage in an Investigator Lead Study:

1. Clinical studies primarily supporting healtheconomic and / or treatment related considerations

NOX Platform

1

Calliditas has expanded pipeline with acquisition of NOX inhibition platform

- In the second half of 2020 Calliditas concluded an acquisition of a controlling block followed by mandatory simplified cash tender offer of Genkyotex. Post the recent capital raise Calliditas owns 90.2% and plans to continue to increase its ownership in line with its previously stated intentions.

2

Lead candidate with focus on fibrosis and inflammation in orphan diseases

- Lead candidate, setanaxib, is a NOX Inhibitor that targets NOX 1 and NOX 4, which are major drivers of fibrogenesis in multiple organs
- They produce reactive oxygen species (ROS) and modulate signalling by oxidising signalling proteins

3

A broad platform for clinical development

- NOX1 and NOX4 have the potential to be effective in several fibrosis related diseases across renal, hepatic and lung
- The novel NOX inhibition technology has the potential to have clinical utility within broader indications such as oncology and NASH, and is being investigated (ILS) in Idiopathic Pulmonary Fibrosis (IPF) and Type 1 Diabetic Kidney Disease (DKD)

4

Phase 1 positive results supports further clinical development

- Evaluated safety and pharmacokinetics of setanaxib in doses up to 1600mg/day
- Calliditas will launch Phase 2/3 study in PBC and Phase 2 study in head and neck cancer, whilst exploring kidney indications

Setanaxib

Primary Biliary Cholangitis

- PBC is a chronic, autoimmune, cholestatic orphan liver disease
- An unmet medical need remains despite existing therapies
- Setanaxib has been investigated in a 24 week Phase 2 trial with 111 patients
  - achieved significant reduction in ALP
  - achieved average reduction of 3kPa (one-point fibrosis score reduction)
  - Significant impact on patients' quality of life, in particular on one of PBC's most common/troublesome symptoms, fatigue
  - Well tolerated

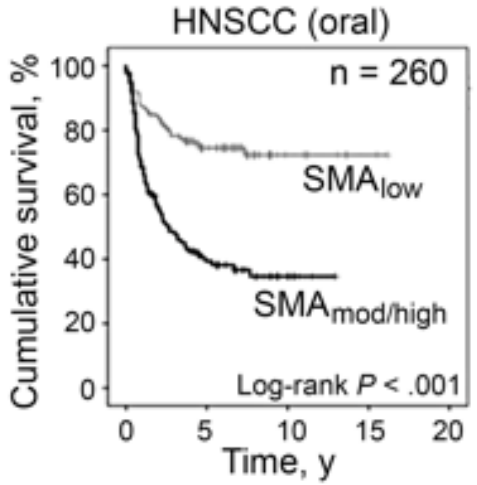
Oncology

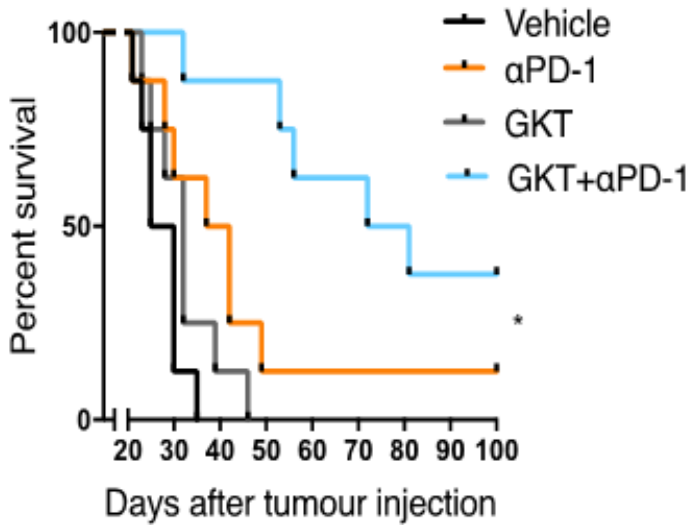
- Immuno-oncology therapies are not as effective in animal models of tumours infiltrated by cancer-associated fibroblasts (CAFs), opening the door for anti-fibrotic agents to be used to improve response to treatment
- NOX4 is over-expressed in CAFs and drives their activation
  - CAFs shield a range of solid tumours from critical tumour-infiltrating CD-8 T-lymphocytes (TILs), and worsen prognosis in patients with high-CAF tumours
- Setanaxib reversed CAF differentiation and overcame TIL exclusion in vivo
  - Showed improved tumour response and survival in a relevant mouse tumour model when administered with anti-PD-1 therapy

Setanaxib in Squamous Cell Carcinoma of the Head & Neck

Scientific rationale

- Cancer-associated fibroblast (CAFs) are phenotypically similar to activated myofibroblasts
- A relationship between CAFs and prognosis in SCCHN has been established
- Immunotherapy (e.g., anti-PD-1/ anti-PD-L1 therapy) continues to expand therapeutic applications across a range of solid tumours
- 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%)
- Setanaxib reversed CAF differentiation and overcame CD8 T-cell exclusion *in vivo*, and improved survival in a relevant mouse tumour model when administered with anti-PD-1 therapy





Anticipated milestones

Anticipated milestones regarding Calliditas' clinical, regulatory and commercial plans

2H 2019

- EMA meeting to discuss surrogate marker ☑
- Fully recruited Part A of NefIgArd with 200 patients ☑
- China IND approval for Nefecon in IgAN, triggering $5mm milestone ☑
- EMA positive opinion regarding pediatric pathway for Nefecon in IgAN ☑
- Filing of Pediatric Investigational Plan submitted to EMA ☑
- Approval of ODD designation for PBC ☑
- Approval of ODD designation for AIH ☑

2020

- In-licensing of a new pipeline project ☑
- Topline readout of Part A of NefIgArd for 200 patients ☑
- China phase 3 recruitment initiated ☑
- Closing of Genkyotex block trade ☑
- Initiate open-label extension trial of NefIgArd ☑
- FDA feedback regarding development plans for AIH ☑
- Closing of Genkyotex tender offer ☑

1H 2021*

- Complete recruitment of NefIgArd (Q1) ☑
- Outcome of Phase 1 high dose PK study of setanaxib (Q1) ☑
- Clinical development plan for NOX inhibitors (Q1) ☑
- Submission of regulatory filing with FDA for approval of IgA Nephropathy (Q1) ☑
- Submission of filing with EMA for approval of IgAN (Q2) ☑
- European commercial partnership (Q2) ☑

2H 2021

- FDA accelerated approval for Nefecon in IgAN
- Initiate pivotal Phase 2/3 trial in PBC
- Initiate proof-of-concept Phase 2 trial in head and neck cancer

2022

- Commercial launch of Nefecon for IgAN in the US, subject to approval
- Conditional approval for Nefecon from EMA (CHMP)
- Commercial launch of Nefecon in Europe, subject to approval

Investment highlights

1. Lead candidate, Nefecon, is a **novel treatment for IgA nephropathy (IgAN), targeting the origin** of this progressive orphan **kidney disease**

2. Nefecon is **positioned to become the first approved drug for IgAN**

3. **Ongoing regulatory interactions with the FDA & EMA**

4. All clinical trials **met primary and secondary endpoints** and demonstrated that Nefecon was well tolerated.

5. **Building integrated orphan / nephrology focused business** through in-licensing or acquisition of product candidates; recently acquired platform of first-in-class NOX Inhibitors.

6. **Pipeline** in orphan liver and kidney indications. POC in head and neck cancer