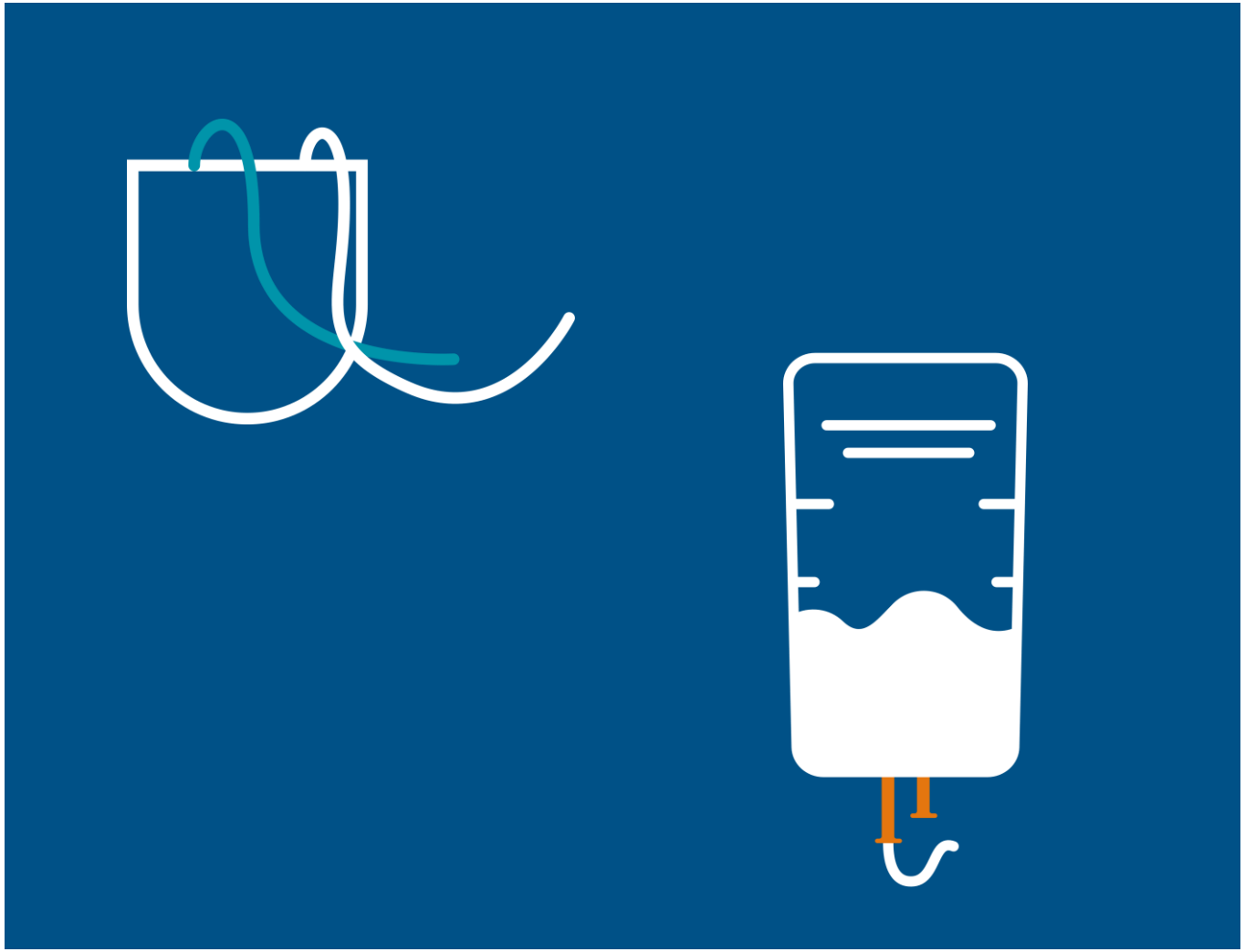
sequanamedical



POSEIDON: additional data on safety, quality of life & survival presented at EASL 2023

Webcast presentation – 21 June 2023

Today's presenters

Ian Crosbie
Chief Executive Officer

Gijs Klarenbeek
Sr Medical Advisor

Disclaimers

Important Notice

IMPORTANT: You must read the following before continuing. The following applies to this document, the oral presentation of the information in this document by Sequana Medical NV (the "Company") or any person on behalf of the Company, and any question-and-answer session that follows the oral presentation:

- This presentation has been prepared by the management of the Company. It does not constitute or form part of, and should not be construed as, an offer, solicitation or invitation to subscribe for, underwrite or otherwise acquire, any securities of the Company or any member of its group nor should it or any part of it form the basis of, or be relied on in connection with, any contract to purchase or subscribe for any securities of the Company or any member of its group, nor shall it or any part of it form the basis of or be relied on in connection with any contract or commitment whatsoever. Prospective investors are required to make their own independent investigations and appraisals of the business and financial condition of the Company and the nature of its securities before taking any investment decision with respect to securities of the Company. This presentation is not a prospectus or offering memorandum.
- The information included in this presentation has been provided to you solely for your information and background and is subject to updating, completion, revision and amendment and such information may change materially. No person is under any obligation or undertaking to update or keep current the information contained in this presentation and any opinions expressed in relation thereto are subject to change without notice. No representation or warranty, express or implied, is made as to the fairness, accuracy, reasonableness or completeness of the information contained herein. Neither the Company nor any other person accepts any liability for any loss howsoever arising, directly or indirectly, from this presentation or its contents.
- The presentation also contains information from third parties. Third party industry publications, studies and surveys may also contain that the data contained therein have been obtained from sources believed to be reliable, but that there is no guarantee of the accuracy or completeness of such data. While the Company reasonably believes that each of these publications, studies and surveys has been prepared by a reputable source, the Company, or any of their respective parent or subsidiary undertakings or affiliates, or any of their respective directors, officers, employees, advisers or agents have independently verified the data contained therein. Thus, while the information from third parties has been accurately reproduced with no omissions that would render it misleading, and the Company believes it to be reliable, the Company cannot guarantee its accuracy or completeness. In addition, certain of the industry and market data contained in this presentation comes from the Company's own internal research and estimates based on the knowledge and experience of the Company's management in the market in which the Company operates. While the Company reasonably believes that such research and estimates are reasonable and reliable, they, and their underlying methodology and assumptions, have not been verified by any independent source for accuracy or completeness and are subject to change without notice. Accordingly, undue reliance should not be placed on any of the industry, market or competitive position data contained in this presentation.
- This presentation includes forward-looking statements that reflect the Company's intentions, beliefs or current expectations concerning, among other things, the Company's results, condition, performance, prospects, growth, strategies and the industry in which the Company operates. These forward-looking statements are subject to risks, uncertainties and assumptions and other factors that could cause the Company's actual results, condition, performance, prospects, growth or opportunities, as well as those of the markets it serves or intends to serve, to differ materially from those expressed in, or suggested by, these forward-looking statements. These statements may include, without limitation, any statements preceded by, followed by or including words such as "target," "believe," "expect," "aim," "intend," "may," "anticipate," "estimate," "plan," "project," "will," "can have," "likely," "should," "would," "could" and other words and terms of similar meaning or the negative thereof. The Company cautions you that forward-looking statements are not guarantees of future performance and that its actual results and condition and the development of the industry in which the Company operates may differ materially from those made in or suggested by the forward-looking statements contained in this presentation. In addition, even if the Company's results, condition, and growth and the development of the industry in which the Company operates are consistent with the forward-looking statements contained in this presentation, those results or developments may not be indicative of results or developments in future periods. The Company and each of its directors, officers and employees expressly disclaim any obligation or undertaking to review, update or release any update of or revisions to any forward-looking statements in this presentation or any change in the Company's expectations or any change in events, conditions or circumstances on which these forward-looking statements are based, except as required by applicable law or regulation.
- This document and any materials distributed in connection with this document are not directed to, or intended for distribution to or use by, any person or entity that is a citizen or resident of, or located in, any locality, state, country or other jurisdiction where such distribution, publication, availability or use would be contrary to law or regulation or which would require any registration or licensing within such jurisdiction. The distribution of this document in certain jurisdictions may be restricted by law and persons into whose possession this document comes should inform themselves about, and observe any such restrictions.
- The Company's securities have not been and will not be registered under the US Securities Act of 1933, as amended (the "Securities Act"), and may not be offered or sold in the United States absent registration under the Securities Act or exemption from the registration requirement thereof.
- By attending the meeting where this presentation is presented or by accepting a copy of it, you agree to be bound by the foregoing limitations.

