calliditas
THERAPEUTICS

Pareto Securities' Healthcare Conference

Presenter: Renée Aguiar-Lucander, CEO

September 2020

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Management Team

RENÉE AGUIAR-LUCANDER

CEO

Selected experience:
Partner and COO of Omega Fund Management, Partner and Co-Head of the European & U.S. legacy healthcare & technology portfolio at 3i group

Dr. RICHARD PHILIPSON

CMO

Selected experience:
Over 16 years at GSK ,incl disease Area Head and Acting Chief Medical Officer for the Rare Diseases Unit. Previously CMO at Trizell Ltd, EMD at Takeda.

FREDRIK JOHANSSON

CFO

Selected experience:
CFO and COO at Birdstep Technology/Techstep, CFO at Phone Family, and Teligent Telecom

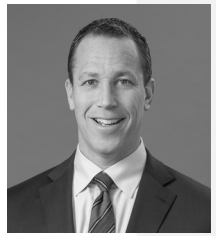
FRANK BRINGSTRUP

VP Regulatory Affairs

Selected experience:
17 years of experience in the pharmaceutical industry within regulatory affairs and health authority interactions. Most recent various positions at Novo Nordisk

ANDREW UDELL

Head North America, Commercial



Selected experience:
20 years of commercial experience in pharma industry; most recent VP of North America Commercial at NeuroDerm; several sales and marketing positions at Purdue Pharma

KATY WELIN-BERGER

VP Operations

Selected experience:
15 years of experience in pharma industry within business operations; most recent VP of Operations at BioGaia AB; several business operations positions at AstraZeneca

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THERAPEUTICS

- A clinical-stage biopharma company focused on novel treatments in orphan indications, with an initial focus on renal and hepatic diseases with significant unmet needs
- Lead product candidate, Nefecon, being developed for the treatment of IgA Nephropathy (IgAN), a serious progressive autoimmune disease of the kidney with no currently approved treatments
- Part A of Pivotal Phase 3 trial in IgAN fully recruited with topline readout expected in 4Q 2020; anticipated NDA and MAA filings in 1H 2021 for accelerated approval in U.S. and conditional approval in E.U.
- Headquartered in Stockholm, Sweden; listed on OMX NASDAQ in Sweden (ticker: CALTX) and on NASDAQ (ticker: CALT)
- Market cap as of August 18, 2020: ~US$600M; Cash balance as of June 30, 2020: US$169M, providing financing through Q3 2022.
- Key institutional shareholders include: Industrifonden, Investinor, BVF Capital, Vivo Capital, Sofinnova Partners, B Julander

Investment highlights

1. Nefecon is a proprietary, novel treatment for IgAN intended to be **disease modifying**
2. Nefecon targets the presumed **origin** of the disease – the area of the ileum where the highest concentration of Peyer's patches are located
3. Nefecon is the **most advanced** product candidate for IgAN. The **only successful** randomized, double-blind, placebo-controlled Phase 2b clinical trial carried out in IgAN to date
4. Ongoing pivotal Phase 3 clinical trial (NefIgArd) **using the same primary endpoint** as previous successful Phase 2b trial
5. Regulatory pathway based on FDA and EMA acceptance of accelerated / conditional approval based on proteinuria as **surrogate marker** for IgAN
6. **Significant unmet medical need** in IgAN with no currently approved treatments; total market opportunity of US$9-10bn in the U.S alone.
7. Additional potential for **pipeline development** and **in-licensing** of product candidates targeting orphan diseases

Our lead indication: IgA Nephropathy – significant unmet medical need

PROFILE

- Progressive autoimmune disease
- Genetic predisposition – required but not sufficient; environmental, bacterial, dietary factors
- Normally diagnosed in ages 20-30
- More prevalent in men than in women in the West
- Up to 50% at risk of developing ESRD within 10-20 years
- Level of protein in the urine (proteinuria) is correlated with traditional outcome measure of kidney function (eGFR)
- High levels of proteinuria indicate disease progression and increased risk of ESRD

ESTIMATED PREVALENCE

MAIN MARKETS	
	**130,000-150,000**
	**200,000**
	**2,000,000[1]**
	**180,000[1]**

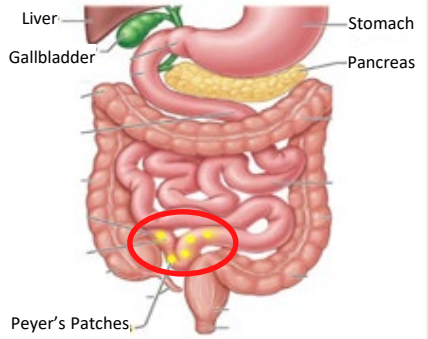
Treatment options

- There is no approved treatment
- Virtually all patients are prescribed blood pressure-lowering agents (ACEs and ARBs)
- As disease progresses, systemic immunosuppressive agents, primarily consisting of high doses of systemic corticosteroids are used by some nephrologists
- Randomized trials involving these off-label immunosuppressant treatments have either failed to show efficacy or shown severe metabolic and infectious side effects, including mortality

Source: 1) Estimates in Greater China and Japan 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

