calliditas
THERAPEUTICS

FDA Approval Presentation

December 2021

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On today's call:

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

FREDRIK JOHANSSON

CFO

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

ANDREW UDELL

President, North America

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

Dr. RICHARD PHILIPSON

CMO

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

calliditas THERAPEUTICS

- 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**.

- In immunoglobulin A nephropathy (IgAN), a large Phase 2b study with 150 patients was published in 2017 and top line data from the ongoing Phase 3 NefIgArd trial read out in November, 2020. Both clinical trials **met primary and key secondary endpoints**.

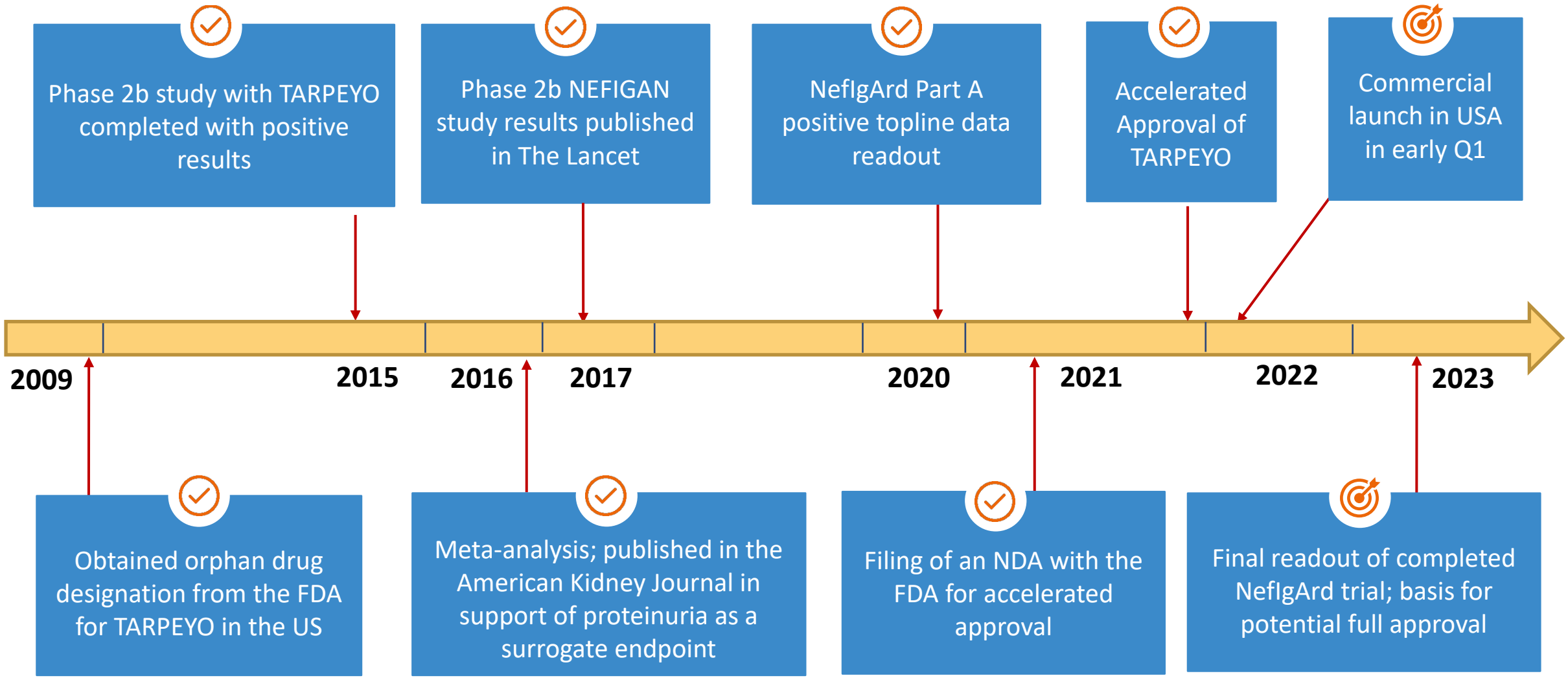
- First commercial product, **TARPEYO™(budesonide) delayed release capsules,** is **the first and only FDA approved drug** in IgAN and was approved under an accelerated approval to reduce proteinuria in adults with IgAN at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) ≥ 1.5 g/g.

- **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.

- Strong cash position - **cash balance as of November 18, 2021: SEK 1,164M** (US$130M).

A PIONEERING JOURNEY



IgA Nephropathy – a significant unmet medical need

PROFILE

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

- Patients are typically diagnosed between 20-30 years of age
- 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

- First accelerated approval of a drug candidate specifically designed for IgAN.