Regulatory disclaimer:

- The **alfa**pump® system has not yet received regulatory approval in the United States and Canada. Any statement in this presentation about safety and efficacy of the **alfa**pump® system does not apply to the United States and Canada. In the United States and Canada, the **alfa**pump® system is currently under clinical investigation (POSEIDON Study) and is being studied in adult patients with refractory or recurrent ascites due to liver cirrhosis.
- DSR® therapy is still under development and it should be noted that any statements regarding safety and efficacy arise from ongoing pre-clinical and clinical investigations which have yet to be completed. There is no link between DSR® therapy and ongoing investigations with the **alfa**pump® system in Europe, the United States or Canada.

General disclaimer:

- Sequana Medical is closely following the evolution of macroeconomic conditions, the geopolitical situation in Ukraine and the COVID-19 global health crisis and is in constant dialogue with its partners to assess the impact and adapt operations accordingly.
- Sequana Medical has put in place mitigation plans to minimise delays. The impact of increased demands on the healthcare systems, limitations on non-essential hospital visits and procedures, social-distancing and travel restrictions may result in further delays to execution of clinical studies and impact sales.
- Sequana Medical will continue to update the market as needed and whenever possible.

Note:

- **alfa**pump® and DSR® are registered trademarks.

POSEIDON – strong clinical messages for alfapump

Data presentation at EASL Congress 2023 by Prof. Wong, Principal Investigator, POSEIDON

✓ Effective in control of ascites, virtually eliminating needle paracentesis

✓ Safety in line with expectations

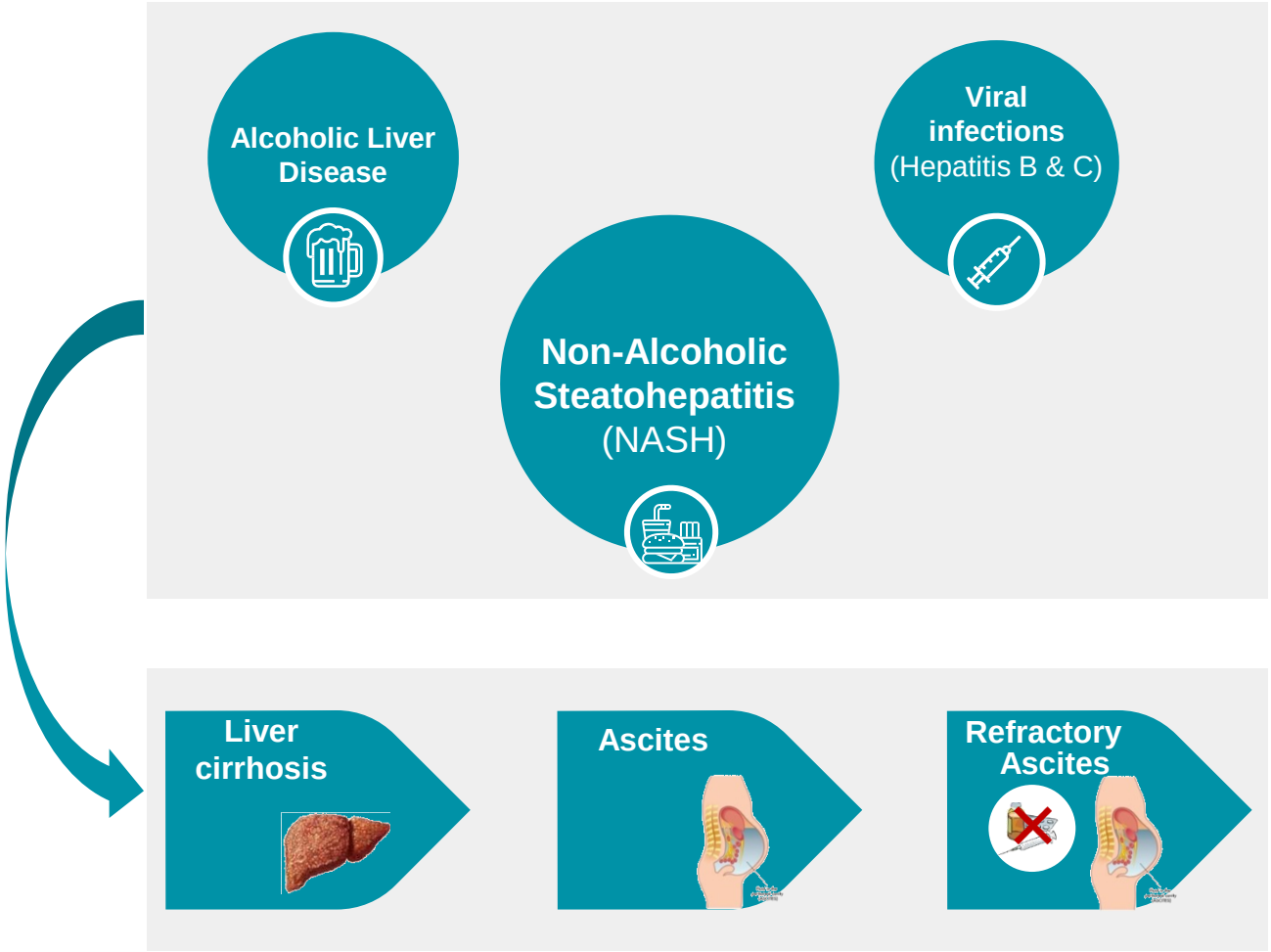
- Six pumps were explanted: three due to skin erosion & three due to moderate bladder discomfort
- Despite disease progression:
  - Similar number of Major Adverse Events (MAEs) in pre- and post-implant period
  - Comparable number of serious infections in pre- and post-implant period
  - Stable kidney function over long-term follow-up