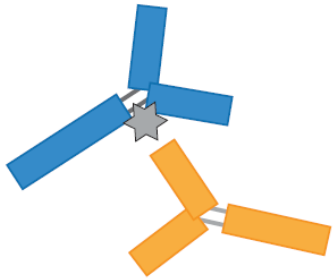


- Follicles of lymphatic tissue, known as Peyer's patches, in the distal part of the small intestine (ileum) produce secretory IgA antibodies

1 Galactose-deficient IgA

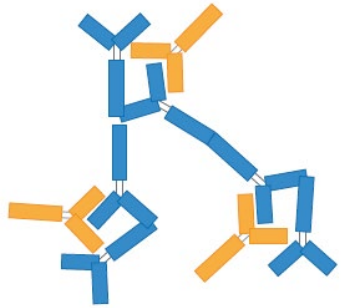
- Patients with IgAN have an increased appearance in the blood of secretory IgA antibodies that lack galactose units (galactose-deficient IgA) in the hinge region, which makes the antibody immunogenic

2 Immune recognition



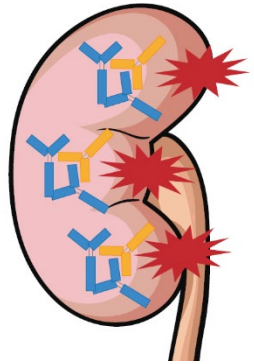
- These IgA antibodies trigger autoantigen production and form autoantibody complexes with autoantibodies directed against the IgA hinge region

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



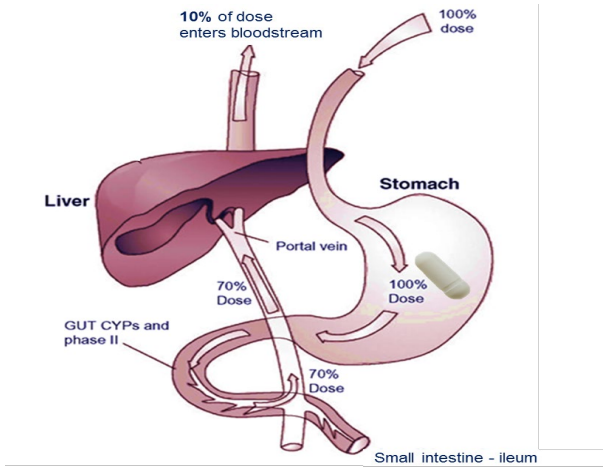
- The deposits of immune complexes in the glomeruli cause an inflammatory cascade that destroys the glomeruli, reducing the kidney's ability to remove waste products from the blood and eventually may result in ESRD

Source: 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

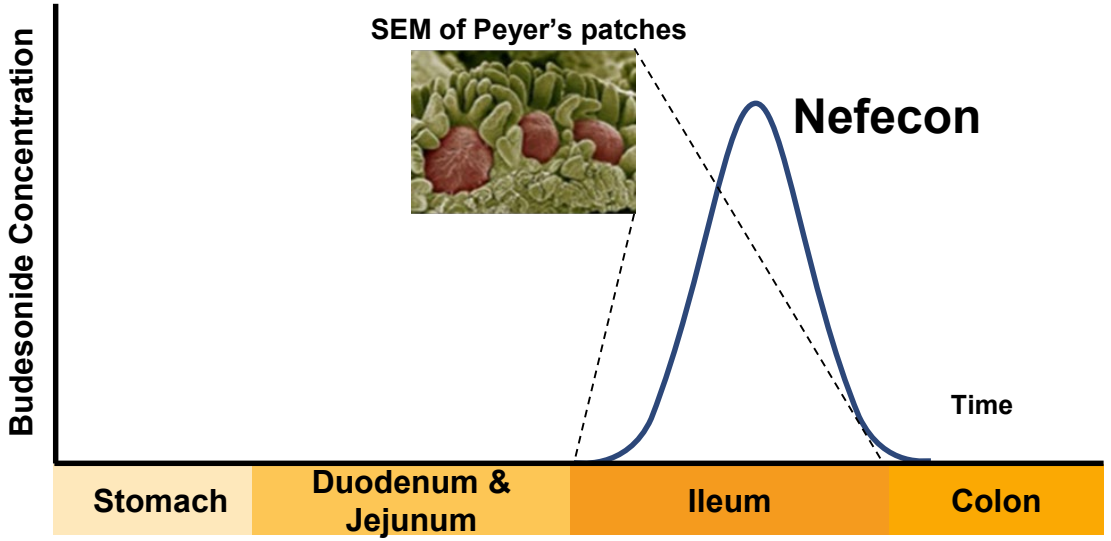
Drug product based on known active ingredient

- 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 of budesonide 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