MARKET OPPORTUNITY

ESTIMATED PREVALENCE

130,000 - 150,000

Annual incidence of approximately 4,000 – 4,500.

We believe that the label as per the accelerated approval represents a very significant market opportunity.

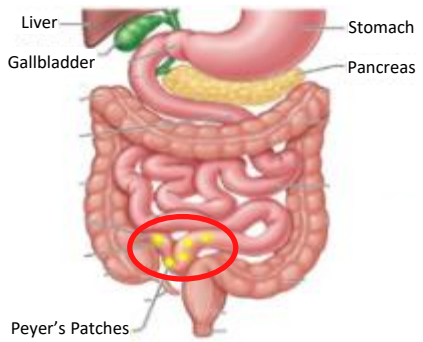
Full approval and potential for label expansion subject to Part B confirmatory data read out.

200,000

Ongoing regulatory review with EMA with a target opinion date of Q1, 2022.

Disease origin and progression – predominant theory

Peyer´s patches

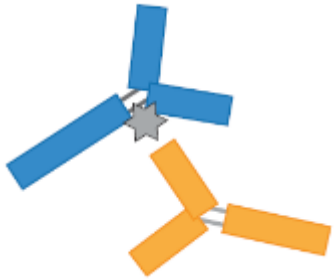


- Follicles of lymphatic tissue, known as Peyer's patches, in the distal part of the small intestine (ileum) produce secretory IgA antibodies

1 Galactose-deficient IgA

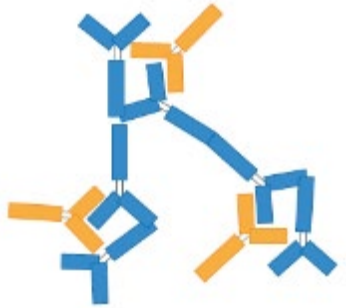
- Patients with IgAN have an increased appearance in the blood of secretory IgA antibodies that lack galactose units (galactose-deficient IgA) in the hinge region, which makes the antibody immunogenic

2 Immune recognition



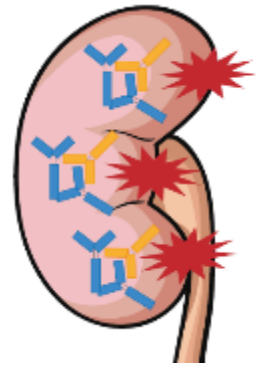
- These IgA antibodies trigger autoantigen production and form autoantibody complexes with autoantibodies directed against the IgA hinge region

