Q1 2021 REPORT

May 18, 2021

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Q1 Highlight - Regulatory Submission

- Filed an NDA with the FDA on March 15th as planned
  - Received priority review on April 27th
  - PDUFA target date is September 15th, 2021

- Submitted request for accelerated assessment in Q1 to EMA
  - Were granted accelerated review on April 23rd
  - Will file with EMA as planned in Q2

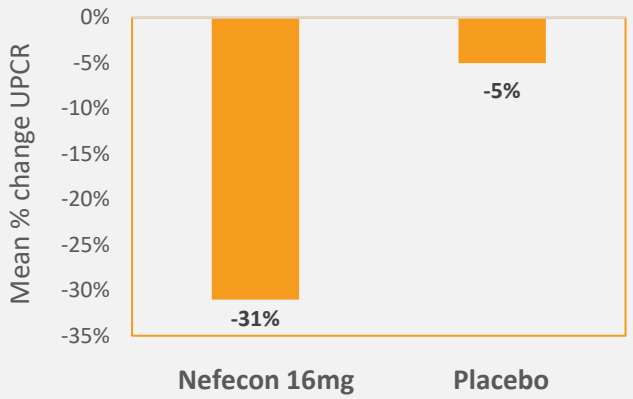
- First ever submission for approval in IgAN
- Looking forward to engaging with regulators

Nefecon: Successful Pivotal Phase 3 Clinical Trial, Part A

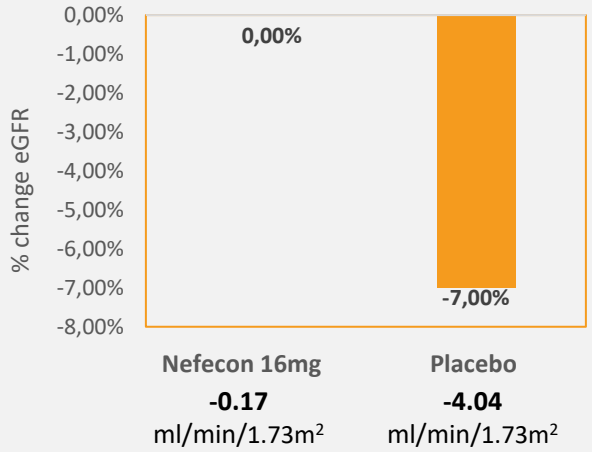
eGFR stabilization support disease modification potential

- Large trial population – 199 patients
- Oral dose taken daily over a nine-month period
- Randomized, double-blinded, placebo-controlled
- Global trial at 146 sites in 19 countries