Strong product protection and product exclusivity for Nefecon

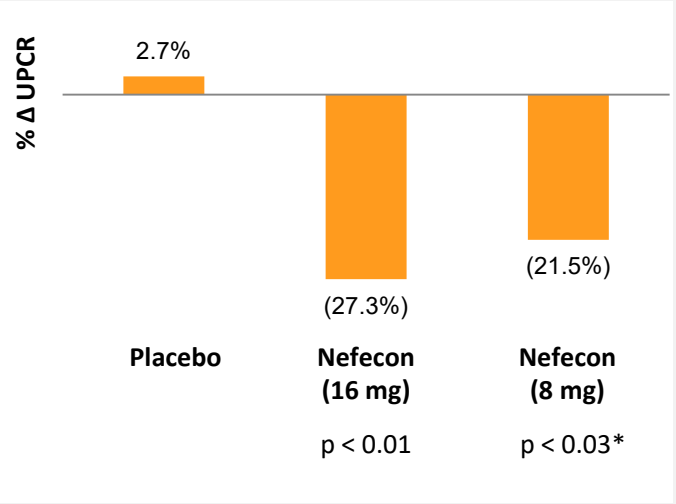
Orphan designation	• Granted orphan drug designation in the U.S. and E.U. Potential data protection and market exclusivity for 7 years (U.S.) and 10 years (E.U.)
Existing patents	• Calliditas has been granted patents covering Nefecon, its formulation and method of manufacturing • The formulation patent runs until 2029
Patent strategy	• Strategic focus on the U.S. and Europe with extension into other geographical markets
Soft barriers	• Significant formulation and manufacturing know-how • Questionable relevance of bioequivalence studies • Nefecon is the most advanced candidate in development

Confirmatory proof of concept observed in Phase 2b trial

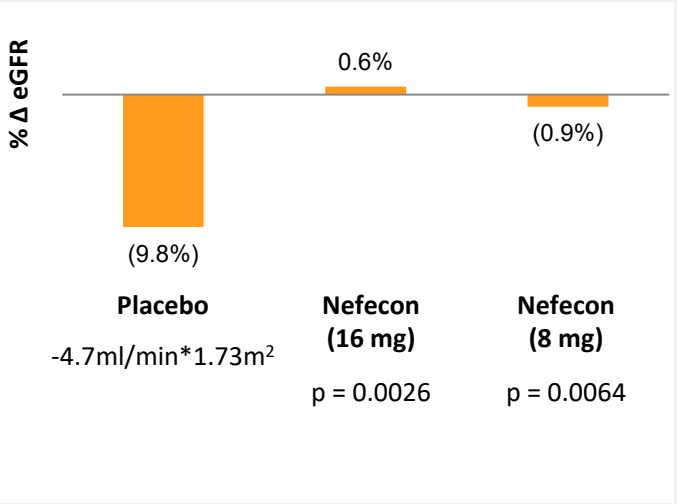
Only Phase 2b trial in IgAN to meet key primary and secondary endpoints

- Large trial population – 150 patients
- Oral dose taken daily over a nine-month period
- Randomized, double-blinded, placebo-controlled
- European trial in 62 sites in 10 countries

Primary endpoint: Reduction in proteinuria



Secondary endpoint: Stabilization of eGFR



Note: Study results published in The Lancet, 2017.
* Not statistically significant based on p=0.0158 to define statistical significance.

Efficacy findings

- ✓ Phase 2b trial of 150 patients demonstrated statistically significant and clinically meaningful reduction in proteinuria and eGFR stabilization in the 16 mg dose cohort
- ✓ Statistically significant UPCR reduction with Nefecon (16 mg) compared to placebo – 9 months treatment ($p<0.01$)
- ✓ Statistically significant eGFR stabilization with Nefecon (16 mg) compared to placebo – 9 months treatment ($p=0.0026$)

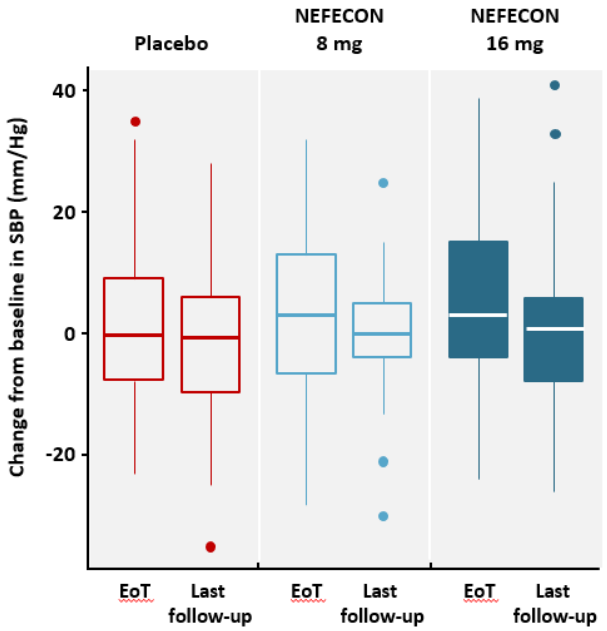
Tolerability findings

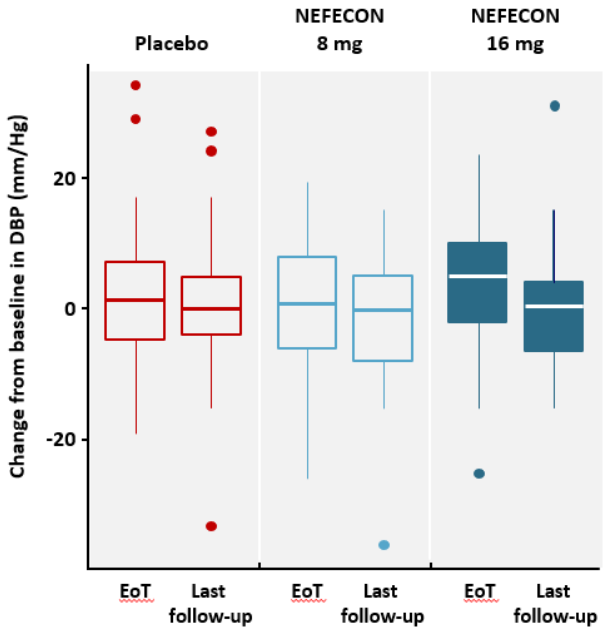
- ✓ Generally well-tolerated, with two possibly treatment-related serious adverse events
- ✓ Treatment-related adverse effects were transient and mainly mild (75.8%) to moderate (22.6%); consistent with those known to be associated with non-systemic corticosteroids
- ✓ No metabolic adverse events (hypertension, diabetes, weight gain)
- ✓ No severe infections

