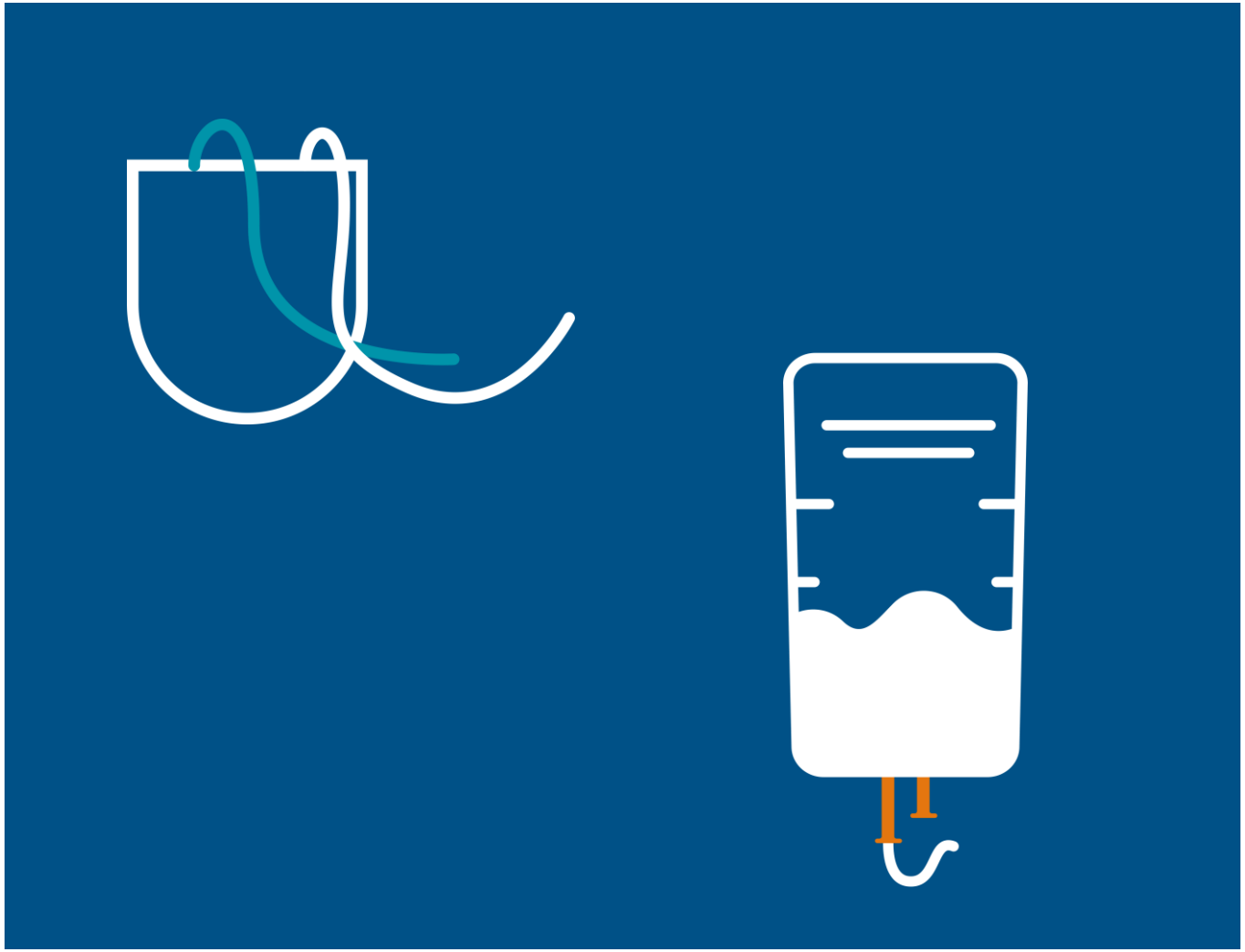
sequanamedical



US Commercial Roll-Out of alfapump® System

KOL Webinar

January 8, 2025

Euronext: SEQUA.BR

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.

General disclaimer:

- Sequana Medical is closely following the evolution of macroeconomic conditions, the geopolitical situation in Ukraine and the middle east and is in constant dialogue with its partners to assess the impact and adapt operations accordingly.
- Sequana Medical will continue to update the market as needed and whenever possible.