✓ Clinically meaningful and statistically significant improvement in quality of life

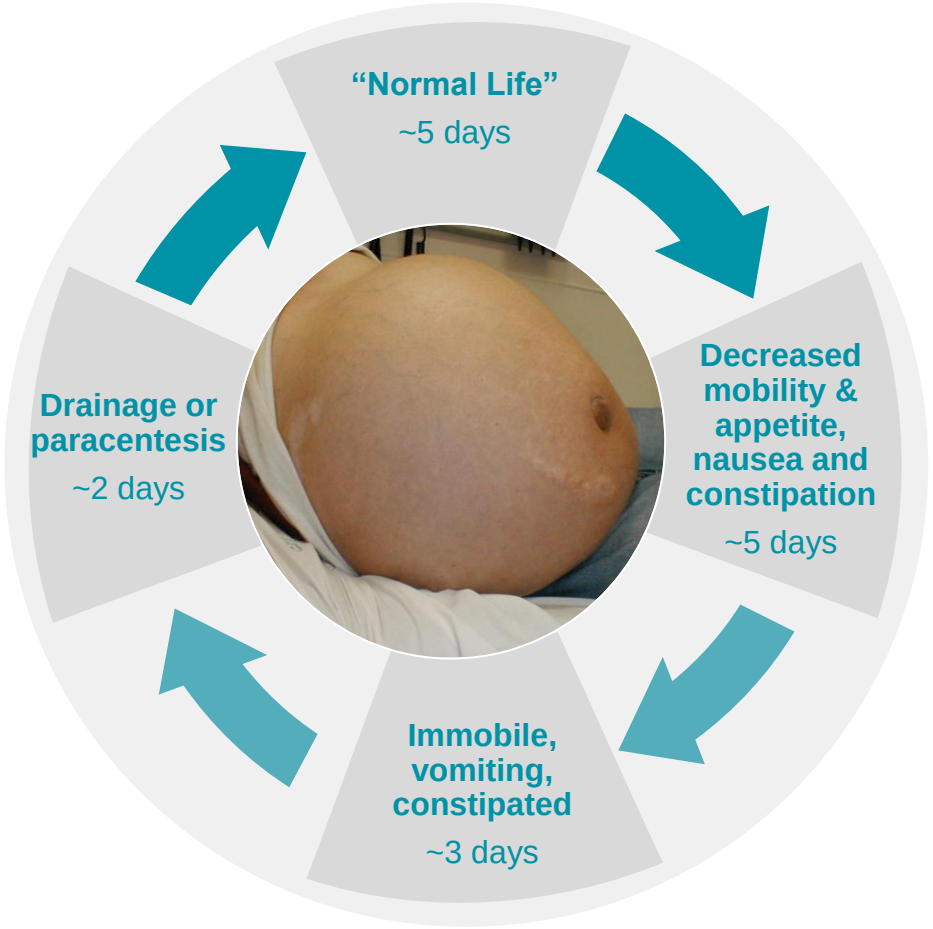
✓ Positive trend in survival, comparing favorably to literature

Refractory ascites – key complication of liver cirrhosis

Fatty liver disease / NASH is driving dramatic growth and change in attitudes to liver cirrhosis patients



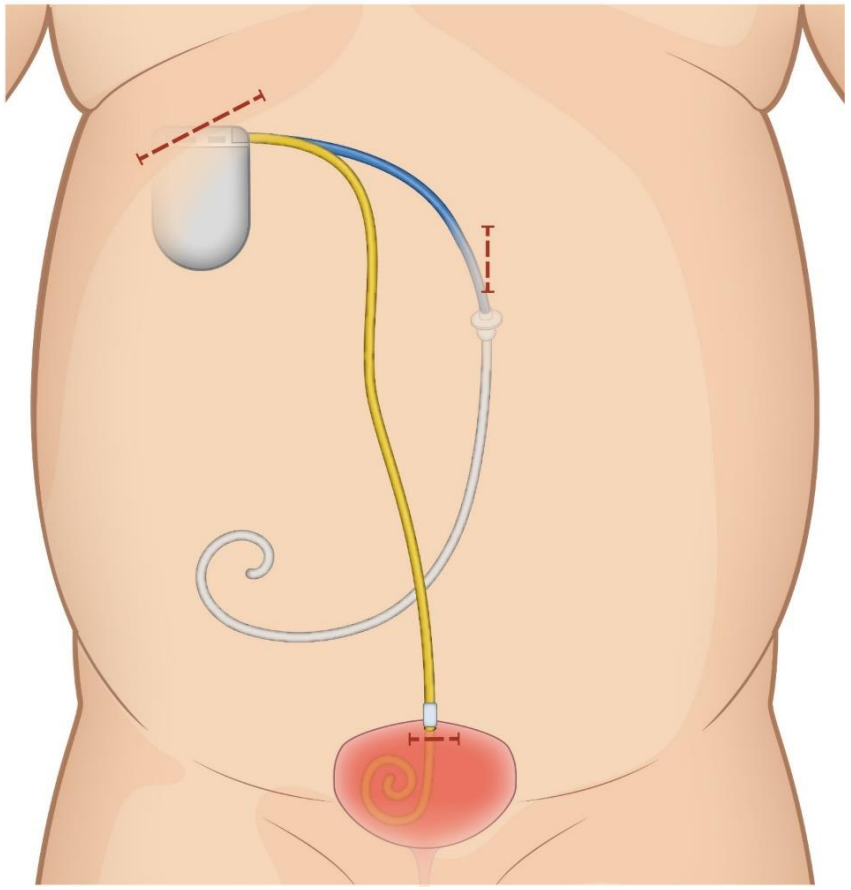
Typical patient life[1]



Source 1: Presentation of Dr. Rajiv Jalan at EASL in 2018, Large Volume Paracentesis (LVP) treatment cycle for refractory ascites

alfapump – strong clinical and economic rationale

FDA breakthrough designation, strong IP, over 950 implants and hundreds of years of patient experience



Breakthrough Device
Designation

- Reduced burden of disease
- Improved patient quality of life
- Cost savings for hospitals and payers