Primary endpoint: Reduction in proteinuria



Secondary endpoint: Stabilization of eGFR



Efficacy findings

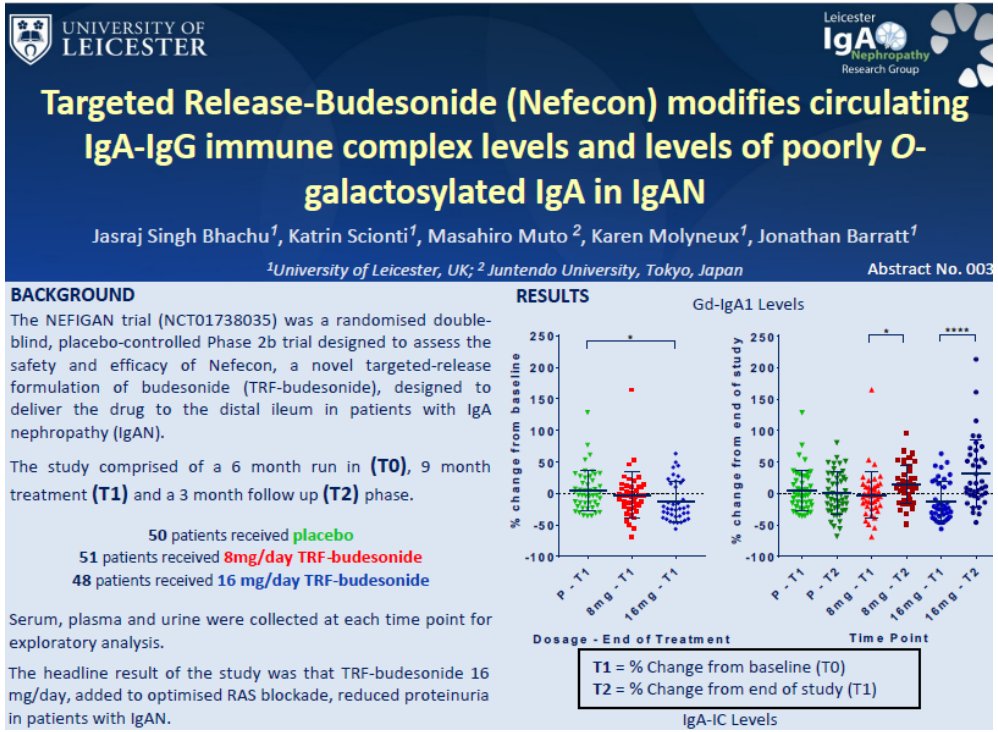
- ✓ Demonstrated statistically significant and clinically meaningful reduction in proteinuria and eGFR stabilization in the 16 mg dose cohort
- ✓ Statistically significant 27% UPCR reduction with Nefecon (16 mg) compared to placebo – 9 months treatment (p=0.0005)
- ✓ Statistically significant eGFR stabilization with Nefecon (16 mg) compared to placebo – 9 months treatment (p=0.0029)
- ✓ Significant continued decline in proteinuria seen after 9 months

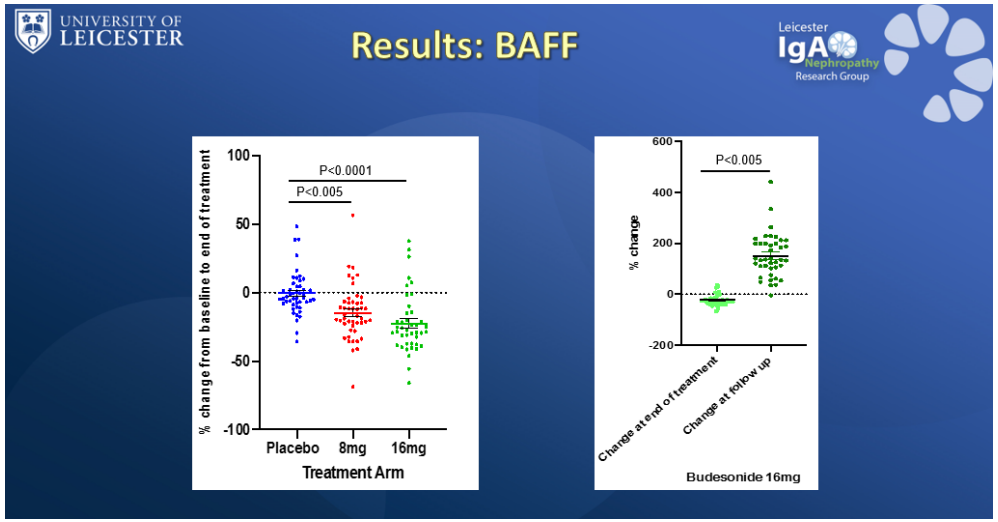
Tolerability findings

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

Biomarker Data Supporting MoA

- 2018 IIGAN Poster from Professor Barratt at the Mayer IgA Nephropathy Laboratories at the University of Leicester
- Showed that Nefecon had a demonstrated impact on
  - levels of IgA-IgG immune complexes in the circulation
  - levels of poorly-galactosylated IgA
- 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 Phase 3 Summary

- Robust demonstration of efficacy (reduction in proteinuria and eGFR stabilization) in Nefecon treated patients
- Tolerability and safety profile in line with the high first pass metabolism (90%) and hence low systemic availability as expected from the active ingredient
- Highly consistent efficacy across phase 2b and phase 3 clinical trials, in a broad range of patients with IgA nephropathy
- eGFR stabilization consistently shown across two large randomized and placebo-controlled studies provide basis for disease modification