Note:

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

Disclaimers (cont'd)

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:

- **Indication for Use:** The alfapump® System is intended for single patient use only in adult patients with refractory or recurrent ascites due to liver cirrhosis. It is indicated for the removal of excess peritoneal fluid from the peritoneal cavity into the bladder, where it can be eliminated through normal urination.
- **Contraindications:** The alfapump® System is MRI unsafe. Hyperbaric oxygen therapy is contraindicated.
- **Warnings, Risks, and Precautions:** Consider risks associated with implanting the alfapump® System including risk of peritoneal cavity infections, Coagulopathy, Small bladder capacity and/or obstructive uropathy. The following procedures or therapies could impact the alfapump® System function: Supersonic therapy and high-frequency heat therapy, Transcutaneous Electrical Nerve Stimulation (TENS), Lithotripsy, Defibrillation, Radiation therapy, Electrocautery, or use of other implantable medical devices and wearable devices.
- **Adverse Events**: In addition to procedure related risks the following Adverse Events may occur: pump pocket hematoma, skin erosion, infection, pump migration, catheter clogging or other catheter complications resulting in tissue damage or loss of or change in therapy, genito-urinary complications, reduced kidney function, hepatic encephalopathy, progression of liver disease, and other systemic effects.
- P230044 PMA approval letter on file
- U.S. Federal law restricts alfapump System to sale by or on the order of a physician.
- The alfapump® System is currently not approved in Canada.
- DSR® therapy is still in development and is currently not approved in any country. The safety and effectiveness of DSR® therapy has not been established

Presenters

alfapump® US commercialisation plans

Ian Crosbie
Chief Executive Officer
Sequana Medical NV

Dr Klarenbeek
Chief Medical Officer
Sequana Medical NV

Martijn Blom
Chief Commercial Officer
Sequana Medical NV

Dr Saab
Professor of Medicine & Surgery,
David Geffen School of Medicine, UCLA

Dr Pagadala
Transplant Hepatologist,
Methodist Dallas Medical Center

US Commercial Roll-Out of alfapump®

Introduction	Ian Crosbie, CEO
Recurrent and Refractory Ascites Due to Liver Cirrhosis – Overview and treatment overview	Dr Saab, UCLA
POSEIDON & Patient Preference Studies	Dr Gijs Klarenbeek, Chief Medical Officer
What the POSEIDON results mean for patients and physicians, and experience from the POSEIDON study	Dr Pagadala, Methodist Dallas Medical Center
US market opportunity & Commercial Roll-Out Plans	Martijn Blom, Chief Commercial Officer
Wrap Up	Ian Crosbie, CEO
Q&A	All

Introduction

Ian Crosbie,

CEO

sequanamedical

Focus on alfapump US commercialisation

Sequana Medical Financing Will be Focused on alfapump® Commercialisation in the US

alfapump

- US FDA approved device for recurrent & refractory ascites due to liver cirrhosis
- Strategic objective is successful US commercialisation
- Focus of Sequana Medical activities & financing at public company level

DSR

- Drug development program for cardiorenal syndrome & diuretic resistance in heart failure
- Clinical proof of concept published in European Journal of Heart Failure
- 100% owned subsidiary (“DSR Co”)
- Future financing planned through private financing at DSR Co level

alfapump – highly attractive US opportunity

US PMA approval in large and growing market with attractive dynamics and direct specialty sales model

- **Recurrent and Refractory Liver Ascites** - $2 billion market with 9% CAGR driven by MASH/NASH & alcoholic liver disease
- **Potential to Transform Underserved Market** – Clear unmet clinical needs from standard of care that is not defended by commercial player, and no competitive devices in development
- **Strong Clinical Message** – POSEIDON pivotal study clearly met efficacy and safety end points
- **Derisked Reimbursement** – Existing coding, together with NTAP and focus on specialist centers
- **Direct Specialty Sales Model Launching H2 2025** - Small specialty salesforce focused on liver transplant centers
- **Positive Market Feedback** – Clear need for improved treatment options from clinicians & patients
- **Platform for Sustained Market Leadership** – Real long term barriers to direct competitors from PMA and FDA Breakthrough Device Designation, plus granted IP and extensive know-how
- **Established and Experienced Leadership** – Derisking scale-up & commercial rollout

US Approval Received(1) – US Launch Planned for H2 25

Broad Indication for Use, Minimal Contraindications and No Post Approval Study Requirements

*The **alfa**pump® system is intended for single patient use only in adult patients with refractory or recurrent ascites due to liver cirrhosis.*

It is indicated for the removal of excess peritoneal fluid from the peritoneal cavity into the bladder, where it can be eliminated through normal urination.