No clinically meaningful changes in blood pressure, body weight or Hb1Ac during Nefecon treatment

Blood pressure

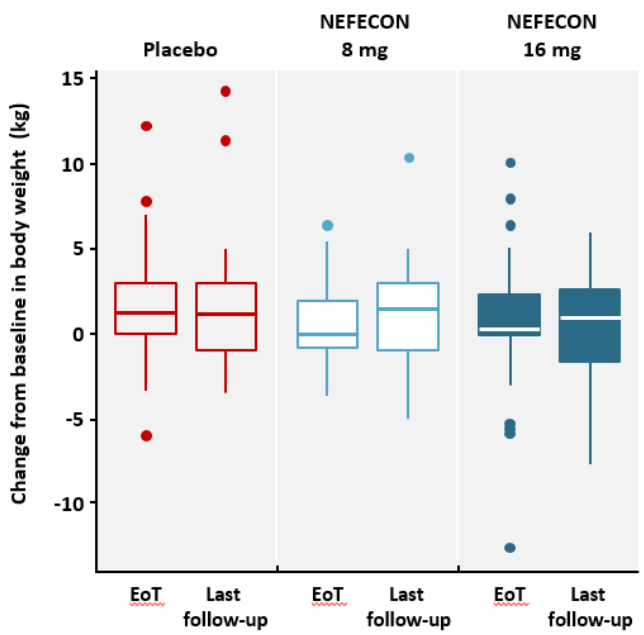
- No clinically meaningful changes from baseline in Systolic Blood Pressure (SBP) and Diastolic Blood Pressure (DBP)





Body weight

- No clinically meaningful changes from baseline in body weight



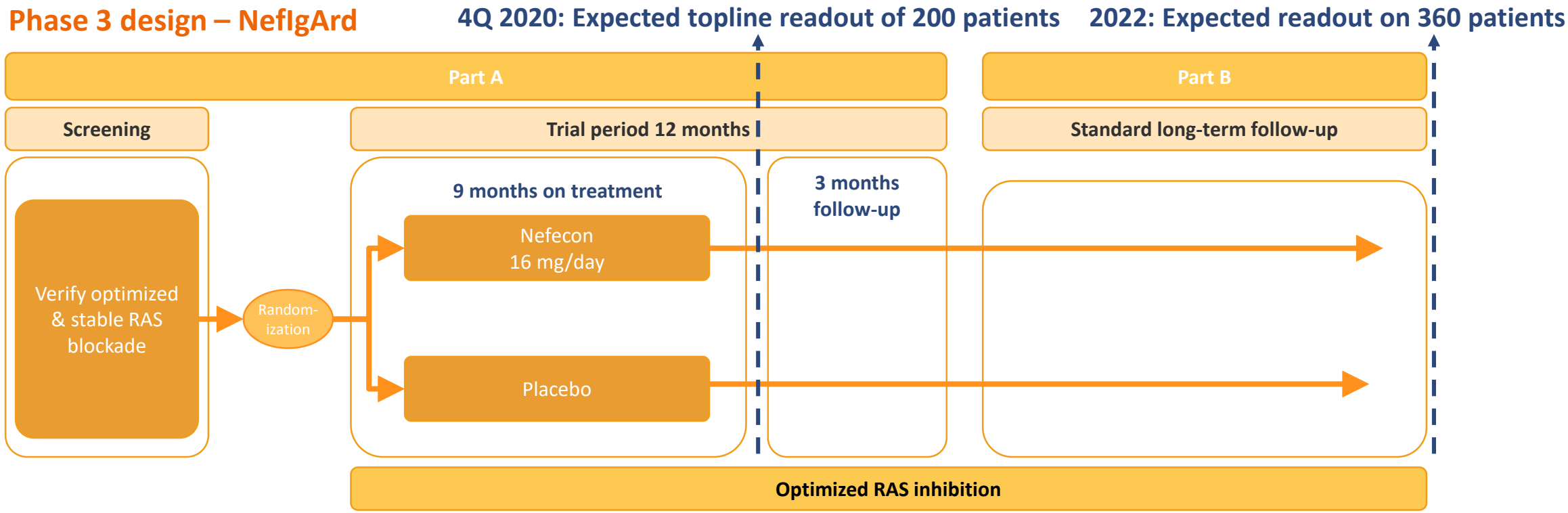
Note: Data on file.