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

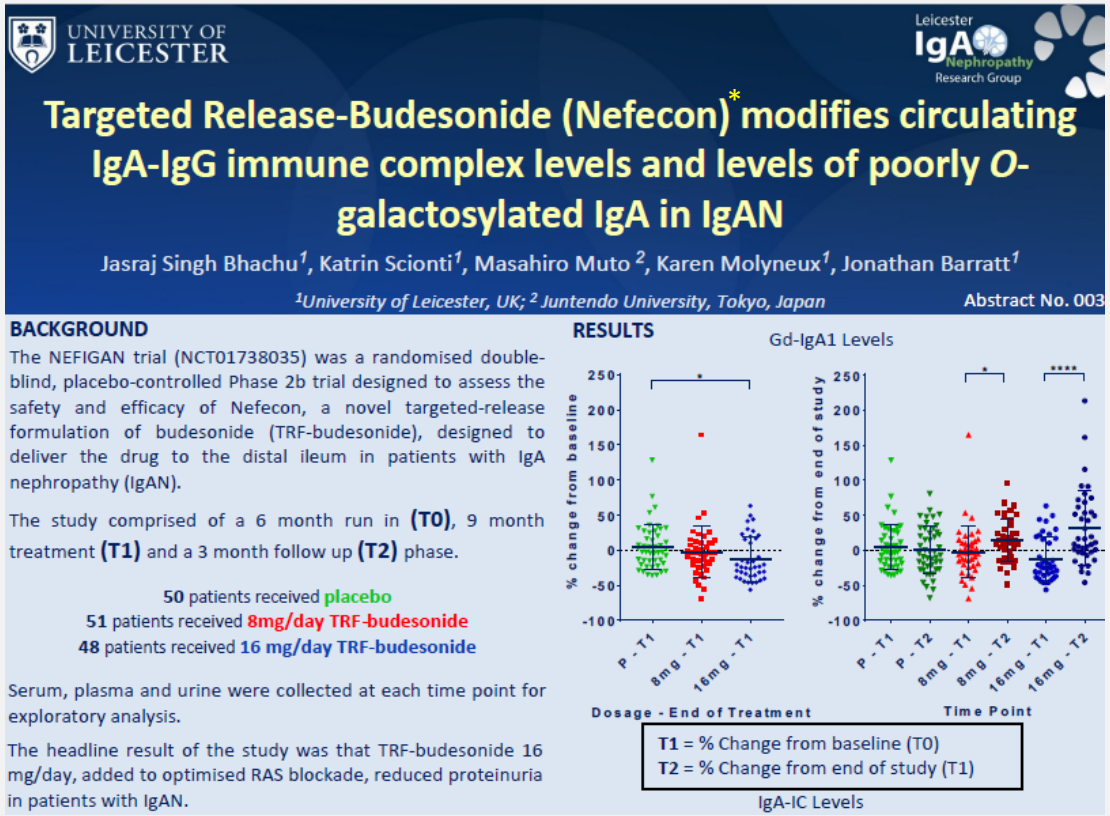


- The deposits of immune complexes in the glomeruli cause an inflammatory cascade that destroys the glomeruli, reducing the kidney's ability to remove waste products from the blood and eventually may result in ESRD

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.

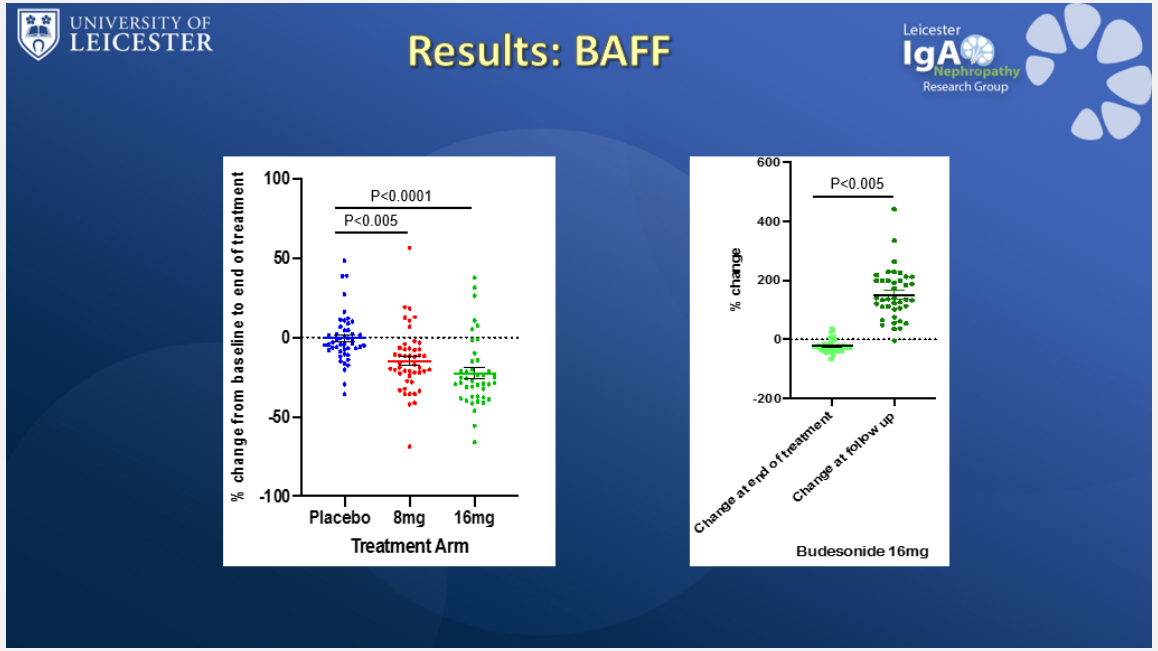
Biomarker data

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 TARPEYO had a demonstrated impact on circulating pathogenic biomarkers in IgAN