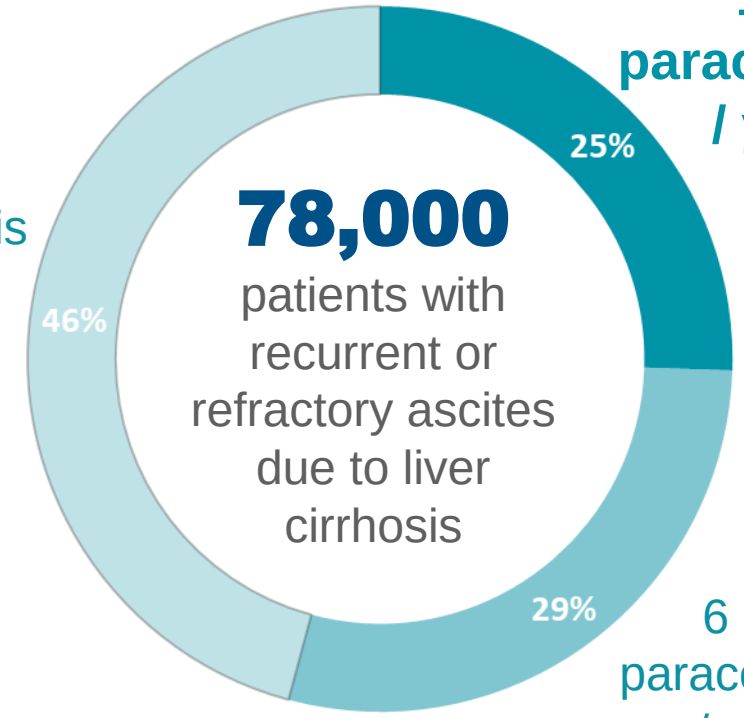
Estimated treatment cost / patient*:

LVP: ~$66K ⟷ **alfapump: ~$37K**

** Management US cost estimate for Large Volume Paracentesis (LVP) (1/month for 24 months) and average Medicare DRG 423 payment for **alfa**pump procedure in 2025, adjusted with Medicare inflation rates; sources: Kwan et al., J Vasc Interv Radiol 2018; Price inflation for Medical care, Consumer Price Index, U.S. Bureau of Labor Statistics; 2018 HVPAA National Conference*

Large and strongly growing North American market

NASH is forecast to drive significant growth for many years – and is changing attitudes to cirrhosis



2025

6-7% CAGR

>$2.5 Bn

alfapump addressable market in US and Canada

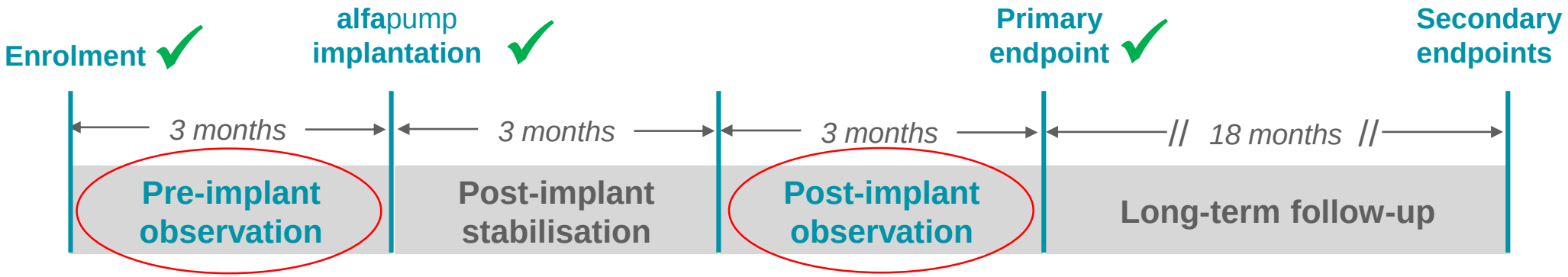
2035

CAGR: *Compound Annual Growth Rate*

*Sources: Based on US and Canada market assessment conducted by highly experienced international consulting group, using claims analysis for commercial and CMS (Center for Medicare and Medicaid Services) patients requiring paracentesis procedure with liver disease diagnosis codes; Medicare Inpatient & Outpatient Hospital Standard Analytical Files 2019.CMS, Baltimore, MD. www.cms.hhs.gov; using incidence rate of 60% and **alfa**pump price of $25K*

POSEIDON – North American pivotal study

Pivotal Cohort of 40 alfapump patients with recurrent or refractory ascites due to liver cirrhosis



Severely decompensated patients – alcohol and NASH as key drivers of cirrhosis

Age (mean)	63.6 ± 9.5 yr
MELD score (mean ± SD)	15.2 ± 3.8
Cirrhosis etiology*	
- Alcohol	- 47.5%
- NASH	- 37.5%
- Viral hepatitis	- 12.5%
- Others	- 11.0%
TP per month prior to study (mean ± SD)	3.2 ± 1.5

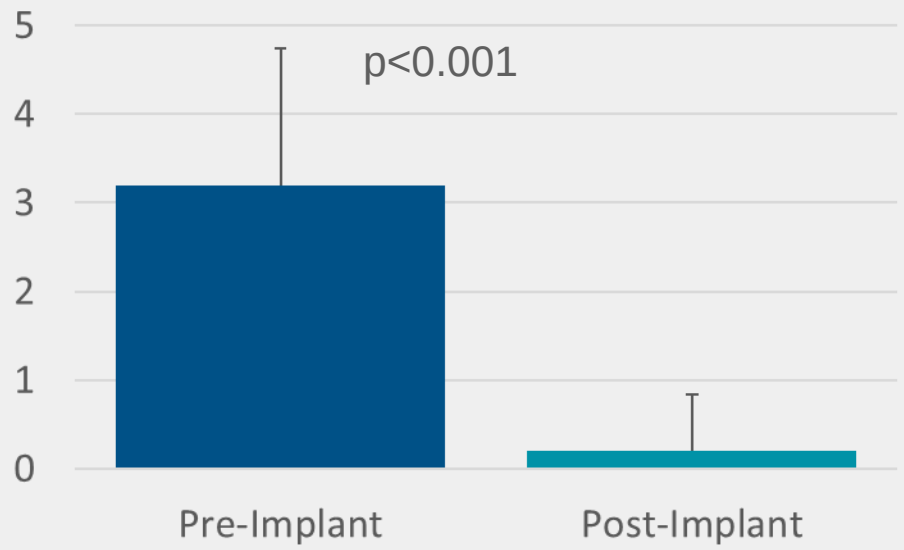
* *Some patients may have more than one etiology of cirrhosis*

MELD: *Model for End-stage Liver Disease;* ***SD:*** *Standard Deviation;* ***NASH:*** *Non-Alcoholic Steatohepatitis;* ***TP:*** *Therapeutic Paracentesis*