Ongoing pivotal Phase 3 clinical trial (NefIgArd) designed to confirm Phase 2b results

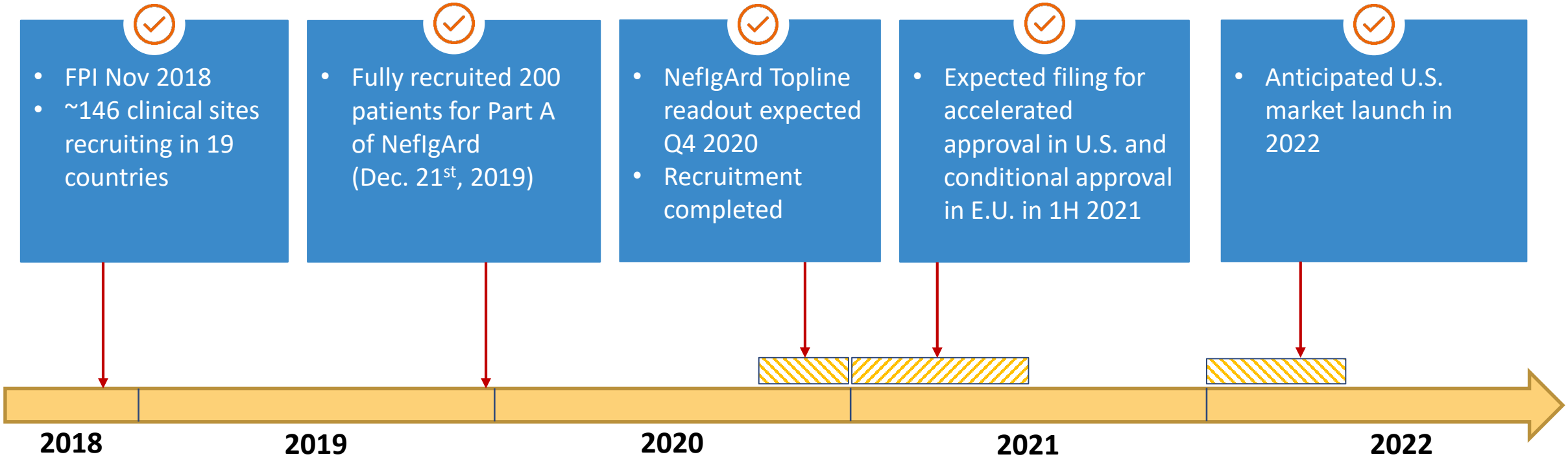
Key highlights

- → Phase 3 study design evaluates the same primary endpoint as Phase 2b trial
- → Fixed 16 mg Nefecon once daily oral dose
- → Reduction of proteinuria: Accelerated approval in U.S. and conditional approval in E.U. based on Part A data
- → Full approval on 2-year eGFR based endpoint – 360 patients

Phase 3 design – NefIgArd



Nefecon – Potential to be first approved treatment for IgAN



- Two-part trial design based on regulatory feedback; Surrogate endpoint: proteinuria, post approval validation of marker: Part B
  - Primary endpoint: difference in kidney function between treated and placebo patients as measured by eGFR over a 2-year period from dosing. N = 360 (including Part A patients.)
- Main differences between Phase 2 and Phase 3: aligning to KDIGO guidelines, accepting slightly more severe patients
  - Total proteinuria from *≥0.75 g/day* to *1g/day*, eGFR from *> 45* to *≥35* and *≤90 mL/min/1.73m²*

Calliditas' global commercialization strategy

	Independent U.S. commercialization / Partner ex-US	
Commercial strategy	• Target IgAN patients at risk of progressing to ESRD (up to 50%) • Earlier-stage treatment to prevent progression and preserve kidney function • Chronic / intermittent dosing	• Targeting of therapeutically focused nephrologists • Collaborate with patient organizations • Partner with leading organizations in each market ex-US
European partner	Commercial Partner, existing distribution channels and / or complementary products	Education of payors regarding disease and severe side effects of existing off-label treatments
Market positioning	• Potentially first approved on-label medication for IgAN, with disease modifying potential. Establish new standard of care for IgAN	
Market opportunity	• U.S. market opportunity of $9-10 billion; Europe & China other significant markets near term • Up to 50% of diagnosed patients represent core target market	
Asia ex-Greater China & Singapore	• Additional partnerships possible – significant unmet medical need	

✓ Orphan drug

✓ Specialist target market

[1] Third party (IQVIA) research commissioned by the Company
[2] Third party (IQVIA) research estimates applied to target population (50%) assuming bi-annual treatment