Contraindications:

i) The **alfa**pump® System is MRI unsafe, and

ii) Hyperbaric oxygen therapy is contraindicated

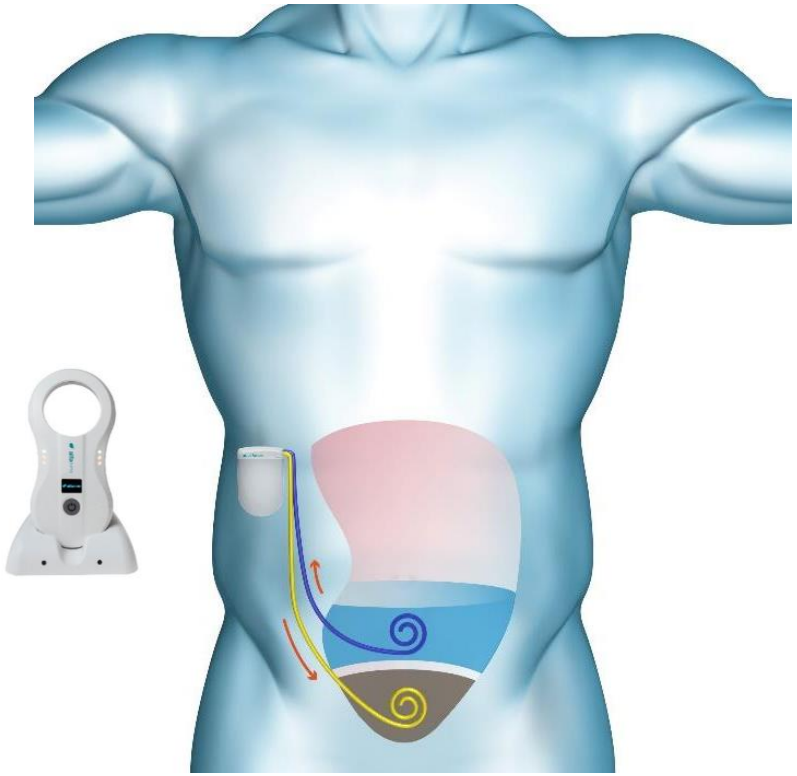
No post approval study requirements

Plan for structured collection of real world data ongoing – required to drive adoption, support additional publications and expand reimbursement

(1) https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P230044

Proven step change in therapy, over 1,000 implanted

Fully implanted automatic device for long term treatment



- Wireless battery charging
- Settings wirelessly adjusted
- Automatic Operation
- Long-term implantation
- Regular reporting to clinicians
- Integrated pressure sensors

PMA Approval from FDA(1)

Breakthrough Device Designation

CE(2)

EASL The Home of Hepatology

(1) https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P230044
(2) *Under MDR 2017/745*

Recurrent and Refractory Ascites Due to Liver Cirrhosis – overview and treatment options