*TARPEYO was developed under the product name Nefecon

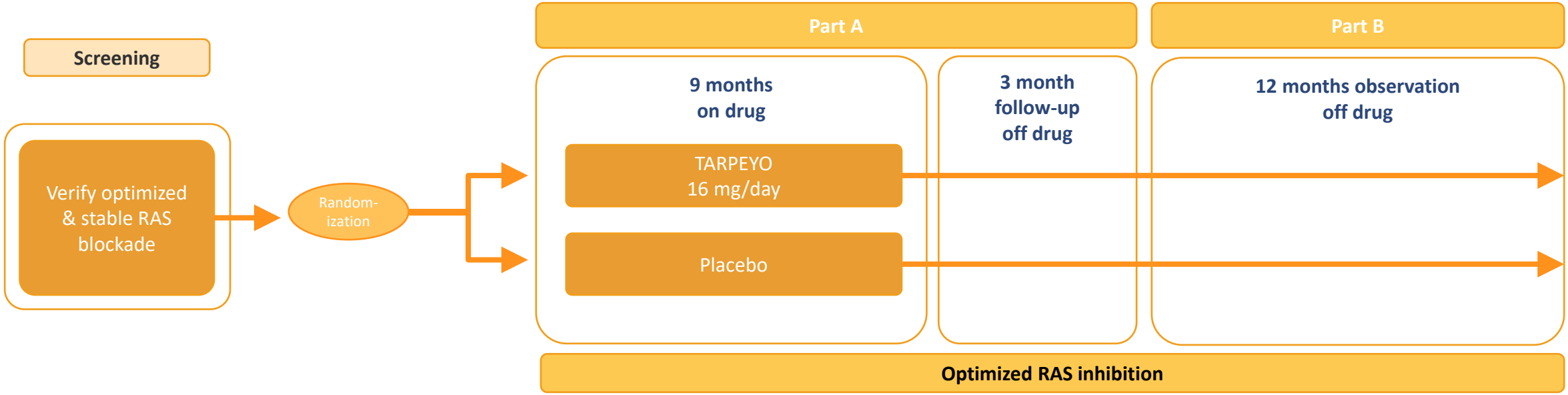
NefIgArd study - basis for FDA's accelerated approval of TARPEYO

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.



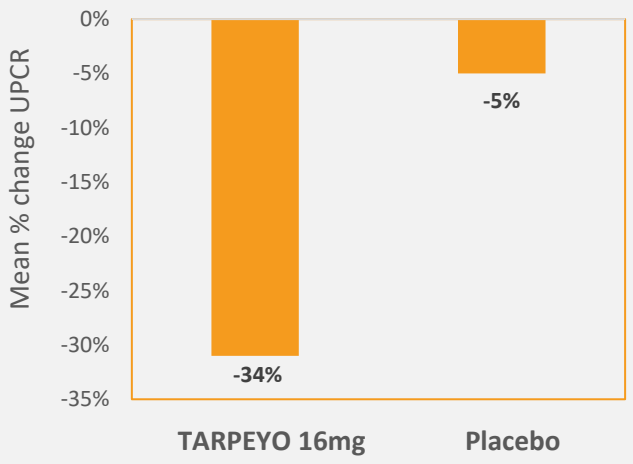
Overall study population

BASELINE CHARACTERISTICS

Age (years) [Median]	44
Sex (n, % male)	135 (67.8%)
Race (n, % White)	171 (85.9%)
Systolic BP/Diastolic BP [Mean]	126 / 79
UPCR (g/gram) [Mean]	1.6
eGFR CKD-EPI (mL/min/1.73 m^2) [Mean]	58

Phase 3 study results – Part A

Primary endpoint: reduction in proteinuria



Efficacy findings

- ✓ At 9 months, reduction in UPCR for TARPEYO-treated patients = 34%; reduction in UPCR for placebo-treated patients = 5%
- ✓ Statistically significant UPCR reduction with TARPEYO (16 mg) compared to placebo following 9 months treatment (p=0.0001)

Selected Safety Data

- ✓ The majority of adverse reactions were mild or moderate in severity
- ✓ The most frequently reported adverse reactions (≥5% of TARPEYO treated patients, and ≥2% higher than Placebo) were: hypertension, peripheral edema, muscle spasms, acne, dermatitis, weight increased, dyspnea, fatigue and hirsutism.

Phase 3 safety summary – Part A

Adverse Reaction	TARPEYO 16 mg (N=97)	Placebo (N=100)
	n (%)	n (%)
Patients with any Adverse Reaction	84 (87)	73 (73)
Hypertension	15 (16)	2 (2)
Peripheral edema	14 (14)	4 (4)
Muscle spasms	13 (13)	4 (4)
Acne	11 (11)	2 (2)
Dermatitis	7 (7)	1 (1)
Weight increased	7 (7)	3 (3)
Dyspnea	6 (6)	0 (0)
Face edema	6 (6)	1 (1)
Dyspepsia	5 (5)	2 (2)
Fatigue	5 (5)	2 (2)
Hirsutism	5 (5)	0 (0)

INDICATIONS AND USAGE

TARPEYO™ (budesonide) delayed release capsules · 4 mg

Indication

- TARPEYO™ (budesonide) delayed release capsules is 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

Please see full Prescribing Information, available at TARPEYOHCP.com

IMPORTANT SAFETY INFORMATION

TARPEYO™ (budesonide) delayed release capsules • 4 mg

Contraindications: TARPEYO is contraindicated in patients with hypersensitivity to budesonide or any of the ingredients of TARPEYO. Serious hypersensitivity reactions, including anaphylaxis, have occurred with other budesonide formulations.