Market landscape research

Overview of research coverage

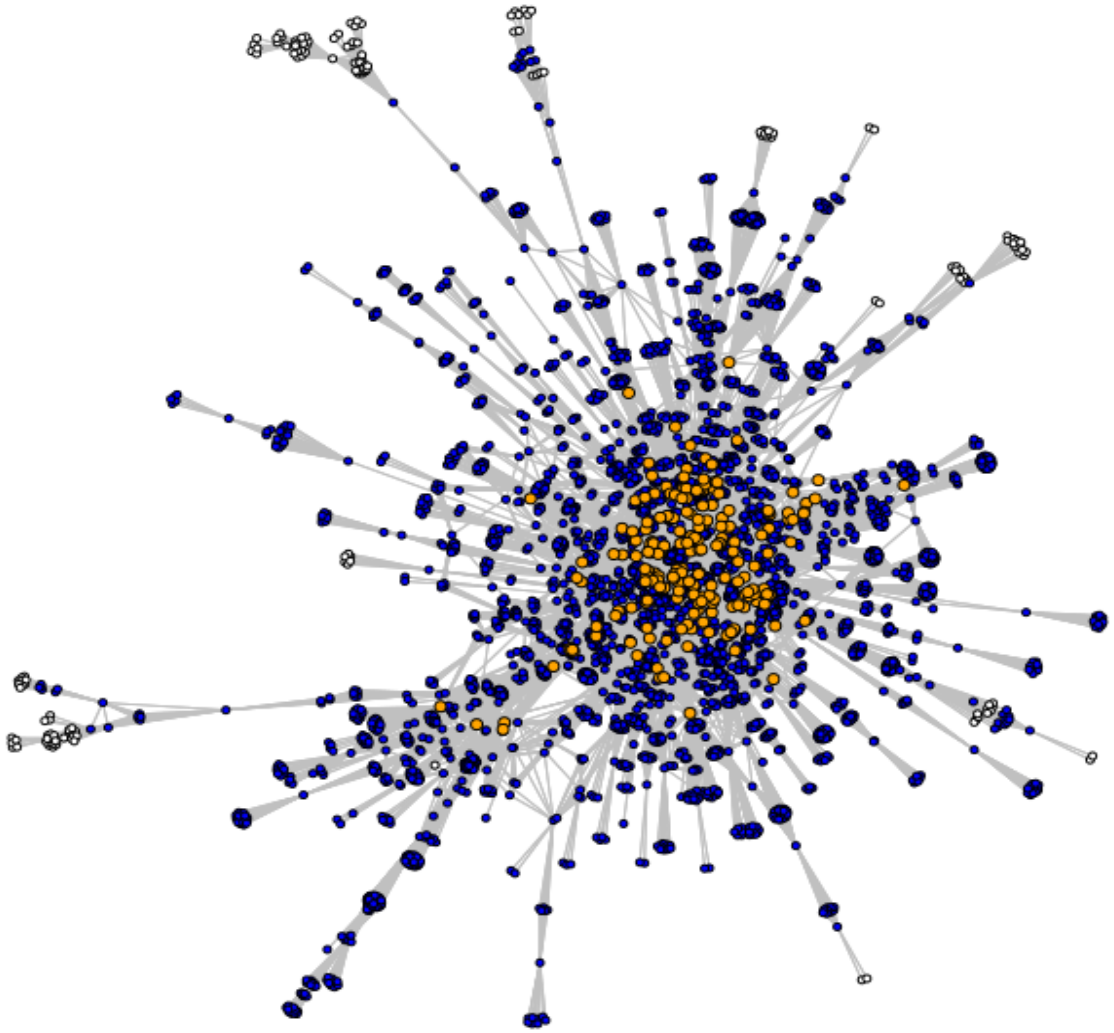
- Quantitative research/survey
  - 102 Nephrologists that, on average, treat 14 IgAN patients per month
- Qualitative interviews:
  - 8 payers covering MCO, PBM, IDN, and FFS for organizations/plans covering over 225 million U.S. lives
  - 12 Nephrologists representing academic centers, community hospitals and private practices that treat a minimum of 10 IgAN patients per month

Perception of Nefecon

- The majority of nephrologists indicated they would prescribe Nefecon:
  - For their IgAN patients within the first year of being on the market (68%), and as the first agent after, or in conjunction with, ACEs/ARBs
- 90% of nephrologists familiar with budesonide had a neutral/favorable opinion when learning that it is the active ingredient in Nefecon
- Anticipate managing as typical for speciality products, within the broad price range of $55 – 85k per year. Restrictions are standard to specialty products and include:
  - Prior authorization to label
  - Prescribed by nephrologist
  - Confirmation of IgAN diagnosis through renal biopsy
  - Step to ACE/ARB

IgAN nephrologist mapping research

- Community size of 3,748 nephrologists in the U.S.
- Entrenched leaders with strong consensus, information flows quickly through most of the network
- 200 KOLs (orange circles) have first degree connections with 90% of the entire community (blue circles)
- Sales force of approximately 40 representatives provides the reach and frequency coverage for U.S. market



Commercialization strategy and market opportunity in the U.S.

Independent U.S. commercialization

Significant unmet medical need	✓ **Orphan Drug** ✓ **130-150k prevalence with up to 50% at risk of developing ESRD within 10-20 years**	✓ **Severe side effects of existing off-label treatments**	✓ **Disease modifying potential – delay or avoid dialysis / transplantation**
Commercial strategy	• Disease modifying potential by delaying or avoiding progression to dialysis / transplant • Earlier stage treatment to preserve kidney function and prevent progression to dialysis / transplant • Chronic / intermittent dosing	• Targeting of therapeutically focused nephrologists – hub-and-spoke structure • Collaborate with patient / advocacy organizations • Relatively small sales (~40) and marketing organization	
Positioning	• Potentially first approved on-label treatment for IgAN with disease modifying potential. Establish a new standard of care for IgAN		
Pricing from research	• $55,000-85,000 per patient per treatment cycle[1]		
Market opportunity	• Total market of $9-10bn; up to 50% at risk of developing ESRD resulting in core target market of $4.5–5bn		