Dr Saab,

UCLA

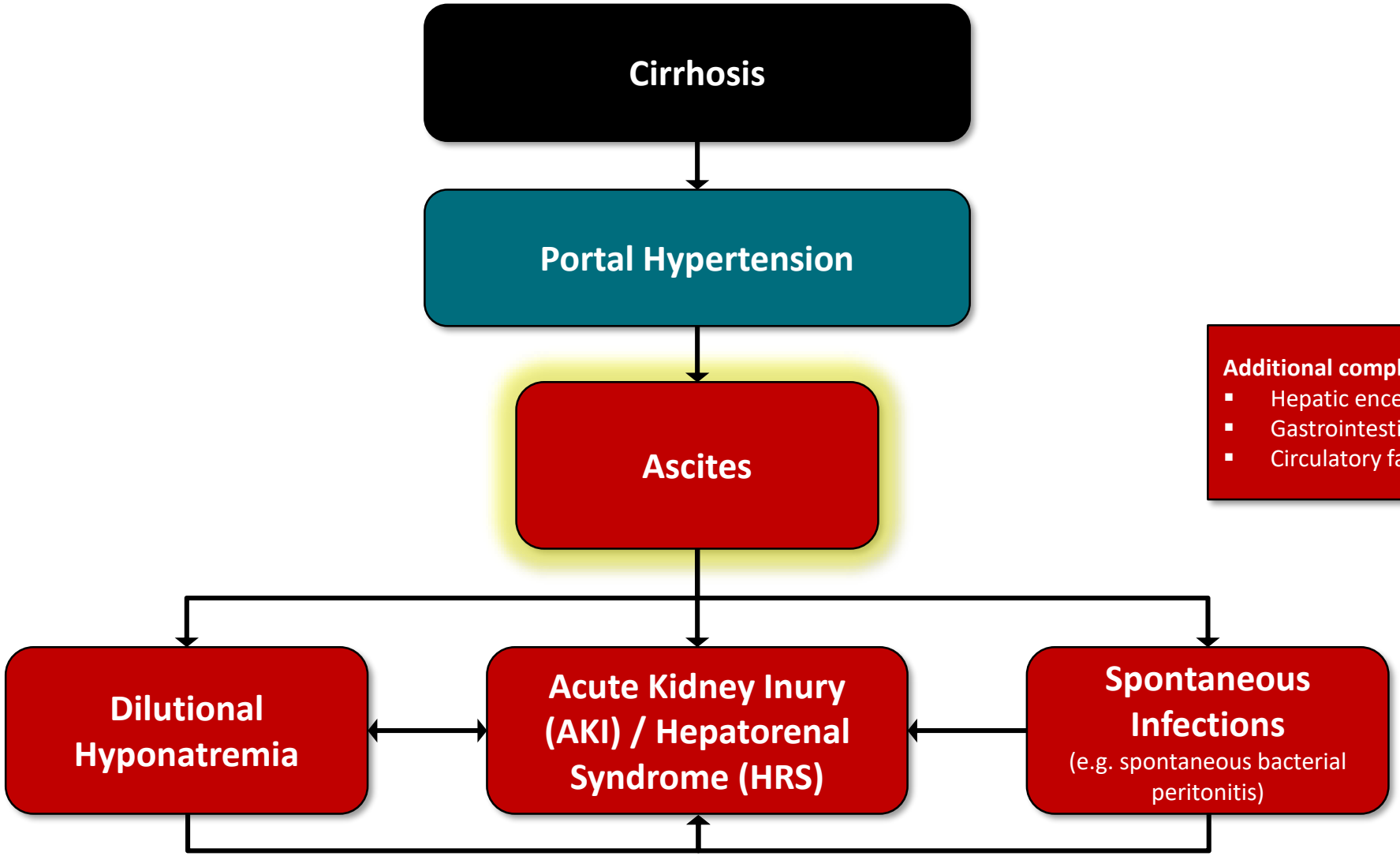
sequanamedical

Cirrhosis - Epidemiology

- Affects ~2.2 million adults in US[1]
  - Continues to rise due to increased incidence of alcohol liver disease and steatotic liver disease
  - > 40,000 progress to liver failure and death each year[2]