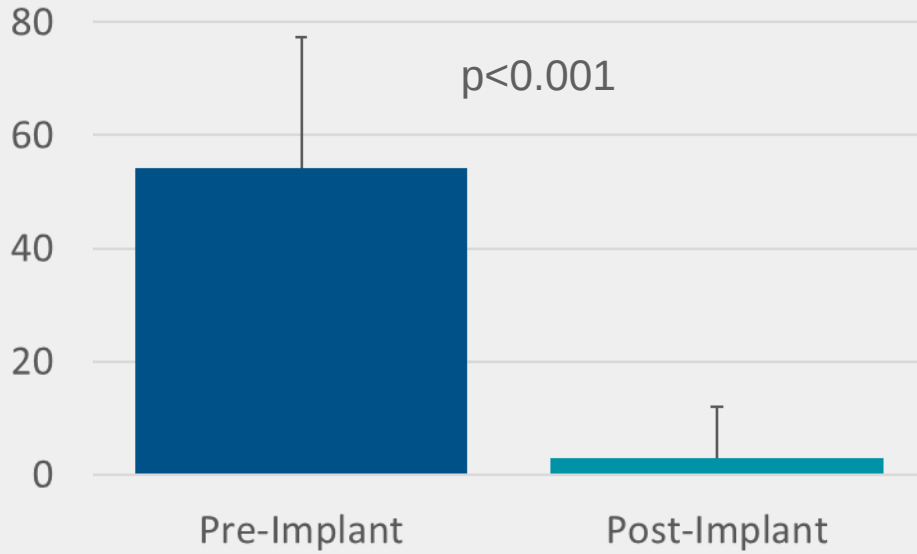
Primary effectiveness endpoints exceed predefined thresholds for study success*

- **100%** median per-patient reduction in therapeutic paracentesis (p<0.001)**
  - *vs hypothesis of at least a 50% reduction*
- **77% of patients** with at least 50% reduction in therapeutic paracentesis (p<0.001)**
  - *vs hypothesis of at least 50% of patients*

Mean number of paracentesis per month:



Cumulative ascites (L) drained by paracentesis:



* *As already reported in Press Release of 25 October 2022; ** Post vs pre-implant observation period*

Primary safety endpoint in line with expectations*

Primary safety endpoint:

- Combined rate of i) open surgical re-intervention due to pump system related AE or to restore pump functionality, ii) pump explant (without replacement) due to pump system related AE, or iii) pump system related death from time of pump implant through 6 months post-implantation as adjudicated by the CEC

- No unanticipated adverse device effects
- Six primary safety events – in line with expectations:
  - Wound erosion – **alfa**pump explant 3 in 3 patients
  - Patient-reported discomfort – **alfa**pump explant 3 in 3 patients ➡ CEC: moderate severity

* *As already reported in Press Release of 25 October 2022*

CEC: *Clinical Events Committee*

Pre-defined MAEs as key secondary safety endpoint

- Major Adverse Events (MAEs) specific to patient population and **alfa**pump as agreed upfront with Principal Investigators and FDA

- In POSEIDON, an MAE is defined as one of the following events (adjudicated by the CEC):
  - AKI > stage 2
  - Hepatorenal syndrome
  - Hepatic encephalopathy > grade 2
  - Spontaneous bacterial peritonitis
  - Recurrent or refractory infection related to paracentesis or the **alfa**pump system, procedure or therapy

Note: MAEs are routinely used in clinical studies, e.g., MACE (Major Adverse Cardiac Events) used in cardiac studies

PI: *Principal Investigator;* ***GCP:*** *Good Clinical Practice;* ***AKI:*** *Acute Kidney Injury;* ***CEC:*** *Clinical Events Committee*

Similar number of MAEs pre vs post implant

Despite disease progression

	3 months pre-implant (Day -90 to Day -1)		3 months post-implant (Day 91 to Day 180)	
	No. of events	No. of subjects with events	No. of events	No. of subjects with events
Major Adverse Events	**5**	3	**5**	4
AKI > stage 2	0	0	1	1
Hepatorenal Syndrome	0	0	1	1
Hepatic Encephalopathy > stage 2	4	2	1	1
Spontaneous Bacterial Peritonitis	1	1	1	1
Recurrent/Refractory Infection*	0	0	1	1

** Related to paracentesis or the **alfa**pump system, procedure or therapy*

Secondary safety endpoint: Pivotal mITT population; events were adjudicated by the CEC; all implanted subjects in the Pivotal Cohort are included (N=40)

Comparable number of serious infections pre vs post

Despite disease progression

	3 months pre-implant (Day -90 to Day -1)		3 months post-implant (Day 91 to Day 180)	
	No. of events	No. of subjects with events	No. of events	No. of subjects with events
All Serious Infections	**2**	2	**3**	3
Of which:				
Ascites-Related Serious Infections	**1**	1	**2***	2

** Of which 1 related to the **alfa**pump system*

Secondary safety endpoint: Pivotal mITT population; events were adjudicated by the CEC; all implanted subjects in the Pivotal Cohort are included (N=40)

Despite AKIs, stable kidney function over long-term

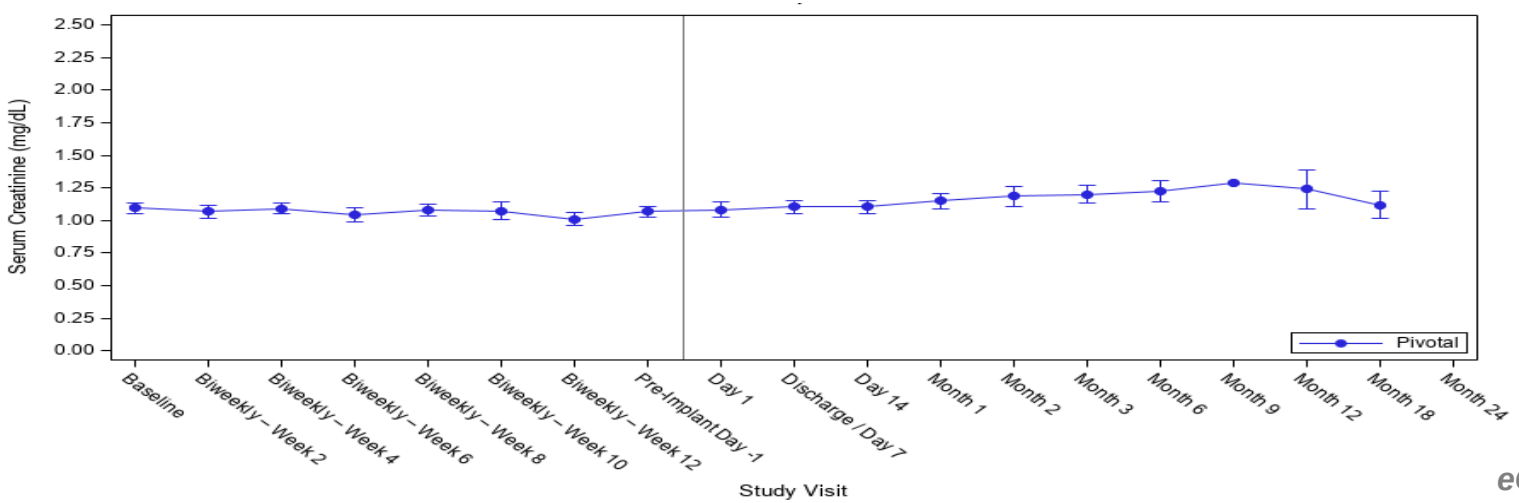
- **AKI events post-implant were manageable**