[1] Third party (IQVIA) research commissioned by the Company

Opportunity for disease modifying treatment of autoimmune liver diseases

- Autoimmune liver diseases originate from the liver
  - The autoimmune process is believed to be initiated by antigen-induced production of cytotoxic T-cells and B-cell derived auto-antibodies.
- Autoimmune Hepatitis (AIH) is a rare, orphan, chronic inflammation of the liver[1]
  - The cytotoxic T-cells and auto-antibodies are directed towards antigens presented on the surface of liver cells, leading to liver impairment, cirrhosis and eventually ESLD
  - There are currently no products approved in the U.S.
  - Standard of care includes immunosuppression with systemic corticosteroids (prednisone) alone or in combination with azathioprine[2]
  - Planned interactions with the FDA
- Primary Biliary Cholangitis (PBC) is a progressive and chronic autoimmune disease of the liver[3]
  - The cytotoxic T-cells and auto-antibodies are directed towards antigens on the surface of the epithelial cells of the small bile ducts in the liver, resulting in inflammation and damage and eventually destroying the bile ducts[4]; this results in an increase of bile to toxic levels, resulting in liver impairment, cirrhosis and eventually ESLD
  - The anti-cholestatic agents Ursodeoxycholic acid (UDCA) and Obeticholic acid (Ocaliva) are the only FDA-approved medical treatments for PBC. Both are FXR agonists.
  - There is still a significant unmet medical need: No targeted anti-inflammatory therapy is approved in the U.S. or Europe

Source: 1) Feld et al, Hepatology 2005;42:53-62, Sahebjam and Vierling, Front Med. 2015 Jun;9(2):187-219. 2) Czaja, Expert Opin Drug Saf. 2008;7(3):319-33; Czaja, Liver Int 2009;29(6):816-23; Manns et al, Hepatology 2010;51(6):2193-213 (AASLD 2010 AIH Guideline). 3) Lindor et al, Hepatology. 2009 Jul;50(1):291-308,EASL PBC Clinical Practice Gudielines, Journal of Hepatology 2017; 67:145–172. 4)) Kim et al, Gastroenterology 2000;119:1631–1636).

Genkyotex

- Calliditas has entered into an agreement to acquire 62.7% of Genkyotex, a pioneer in NOX inhibition therapies, for €20.3M in cash
  - The off-market block trade is expected to close in early October 2020, subject to clearance by the French Ministry of Economy and Finance
  - Following closing, Calliditas will file a mandatory simplified cash tender offer for the remaining Genkyotex shares
- NOX Inhibitors
  - Setanaxib targets NOX 1 and NOX 4 inhibition
  - NOX 1 & NOX 4 are major drivers of fibrogenesis in multiple organs. They produce reactive oxygen species (ROS) and modulate signalling by oxidising signalling proteins, which drives multiple inflammatory & fibrogenic pathways.
  - Genkyotex's novel NOX inhibition technology has the potential to have broad clinical utility beyond PBC, as a platform to target other fibrotic indications, including Primary Sclerosing Cholangitis (PSC), selected kidney diseases and Idiopathic Pulmonary Fibrosis (IPF)
- Setanaxib
  - Genkyotex's lead clinical candidate, setanaxib (GKT831), is in development for PBC
  - In a Phase 2 clinical trial, setanaxib demonstrated evidence of anti-fibrotic activity combined with a favorable tolerability profile, as well as a statistically significant impact on fatigue.
  - Genkyotex is in ongoing dialogue with the FDA and EMA to provide a path forward for the late stage development and potential registration of setanaxib in PBC

Anticipated milestones

Anticipated milestones regarding Calliditas' clinical, regulatory and commercial plans

1H 2018

- IPO raising $82m on Nasdaq OMX ✓

2H 2018

- NefIgArd first patient in ✓
- Application for Orphan Drug Designation (ODD) for PBC submitted ✓
- Application for ODD for AIH submitted ✓

1H 2019

- Filing of Pediatric Investigational Plan submitted to EMA ✓
- Approval of ODD designation for PBC ✓
- Approval of ODD designation for AIH ✓

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 ✓

2020*

- In-licensing of a new project to the pipeline (closing expected early 2020) ✓
- Topline readout of Part A of NefIgArd for 200 patients (4Q 2020)
- Initiate open-label extension trial for Nefecon in IgAN (4Q 2020)
- Complete recruitment of Part B of NefIgArd trial of additional 160 patients (2020)
- FDA feedback regarding development plans for AIH (2020)
- China part of phase 3 recruitment initiated (2020)

2021

- FDA meeting regarding development plans for PBC (1Q 2021)
- NDA / MAA filings with FDA and EMA for accelerated / conditional approval of Nefecon in IgAN (1H 2021)
- Initiate open-label chronic dosing trial for Nefecon in IgAN (2021)
- Late stage clinical program initiated

2022

- Commercial launch of Nefecon for IgAN in U.S. (1H 2022)
- Readout of Part B of NefIgArd trial based on 360 patients for validation of surrogate marker to support full approval (2022)*

* Subject to uncertainty due to COVID-19 outbreak.