1. Tapper and Parikh 2023; 2. NIAAA surveillance report 2022

Ascites is a main complication of cirrhosis

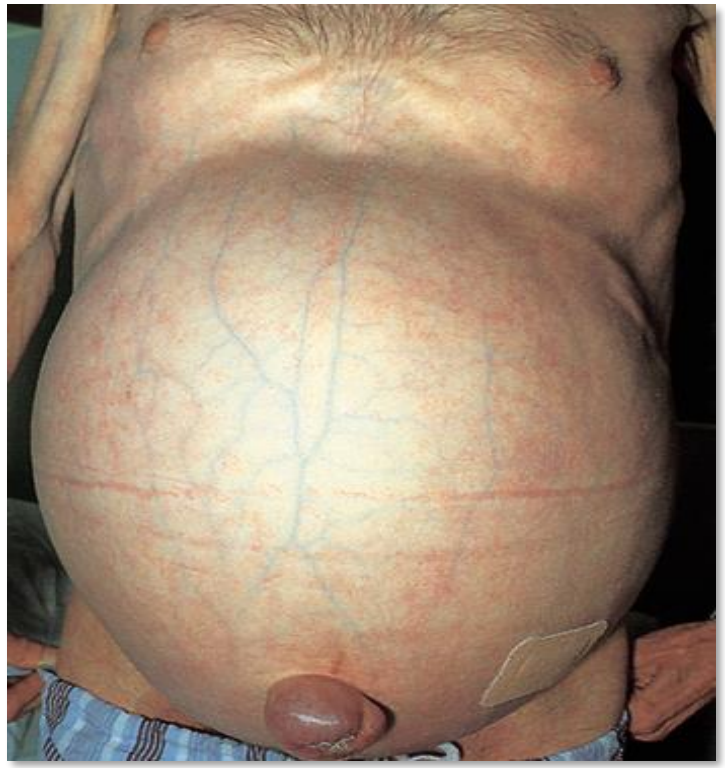


Additional complications

- Hepatic encephalopathy (HE)
- Gastrointestinal/variceal bleeding
- Circulatory failure

Figure adapted from Biggins et al. 2021

Unmet need for effective treatment to reduce need for repeated invasive procedures