	6 months post-implant (Day 0 to Day 180)	
	No. of events	No. of subjects with events
AKI stage 1	16	14
AKI stage 2	4	4
AKI stage 3	2	2

AKI 1 of limited clinical relevance

AKI 2 and 3: three events resolved and three events were unresolved at the time of death from unrelated cause

- **Average serum creatinine (and eGFR) remained stable over time:**



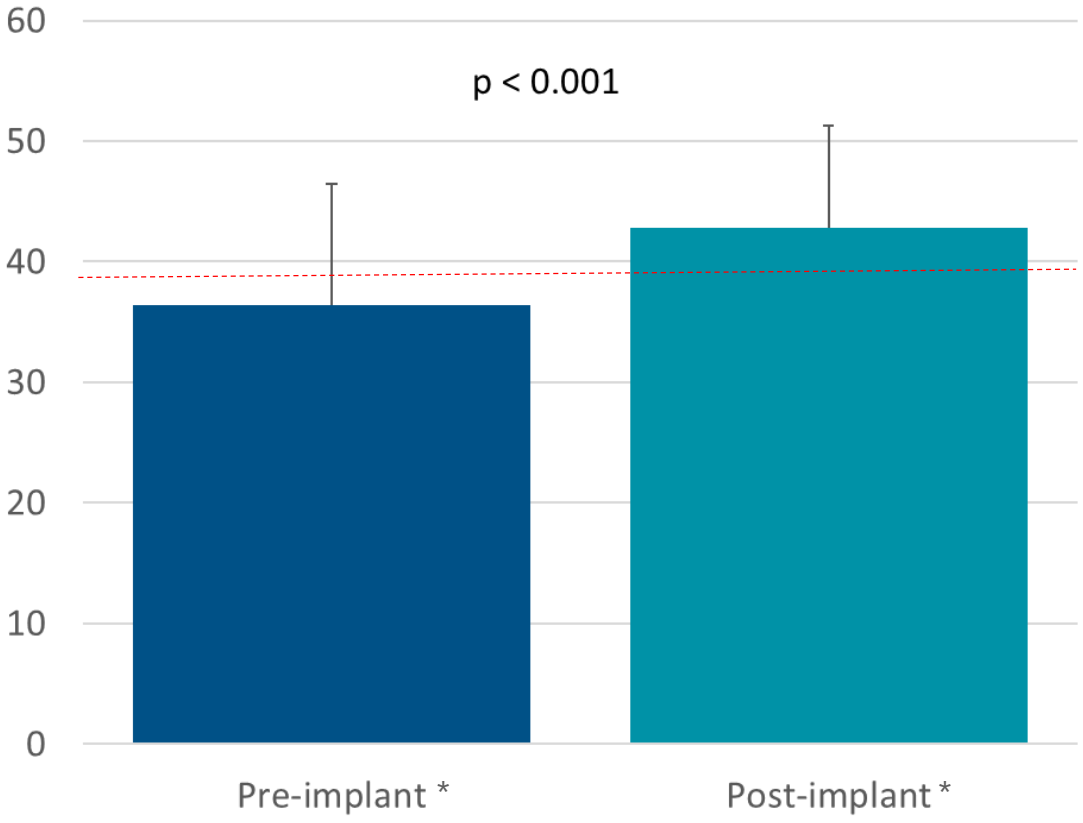
eGFR: *estimated Glomerular Filtration Rate*

Pre and Post implant AKI rates are not comparable

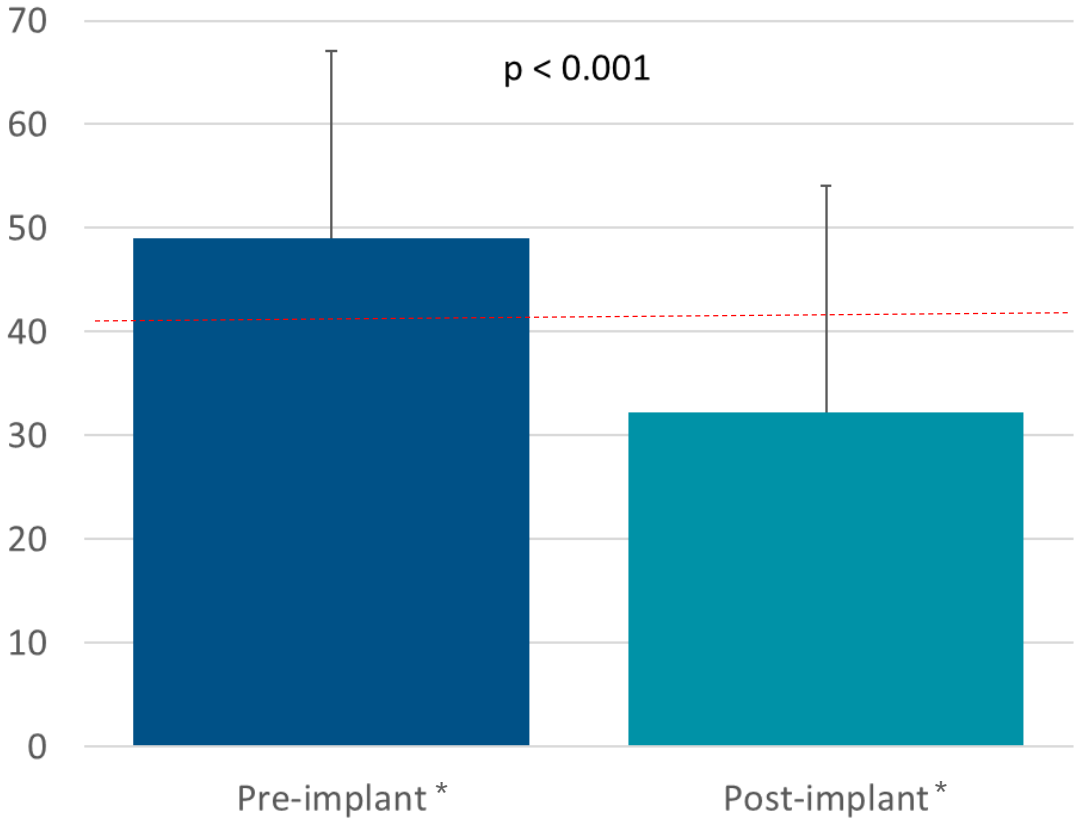
- Renal function is often impaired in patients with advanced cirrhosis
- Patients in POSEIDON were closely monitored for AKIs, hence more events diagnosed
- No comparison pre vs post implant – any patient with non-transient AKI in pre-implant period was excluded from implant (ie Pivotal Cohort)
- Impact of disease progression is an important factor in this patient population

QoL: Clinically meaningful and statistically significant improvement despite disease progression

SF-36 Physical Component Score (higher is better):



Ascites Q Score (lower is better):