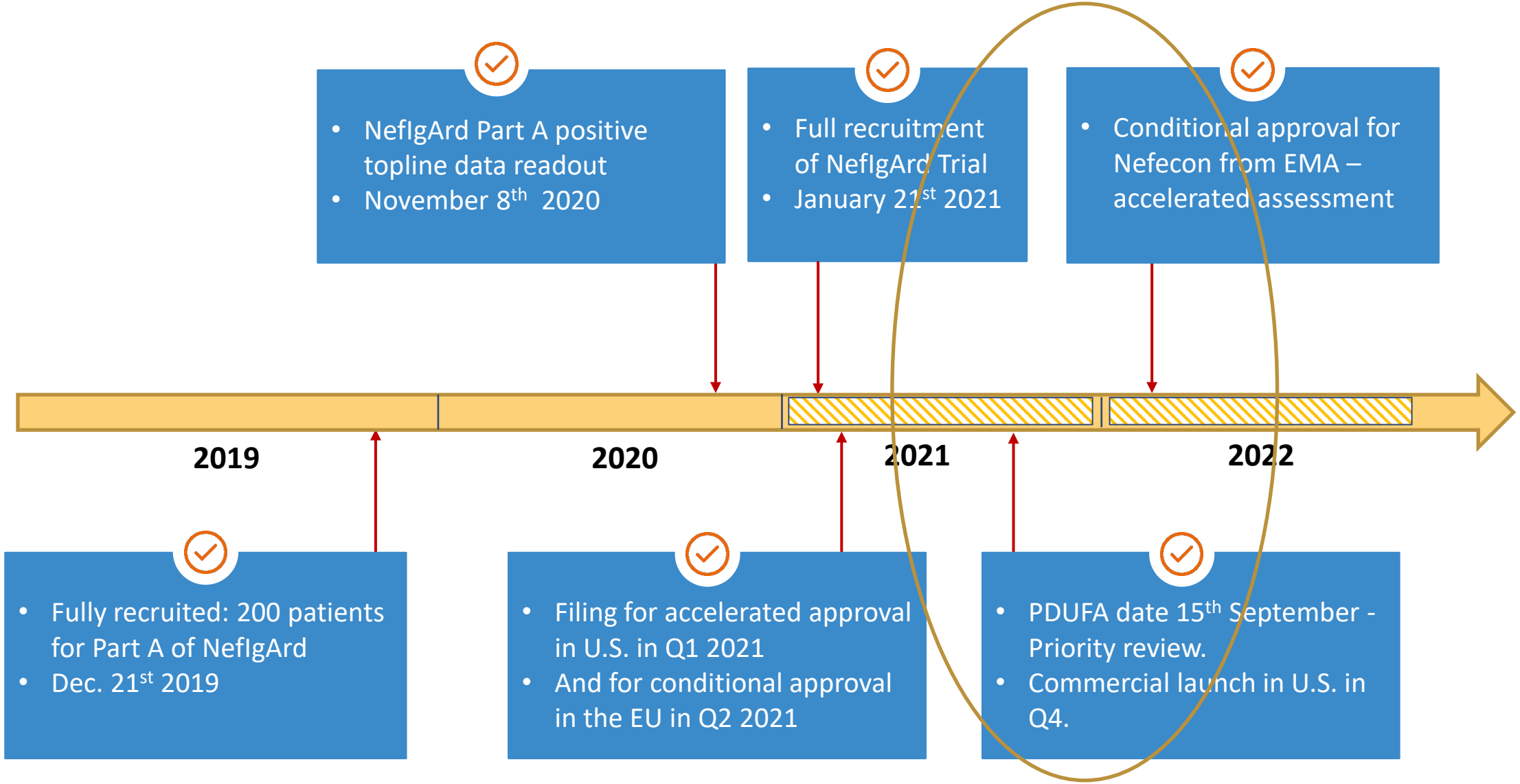
Other Events in Q1, 2021

- In Q1 NefIgArd was also fully enrolled, reflecting a major achievement of enrolling 360 IgA nephropathy patients into the trial in just over 2 years
- First patient in the open-label extension (OLE) study was dosed in February 2021
- Q1 saw the successful readout of the Phase 1 study investigating higher doses of setanaxib
- The study assessed the safety and pharmacokinetics of oral setanaxib at selected doses in 46 healthy adult male and female subjects
  - The trial consisted of a single ascending dose (SAD) part and a multiple ascending dose (MAD) part with dosing up to 1600mg/day (800mg BID)
  - No safety signals or dose limiting toxicity was identified
- Results support the initiation of a Phase 2b/3 clinical trial in PBC