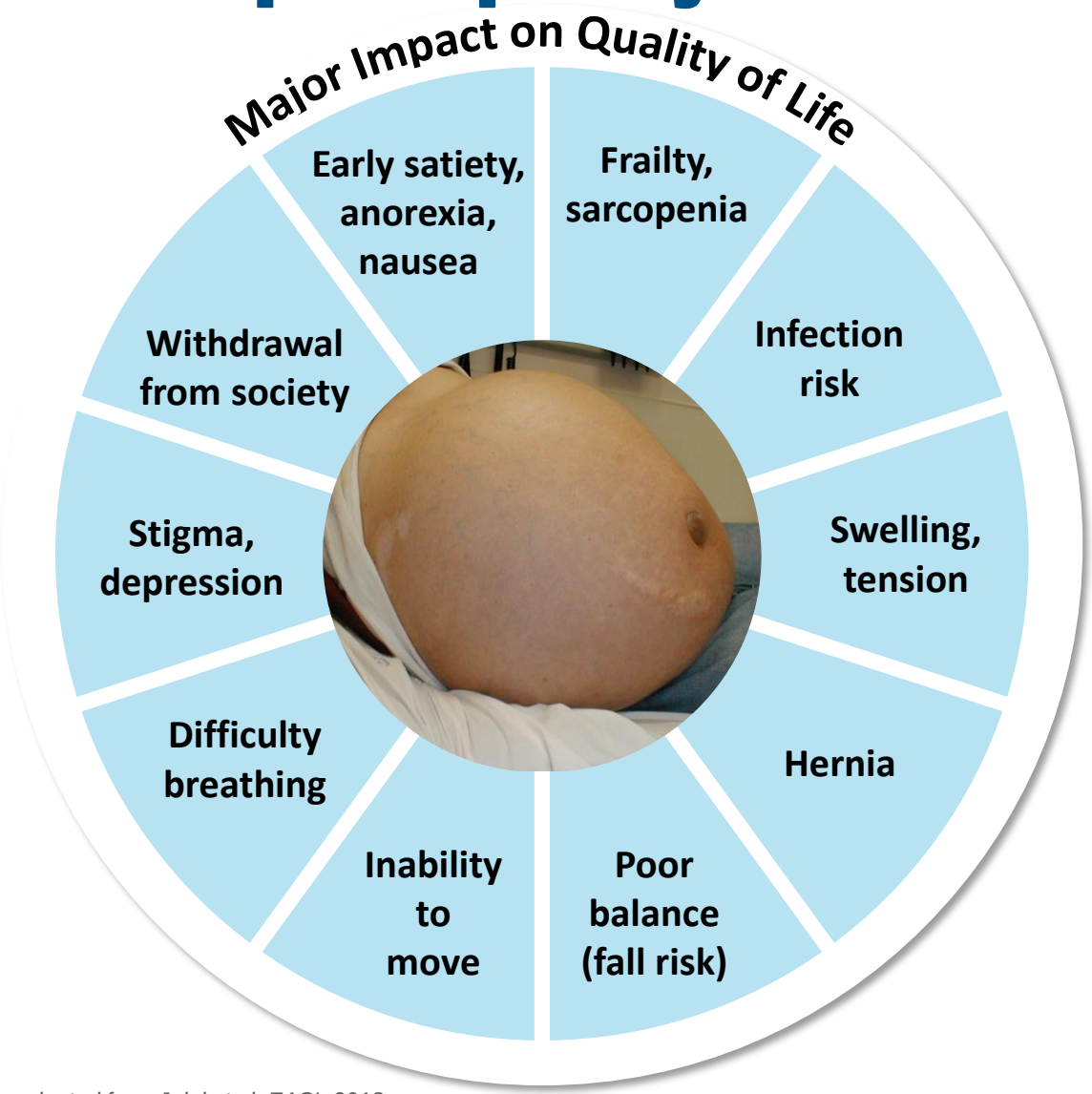


- Patients continue to suffer debilitating symptoms and poor QoL
- One-year mortality is high so QoL is key in evaluation of therapeutic interventions

Need effective treatment that will reduce need for repeated invasive procedures, improve day to day symptoms, and allow patients to lead more independent, fulfilled life

Photograph courtesy of Dr. F. Wong, University of Toronto

Patients with ascites suffer debilitating symptoms & poor quality of life



Perceived stigma associated with adverse attitudes and behaviors[1]

- Increased depression

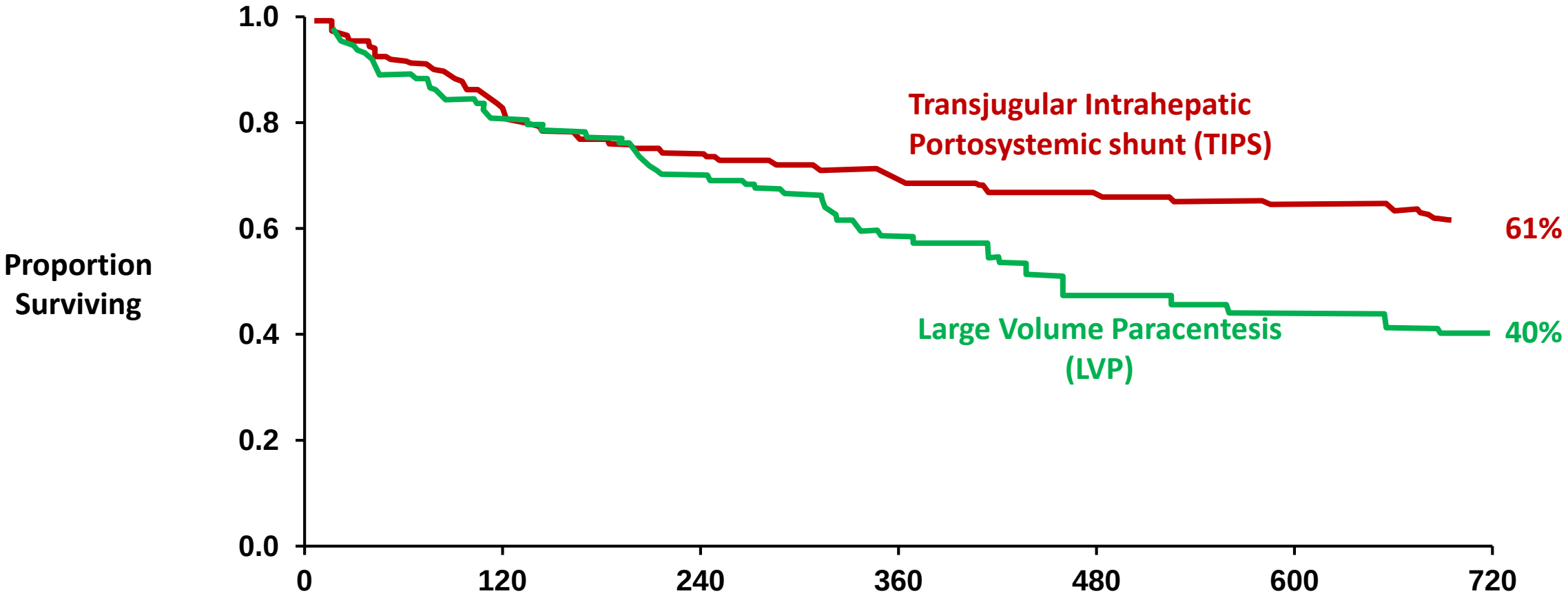
Caregiver Burden[2,3]

- Provide transportation and support for medical appointments
- Help with routine activities of living
- ~9 hours per week