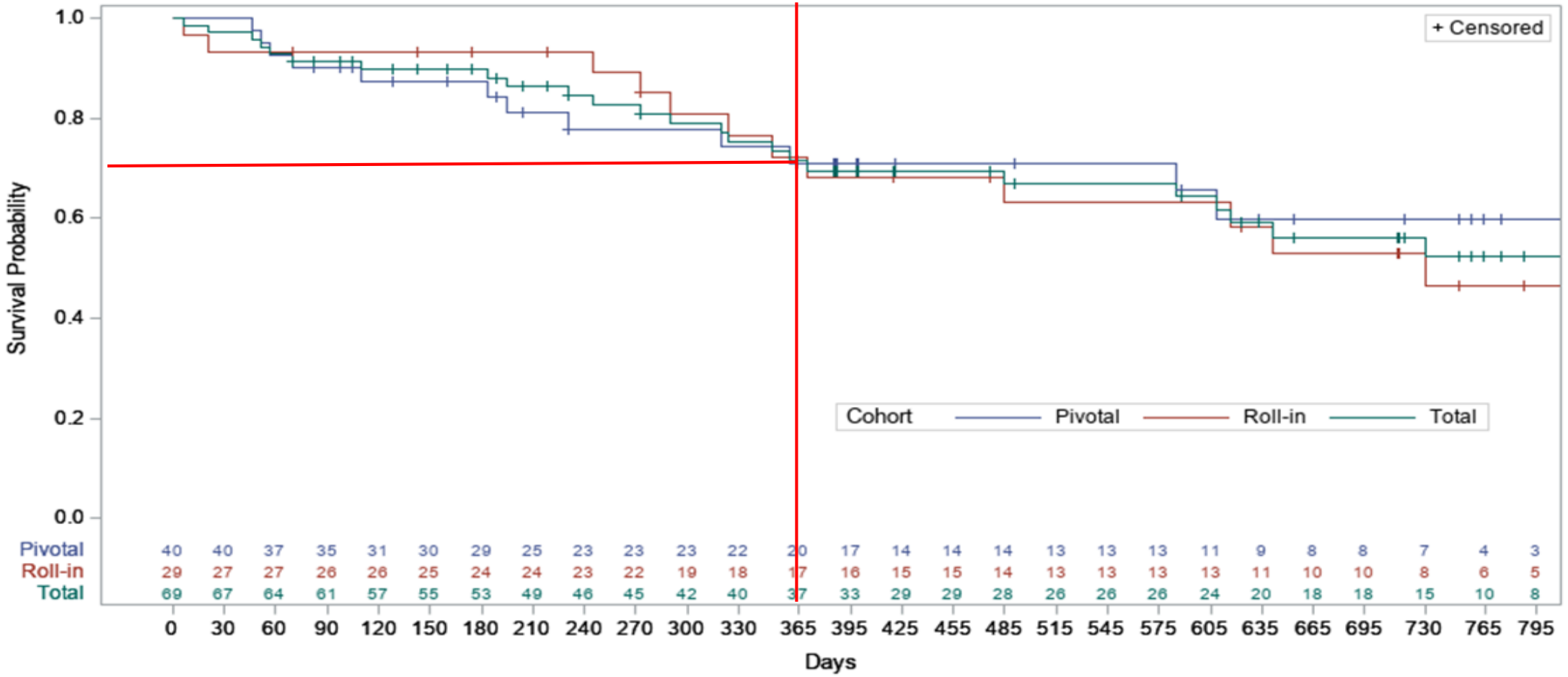


QoL: *Quality of Life*

* *Pre-implant = at baseline; Post-implant = at 6 months post-implantation*

Survival: 70% at one year post-implantation

Compares favorably to published literature citing 50% survival at 1 year from diagnosis of refractory ascites[1]



Note: POSEIDON study not powered for survival

Source 1: Biggins et al., Hepatology, Vol. 74, No. 2, 2021, AASLD Practice Guidance; Moreau R et al., Liver International 2004: 24: 457-464

Strong clinical profile of alfapump

Conclusions of presentation by Prof. Wong (POSEIDON PI) at EASL Congress 2023

- **alfa**pump system was **very effective** in the control of ascites, virtually eliminating the need for LVP
- Associated **improvement** in physical aspect of **quality of life**
- Patients with the **alfa**pump need **close monitoring for the development of AKI or infection**, which must be treated promptly to prevent adverse outcomes
  - *Patients were monitored regularly in the study – adverse events do occur, particularly in the post-implant period but are readily resolved with usual care*
- In carefully selected patients with recurrent or refractory ascites, **the alfapump is an alternative to repeat LVP**
  - *Carefully selected refers to strict trial enrolment criteria – not intended to suggest only carefully selected patients should be treated*

Gearing up for US approval in 2024

Existing DRG payment and breakthrough device designation de-risk reimbursement of alfapump