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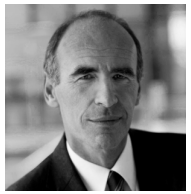
2. Nefecon targets the presumed **origin** of the disease – the area of the ileum where the highest concentration of Peyer's patches are located
3. Nefecon is the **most advanced** product candidate for IgAN. The **only successful** randomized, double-blind, placebo-controlled Phase 2b clinical trial carried out in IgAN to date
4. Ongoing pivotal Phase 3 clinical trial (NefIgArd) **using the same primary endpoint** as previous successful Phase 2b trial
5. Regulatory pathway based on FDA and EMA acceptance of accelerated / conditional approval based on proteinuria as **surrogate marker** for IgAN
6. **Significant unmet medical need** in IgAN with no currently approved treatments; total market opportunity of US$9-10bn in the U.S alone.
7. Additional potential for **pipeline development** and **in-licensing** of product candidates targeting orphan diseases

Board of directors

ELMAR SCHNEE

Chairman

Selected experience:
Previously CEO of Merck Serono and instrumental in the acquisition of Serono by Merck KGaA. He has also served as General Partner and member of the Executive Board of Merck KGaA and held several senior global management positions with UCB and Sanofi



HILDE FURBERG

Board member

Selected experience:
Currently Senior VP of Rare Disease EMEA at Sanofi Genzyme and Non-executive Director at BerGenBio. Previously, held board memberships at Algeta, Clavis Pharma and Probi

LENNART HANSSON

Board member

Selected experience:
Currently Senior Advisor at Industrifonden. Previously executive positions at KabiGen, Symbicom, AstraZeneca and Biovitrum

MOLLY HENDERSON

Board member

Selected experience:
Served as CFO of several listed life science companies for over 17 years. Currently, CFO and Executive Vice President of Advaxis, Inc. Previously CFO of Iovance Biotherapeutics, Inc. and Chief Business and Financial Officer and Senior Vice President of VirtualScopics, Inc.

DIANE PARKS

Board member

Selected experience:
Deep sales and marketing experience from the US; has held positions such as Head of U.S. Commercial for Kite Pharma, VP of Sales for Amgen and Head of Global Marketing at Pharmacyclics.

Clinical advisory board comprising world leading IgAN specialists

Global Advisory Board

Prof Jonathan Barratt
Nephrologist Leicester University, UK

SELECTED EXPERIENCE:

- On the steering committee of the International IgA Nephropathy Network
- Involved in many clinical trials involving IgA Nephropathy

Prof Jürgen Floege
Nephrologist Aachen University, Germany

SELECTED EXPERIENCE:

- Executive council member International Society of Nephrology and scientific advisory board of ERA/EDTA
- Responsible for the STOP-IgAN study

Prof Brad Rovin
Nephrologist Ohio State University, USA

SELECTED EXPERIENCE:

- Experienced nephrologist working closely with Calliditas
- Focused on biomarker development for glomerular diseases

Prof Daniel Cattran
Nephrologist University of Toronto, Canada

SELECTED EXPERIENCE:

- Kidney Foundation of Canada, PSI, the National Institutes of Health and the Canadian Institutes for Health Research

Prof Hong Zhang
Nephrologist
Peking University First Hospital, Beijing

SELECTED EXPERIENCE:

- Experienced nephrologist with many board committee positions in China

Prof Bengt Fellström
Nephrologist Akademiska sjukhuset, Sweden

SELECTED EXPERIENCE:

- Senior professor at Department of Medical Sciences
- Inventor of Nefecon

Prof Richard Lafayette
Nephrologist Stanford University, USA

SELECTED EXPERIENCE:

- Editor-in-Chief of ASN Kidney News
- Member of the Glomerular Disease Advisory Committee, ASN

Dr Hernan Trimarchi
Nephrologist Universidad de Buenos Aires, Argentina

SELECTED EXPERIENCE:

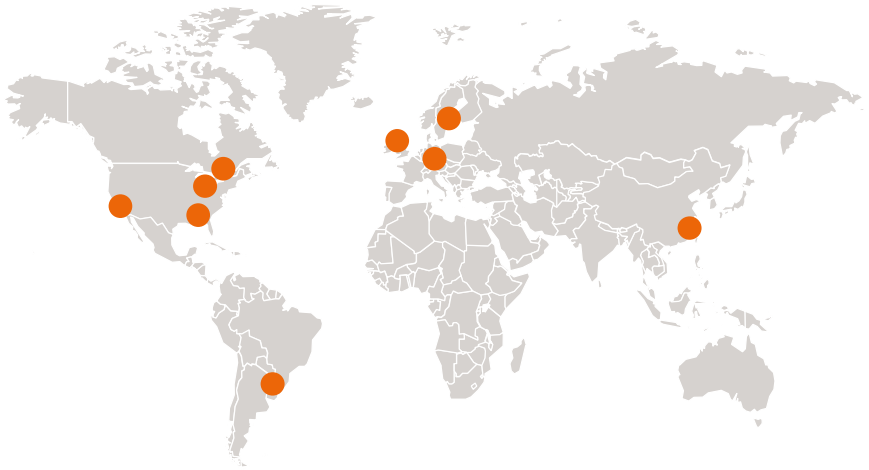
- Experienced nephrologist
- Part of the global IgAN steering committee

Prof Vladimir Tesar
Nephrologist Charles University in Prague, Czech Republic

SELECTED EXPERIENCE:

- Scientific Advisory Board of ERA/EDTA and ASN
- Was responsible for the VALIGA study

calliditas
THERAPEUTICS



Broad support from key opinion leaders underpin global development program