Warnings and Precautions

Hypercorticism and adrenal axis suppression: When corticosteroids are used chronically, systemic effects such as hypercorticism and adrenal suppression may occur. Corticosteroids can reduce the response of the hypothalamus-pituitary-adrenal (HPA) axis to stress. In situations where patients are subject to surgery or other stress situations, supplementation with a systemic corticosteroid is recommended. When discontinuing therapy *[see Dosing and Administration]* or switching between corticosteroids, monitor for signs of adrenal axis suppression.

Patients with moderate to severe hepatic impairment (Child-Pugh Class B and C, respectively) could be at an increased risk of hypercorticism and adrenal axis suppression due to an increased systemic exposure to oral budesonide. Avoid use in patients with severe hepatic impairment (Child-Pugh Class C). Monitor for increased signs and/or symptoms of hypercorticism in patients with moderate hepatic impairment (Child-Pugh Class B).

Risks of immunosuppression: Patients who are on drugs that suppress the immune system are more susceptible to infection than healthy individuals. Chicken pox and measles, for example, can have a more serious or even fatal course in susceptible patients or patients on immunosuppressive doses of corticosteroids. Avoid corticosteroid therapy in patients with active or quiescent tuberculosis infection; untreated fungal, bacterial, systemic viral, or parasitic infections; or ocular herpes simplex. Avoid exposure to active, easily transmitted infections (eg, chicken pox, measles). Corticosteroid therapy may decrease the immune response to some vaccines.

Other corticosteroid effects: TARPEYO is a systemically available corticosteroid and is expected to cause related adverse reactions. Monitor patients with hypertension, prediabetes, diabetes mellitus, osteoporosis, peptic ulcer, glaucoma, cataracts, a family history of diabetes or glaucoma, or with any other condition in which corticosteroids may have unwanted effects.

Adverse reactions: In clinical studies, the most common adverse reactions with TARPEYO (occurring in ≥5% of TARPEYO patients and ≥2% higher than placebo) were hypertension (16%), peripheral edema (14%), muscle spasms (13%), acne (1%), dermatitis (7%), weight increase (7%), dyspnea (6%), face edema (6%), dyspepsia (5%), fatigue (5%), and hirsutism (5%).

Drug interactions: Budesonide is a substrate for CYP3A4. Avoid use with potent CYP3A4 inhibitors, such as ketoconazole, itraconazole, ritonavir, indinavir, saquinavir, erythromycin, and cyclosporine. Avoid ingestion of grapefruit juice with TARPEYO. Intake of grapefruit juice, which inhibits CYP3A4 activity, can increase the systemic exposure to budesonide.

Use in specific populations

Pregnancy: The available data from published case series, epidemiological studies, and reviews with oral budesonide use in pregnant women have not identified a drug-associated risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes. There are risks to the mother and fetus associated with IgAN. Infants exposed to in utero corticosteroids, including budesonide, are at risk for hypoadrenalism.

Commercial Readiness

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TARPEYO™
(budesonide) delayed release capsules

Market size and high cost of IgAN

U.S. prevalence is estimated between 130,000 – 150,000

More than 50% of patients potentially progress to ESRD

Cost of dialysis to commercial payers is over $200k annually and the cost of kidney transplant is over $440k*

*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/).

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

80% Believe early intervention is critical to successful outcomes

Source: Spherix Global Insights, RealWorld Dynamix IgA Nephropathy 2021

High recognition and receptivity

Awareness (based on Phase 3 results)[1]:

- Unaided – more than four times any other agent in development
- Of those with moderate or greater familiarity – 92% rated product "highly positive" in likelihood for success in IgAN
- Highest rated product in development as the first "most desired"

Nephrologists self rated as familiar, are ***extremely likely*** to prescribe a product with this profile for[2]