Publications

Submit POSEIDON data for publication in peer-reviewed journal in **2023**

Additional data

Patient preference study: top-line data expected in **Q3 2023**

NACSELD registry: propensity matched interim analysis expected in **Q3 2023**

US filing & approval

PMA filing planned for **Q4 2023**

FDA approval anticipated in **H2 2024**

Reimbursement for alfapump de-risked

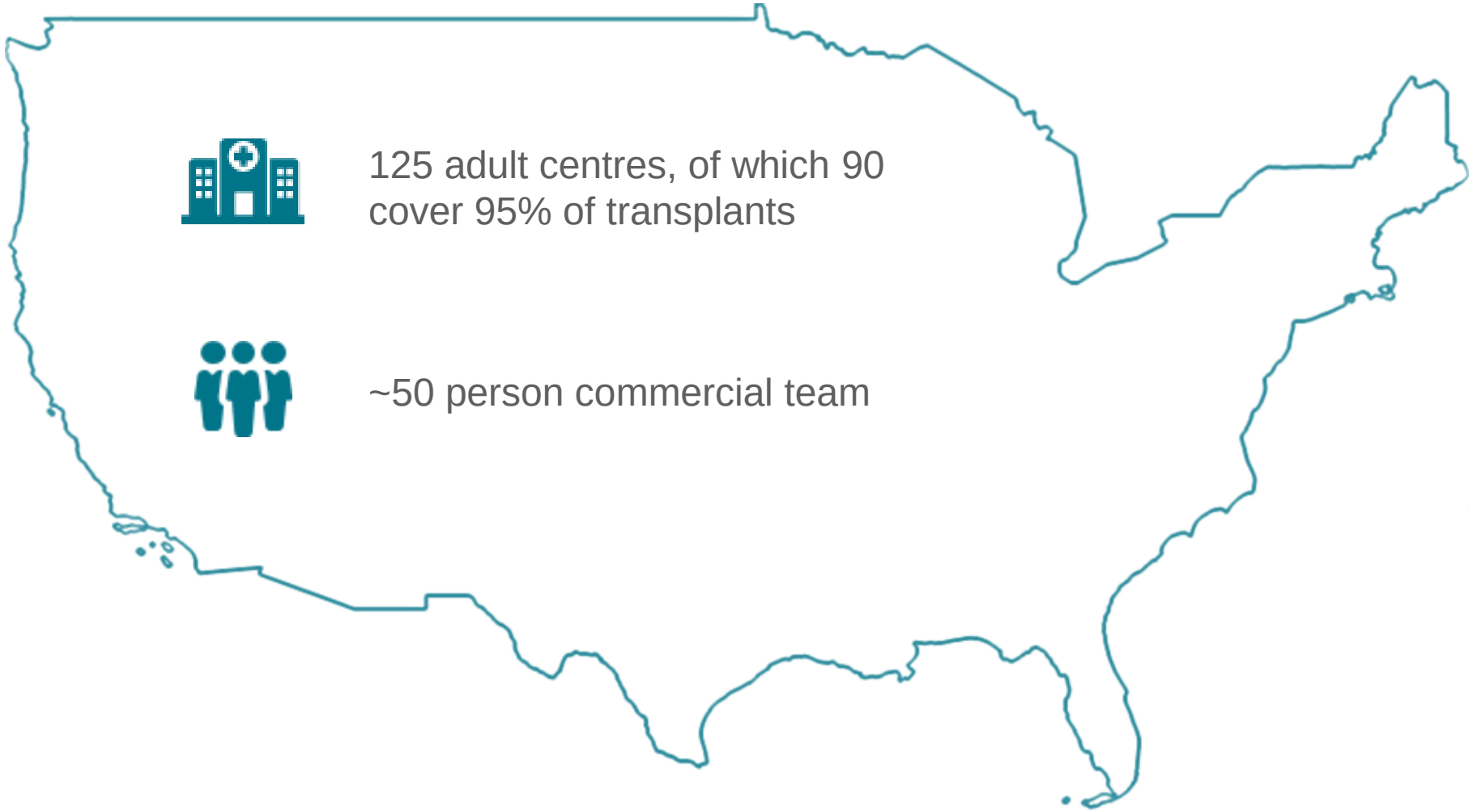
- ✓ Existing hospital DRG payment for **alfa**pump procedure*
- ✓ NTAP for breakthrough devices provides additional reimbursement in key Medicare population
- ✓ Proposed TCET pathway could lead to automatic coverage of breakthrough devices for a defined period by Medicare – our key population

On the basis of existing ICD-10 codes issued for the **alfapump, the likely DRG coding will be 423 "OTHER HEPATOBILIARY OR PANCREAS O.R. PROCEDURES"*

***NACSELD:** North-American Consortium for the Study of End-stage Liver Disease**; PMA:** Pre-Market Approval; **NTAP:** New Technology Add-On Payment; **TCET:** Transitional Coverage of Emerging Technologies*

US – Go direct to 90 liver transplant centers

Highly efficient approach to target doctors and patients – driven by treatment guidelines

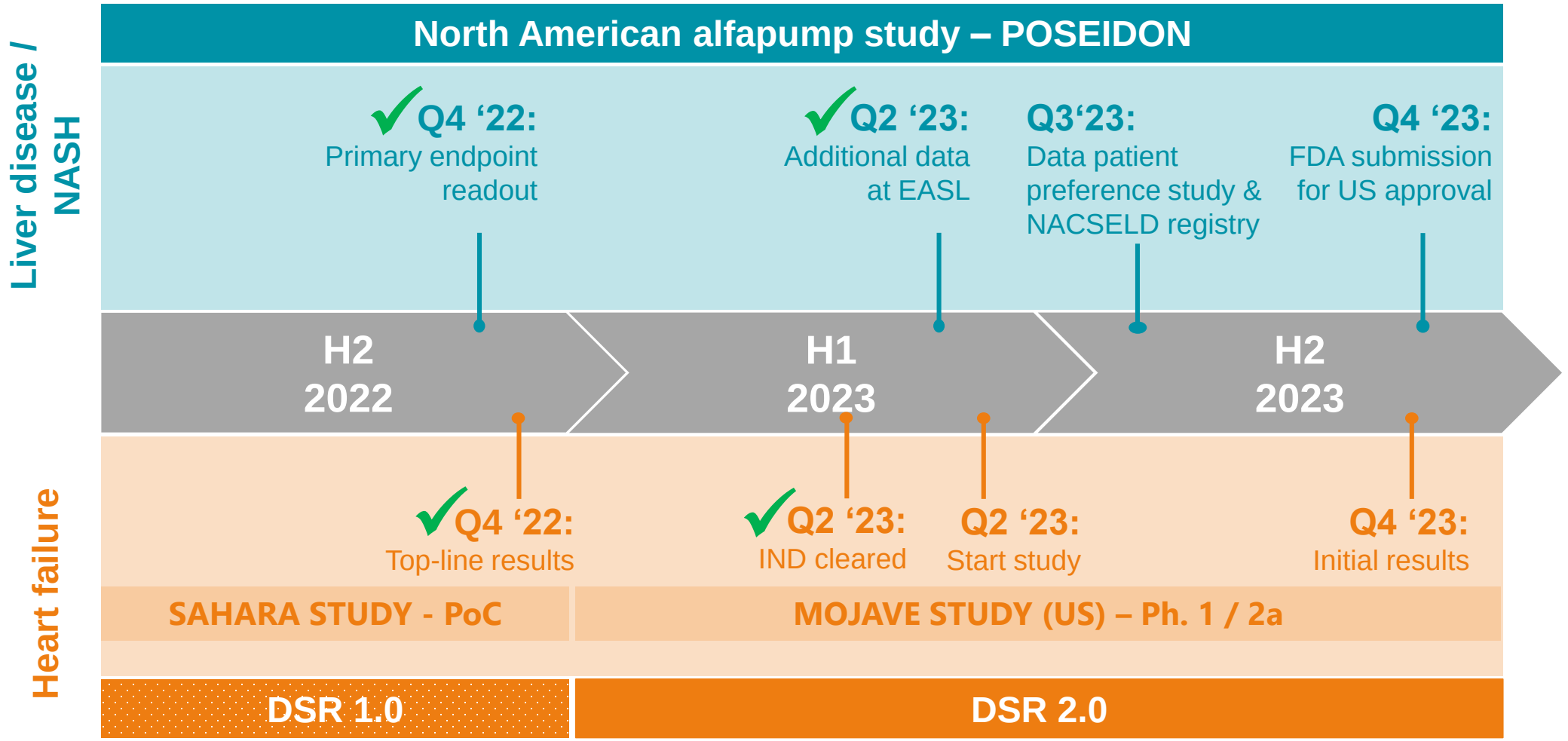


125 adult centres, of which 90 cover 95% of transplants

~50 person commercial team

Source: Organ Procurement & Transplantation Network, US Dept of HHS (optn.transplant.hrsa.gov)

Strong outlook for value drivers



***PoC**: Clinical Proof-of-Concept*

Q&A

IR@sequanamedical.com

+32 498 053579

www.sequanamedical.com

sequanamedical