  - In earlier trials at doses of up to 800mg/day (400mg BID), setanaxib achieved reductions in markers of cholestasis, including alkaline phosphatase, and in multiple non-invasive markers of liver fibrogenesis, including liver stiffness and PRO-C3 and C3M.
  - Statistically significant improvement in fatigue was also achieved

Continued build out in the US

- Andrew Udell promoted to President of North America
- Addition of a Head of Marketing, Head of Sales and VP Medical Affairs
- The US team will continue to grow significantly over the next 2-3 quarters
- Executing on existing plans for commercialization in Q4, 2021
- Larger NY office

Nefecon – Positioned to be first approved treatment for IgAN



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 that early intervention is critical to successful outcomes

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

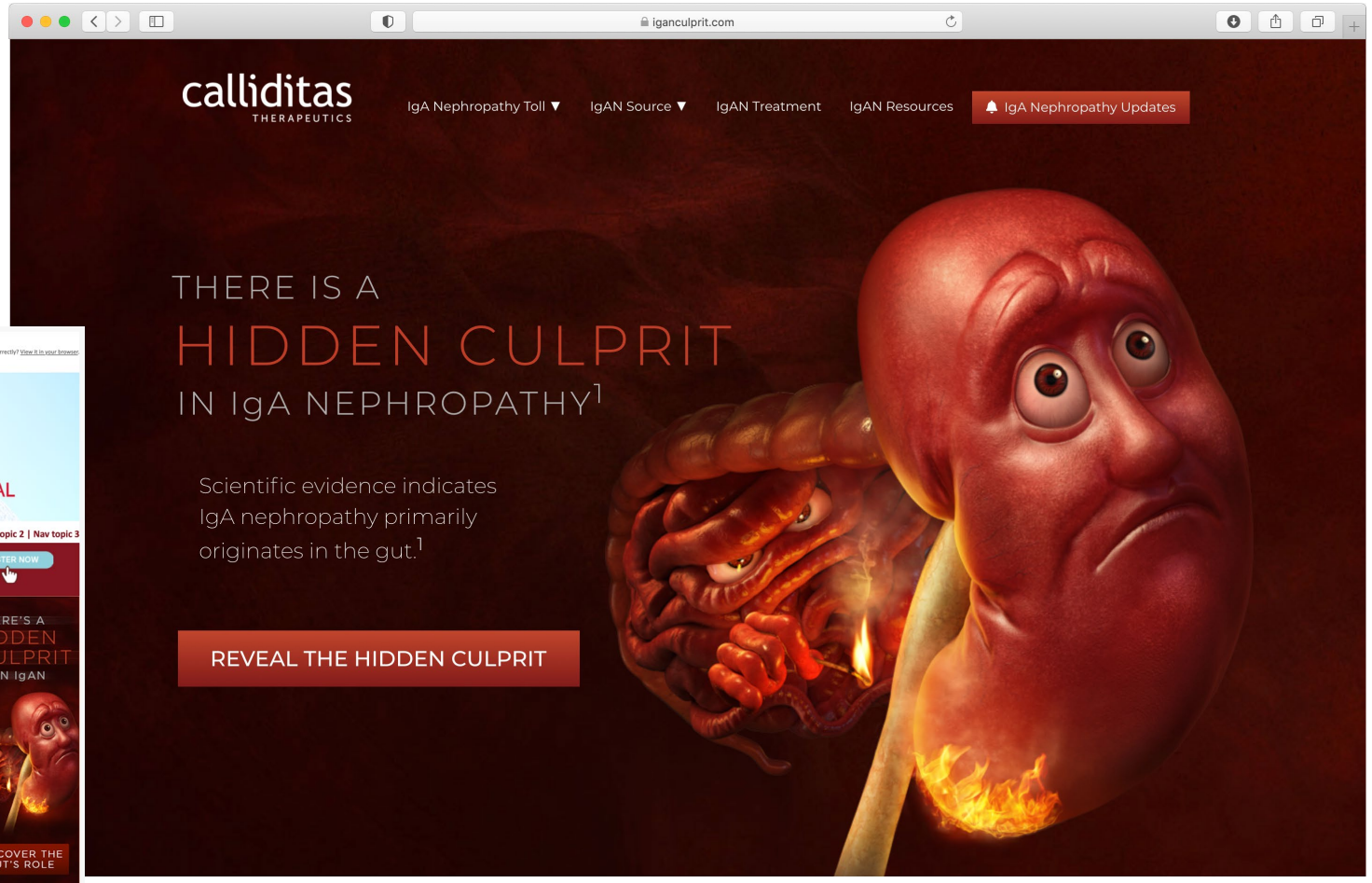
These HCPs are ***extremely likely*** to prescribe Nefecon for