~70% of their patients

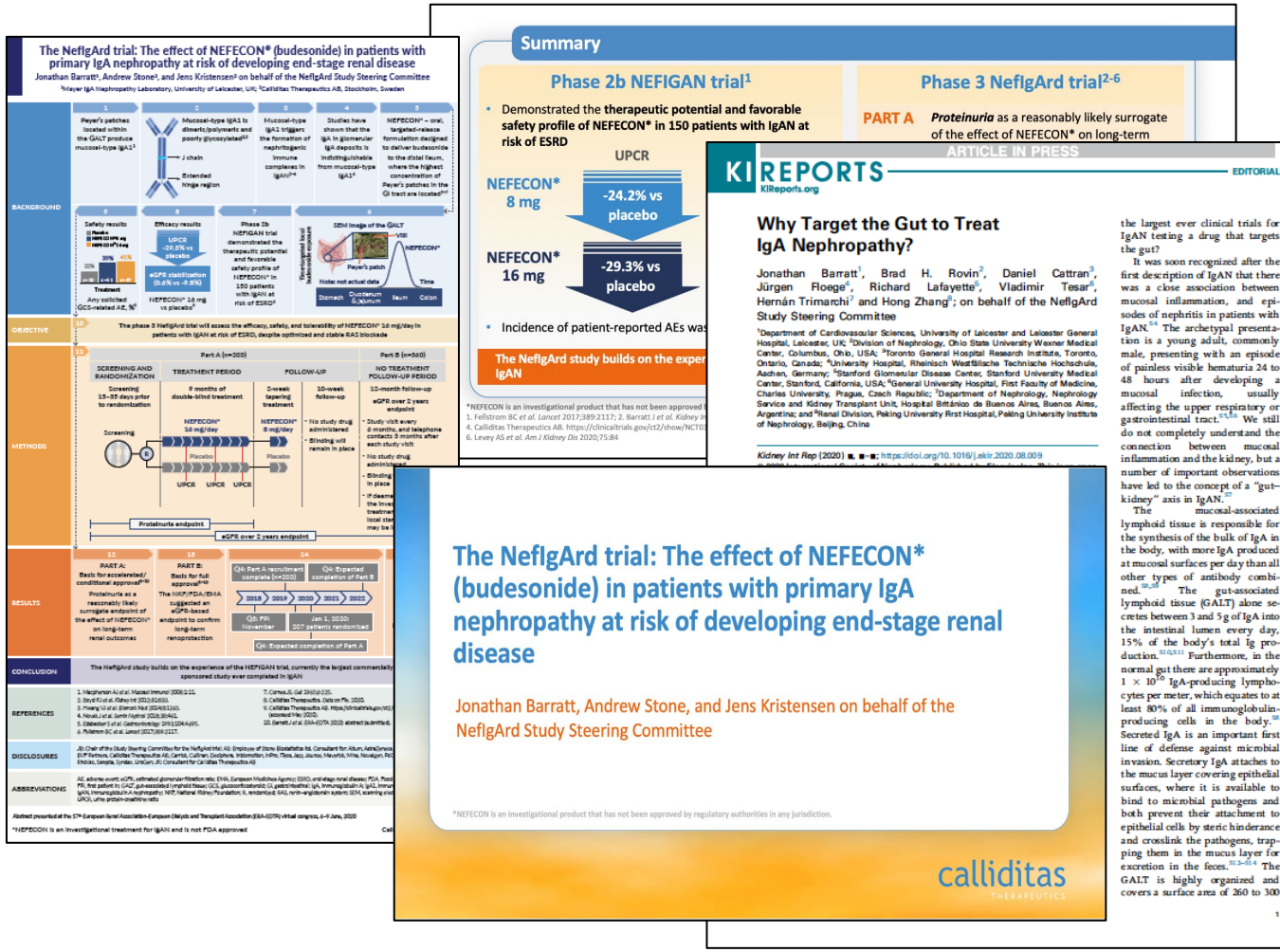
[1]Spherix Global Insights, Market Dynamix IgA Nephropathy (US), 2021 with 100 nephrologists (note Nefecon was the product name used in the research)
[2] Spherix Global Insights, RealWorld Dynamix IgA Nephropathy 2021 with 188 nephrologists (note Nefecon was the product name used in the research)

Commercial launch early first quarter 2022

- Experienced leadership team in Medical Affairs, Marketing, Market Access and Sales
- Sales force contingent offers became effective upon FDA approval
- Trade, distribution and patient support services all operational
- Targeted promotional campaign (both in person and remote interactions)
- Focused and eager nephrologist market and advocacy community

Medical Affairs - expanding scientific knowledge

- Medical Science Liaison Team formed in early 2020
- Published articles & posters
- Advisory boards and work with KOLs
- Continued congress presence



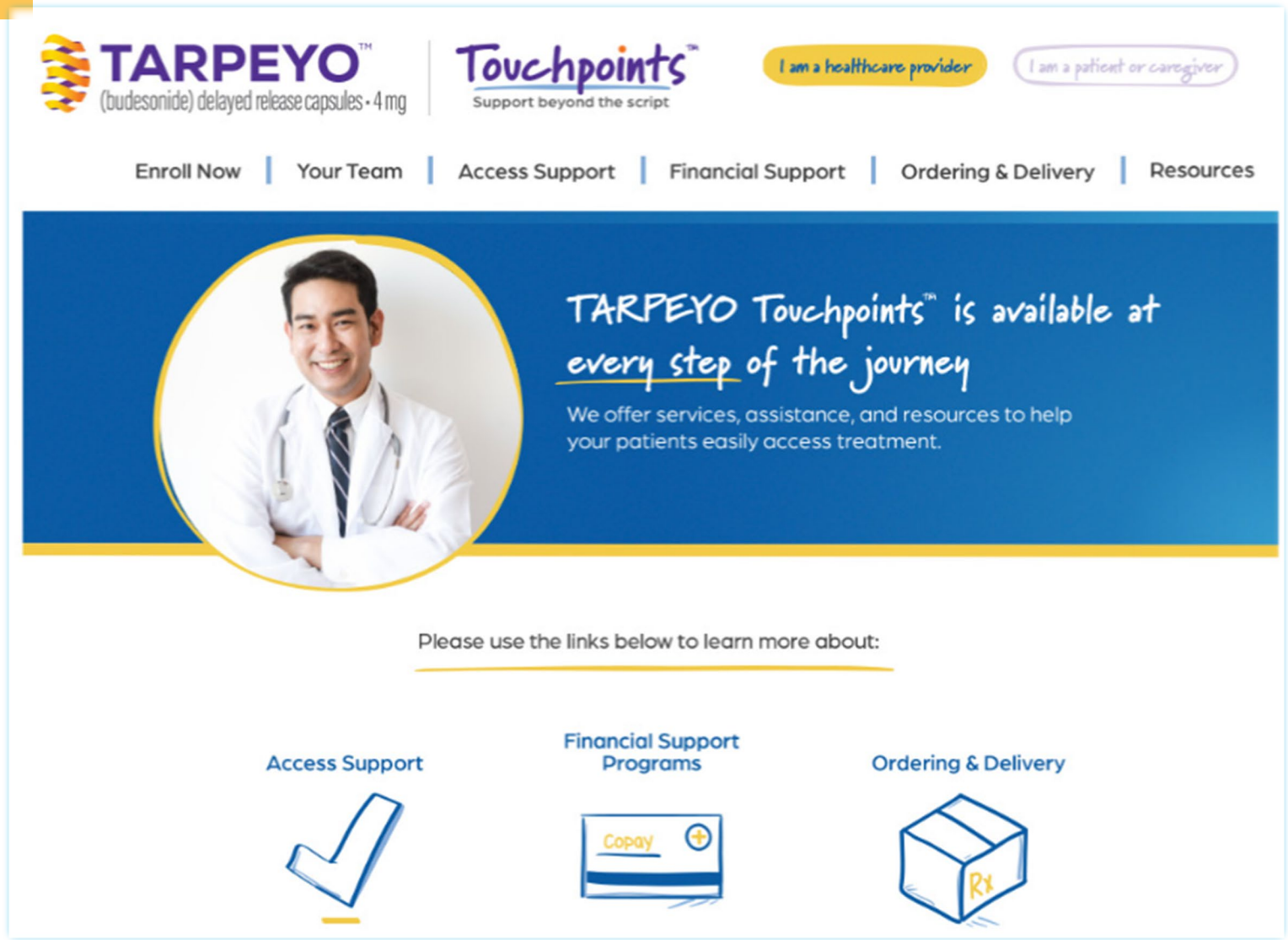
Minimizing barriers to Market Access

- Well established trade and distribution partners operational
- National Account Managers in place since 3Q 2021
- Wholesale acquisition cost (WAC) of $14,160 for a 30-day supply
- Goal is to minimize time from prescription to patient taking medication