~70% of their patients

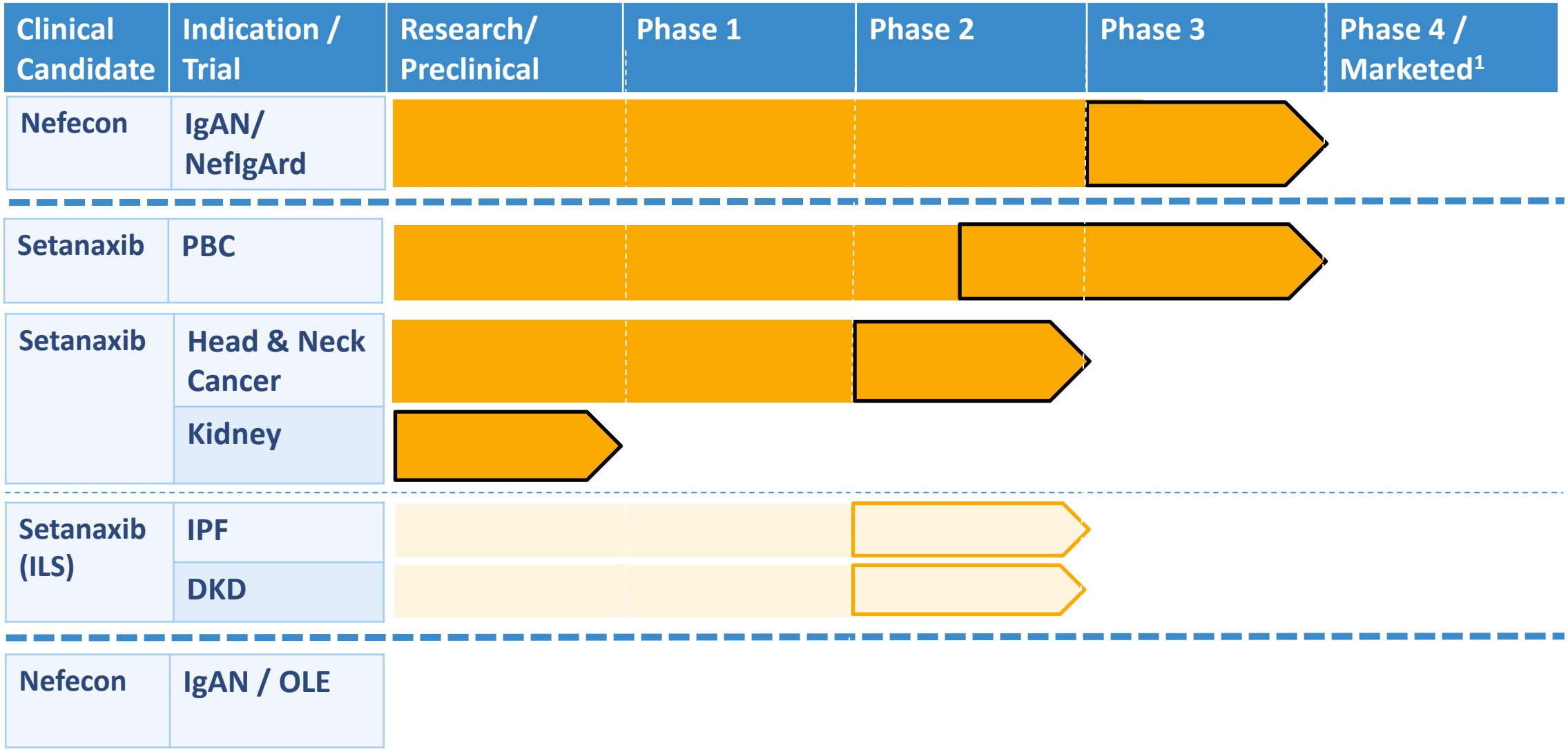
Disease Awareness Campaign Launch

Present Day → PDUFA Approval

- **IgANCulprit.com**



Clinical Activities



Depicts ongoing/planned clinical trial stage:

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

Primary Biliary Cholangitis

- Primary Biliary Cholangitis is a cholestatic autoimmune liver disease
  - A chronic and progressive orphan disease causing injury to the intrahepatic bile ducts
  - It is characterized by biliary destruction, progressive cholestasis, and in some cases liver cirrhosis[1]
- Patients with PBC have elevated serum markers of cholestasis including
  - alkaline phosphatase (ALP)
  - gamma-glutamyl transferase (GGT)
  - total bilirubin
- Clinical symptoms include fatigue and pruritus (itching)
- PBC incidence rates range from 0.33 to 5.8 per 100,000 inhabitants/year[2]
  - prevalence rates range from 1.91 to 40.2 per 100,000 inhabitants, and prevalence rates are increasing over time[2]
- PBC typically affects women who are 30-60 years old

1) Lleo A, Marzorati S, Anaya JM, Gershwin ME. Primary biliary cholangitis: a comprehensive overview. Hepatol Int. 2017 Nov;11(6):485-499. doi: 10.1007/s12072-017-9830-1. Epub 2017 Nov 21. PMID: 29164395.
2) Boonstra K, Beuers U, Ponsioen CY. Epidemiology of primary sclerosing cholangitis and primary biliary cirrhosis: a systematic review. J Hepatol. 2012 May;56(5):1181-1188. doi: 10.1016/j.jhep.2011.10.025. Epub 2012 Jan 13. PMID: 22245904.

PBC – An Unmet Need

- An unmet medical need remains despite existing therapies
  - Disease symptoms such as pruritus and fatigue that not adequately addressed by current PBC therapies
  - Data related to impact on transplant free survival still to be generated

- Current standard of care:
  1. First line therapy: Ursodeoxycholic Acid (UDCA)
     - ~40% inadequate responders
     - Additional ~5% are intolerant to therapy
  2. Second line therapy: Obeticholic Acid (Ocaliva)
     - Add on therapy to UDCA
     - ~50% inadequate responders
     - Can cause or worsen pruritus

- Setanaxib has a distinct profile compared to other drug candidates presently being tested for 2/3 line
  - Anti fibrotic and anti-inflammatory properties
  - Demonstrated impact on liver stiffness and fatigue
  - Unremarkable safety profile to date

PBC – Clinical Trial Outline

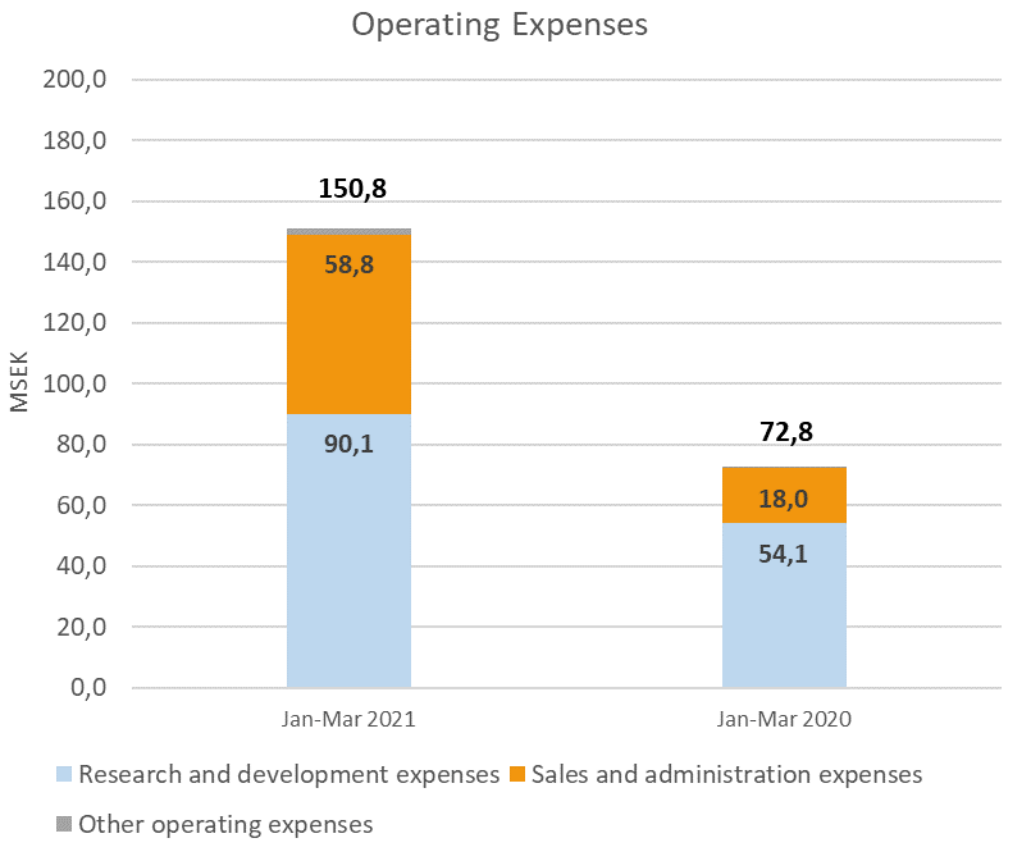
- Setanaxib trial in early PBC

- 52-week, randomized, placebo-controlled, double-blind, adaptive phase 2b/3 trial
  - Primary endpoint: ALP Reduction
  - Setanaxib at doses of 1200mg/day and 1600mg/day will be administered as add-on therapy in patients with early PBC, elevated liver stiffness, and intolerance or inadequate response to UDCA
  - Approximately 318 patients will be enrolled at up to 150 investigational centres in North America, Europe, Israel, Australia, and New Zealand

- An interim analysis comprising approximately 30% of the planned sample size (approximately 33 patients per arm) will be conducted once the 99th randomized patient has completed the Week 24 visit

- Futility analysis is expected H1 2023, data read out in late 2024 / early 2025
  - Subject to FDA feedback on the protocol

Financial overview – Q1 2021



- No revenues during the quarter vs SEK 0.4 M for the same period last year
- Operating loss of SEK 150.8 M vs SEK 72.3 M
  - Research and development expenses increased to SEK 90.1 M vs SEK 54.1 M, representing 60% of total operating expenses. Increase due to patient numbers in the NeflgArd studies and preparations for setanaxib trials
  - Sales and administrative expenses increased to SEK 58.8 M vs SEK 18.0 M, mainly due to intensified preparations for commercial and medical affairs activities in US
- Cash flow used in operating activities was SEK 134.2 M vs SEK 18.8 M
- Solid cash position per end of March 2021 of SEK 867.3 M vs SEK 728.6 M