Biologics By McKesson

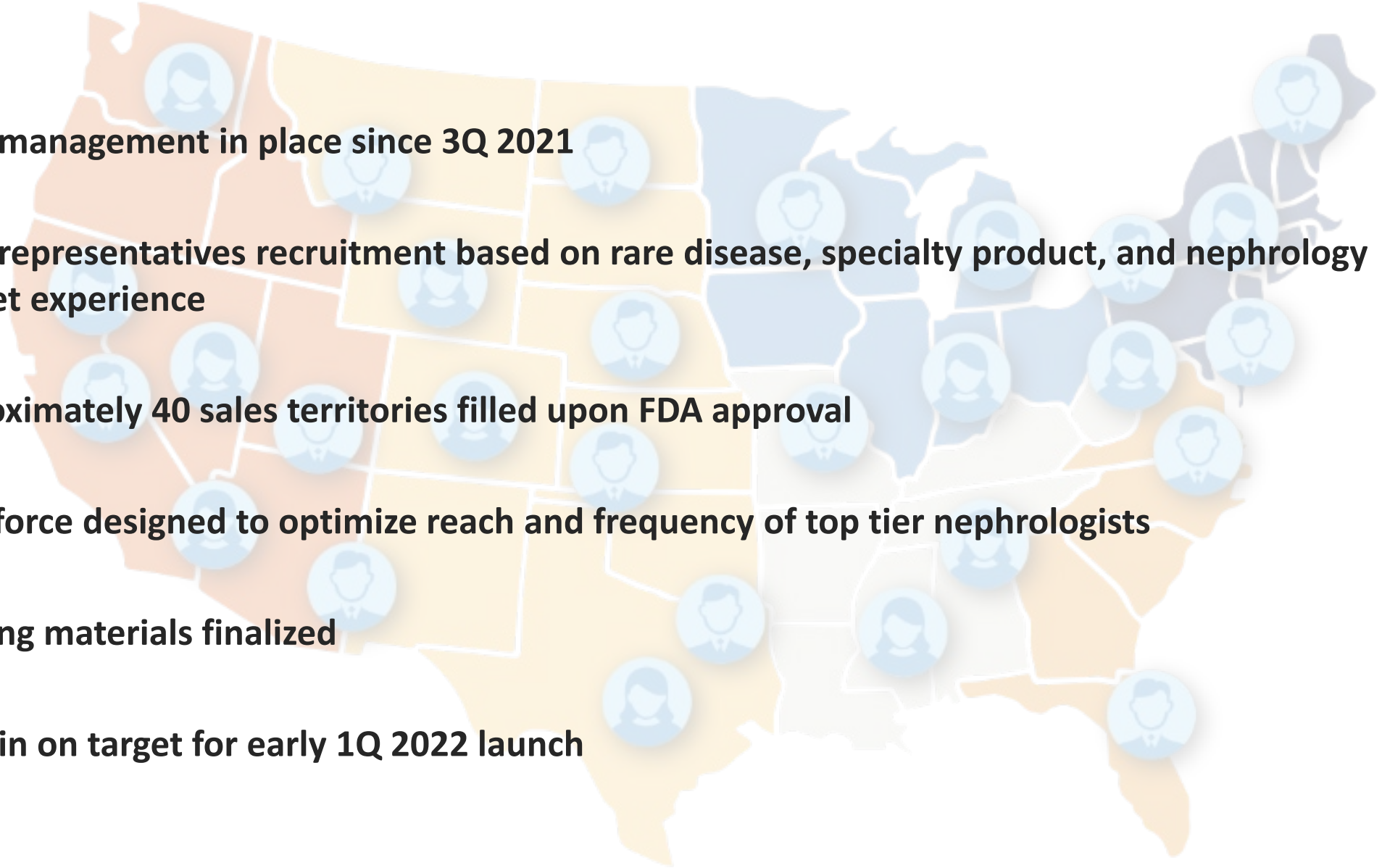
AmerisourceBergen ICS

Patient support services: TARPEYO Touchpoints™



- **TARPEYO Touchpoints™** is a full-service patient and provider support program, designed to accelerate and streamline access to TARPEYO™
- Utilizes **Biologics** by McKesson's *PharmacyElite*™ model – integrated Hub and exclusive Specialty Pharmacy under one roof
- Staffed by **Care Navigators** (dedicated Case Managers) and a designated Rare Pod Team (Nurses, Pharmacists, fulfillment and distribution team)

Sales force readiness



- Sales management in place since 3Q 2021
- Sales representatives recruitment based on rare disease, specialty product, and nephrology market experience
- Approximately 40 sales territories filled upon FDA approval
- Field force designed to optimize reach and frequency of top tier nephrologists
- Training materials finalized
- Remain on target for early 1Q 2022 launch

Strong balance sheet

Strong financial position

- At September 30, 2021, Calliditas had cash of 1,163.8 MSEK (appr. USD 130M)

Access to up to additional USD 50M of non dilutive debt capital

Eligible to receive up to USD 190M in development and commercial milestones under Stada and Everest Medicines agreements, plus royalties

Cash flow positive target H1 2023