Figure adapted from Jalal et al. EASL 2018

1. Vaughn-Sandler et al. 2013 ; 2. Rakoski et al. 2012; 3. Lai et al. 2019

Survival in patients with refractory ascites declines rapidly



At risk							
TIPS	169	138	125	114	83	77	72
SOC	104	84	73	61	25	23	21

Adapted from Larrue 2023; Cross-study comparison

Treatment options for recurrent / refractory ascites

ONLY CURE

- Liver transplant

FIRST LINE

- Large Volume Paracentesis (> 5L)

SECOND LINE

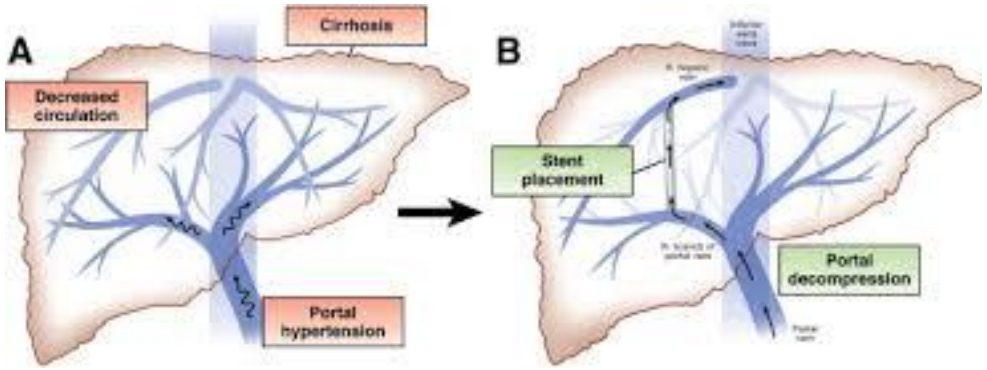
- Transjugular intrahepatic portosystemic shunt (TIPS)

LVP is first-line treatment

- Direct aspiration of > 5 L of ascites[1]
- Invasive, time consuming, and costly
  - In-hospital or outpatient clinic
  - Simultaneous administration with IV albumin solution[1]
- Risk of paracentesis-induced circulatory dysfunction (PICD)[2]
  - Severe complication associated with faster re-accumulation of ascites, hyponatremia, renal impairment, and shorter survival[3]
- Repeated frequently (average every 10-14 days[4])
  - High proportion of days with debilitating symptoms between treatments[1]

1. Jalan 2018 ; 2. Zhao et al. 2018; 3. Giri et al. 2023 ; 4. EASL 2010

TIPS is Second-Line Treatment but Many Patients Are Not Eligible for the Procedure



- Less than 40 % are eligible for TIPS[1]
- Some eligible patients refuse TIPS due to high risk of hepatic encephalopathy

Relative Contraindications	Absolute Contraindications
Advanced age	Severe or poorly controlled HE
Remote history of HE	Severe liver failure
Elevated MELD	Heart failure or severe cardiac valvular insufficiency
Elevated right or left heart pressures	Marked pulmonary arterial hypertension
Extensive primary or metastatic hepatic malignancy	Unrelieved biliary obstruction
Severe uncorrectable coagulopathy	Active systemic infection or sepsis
Severe uncorrectable thrombocytopenia	

Source: Saab et al 2020; (1) Copelan et al. 2014

Other Secondary Treatment Options are Limited and Negatively impact QoL

- Indwelling external drains
  - Only SoC in patients with < 6 months to live due to tendency for infection[1]
- Permanent catheter
  - Risk for infection, limits daily activities, stigma (stick out of skin, can't get wet), frequently gets blocked[2]
- Peritoneovenous shunt rarely used
  - High risk of disseminated intravascular coagulation, sepsis and heart failure[3]

1. P. Kathpalia et al: 2 J. Caldwell et al: 3. Salerno et al 2007

Summary

- Treatment of recurrent or refractory ascites is major unmet need in medicine

- Treatment options are limited:
  - Repeat paracentesis associated with risks of infection, bleeding, and organ puncture
  - TIPS can be associated with precipitation or worsening of hepatic encephalopathy and there is a possibility of liver failure in select patients

- alfapump approval is a welcome addition to the available treatment options, addressing many of the key limitations

POSEIDON & Patient Preference Studies

Dr Gijs Klarenbeek,

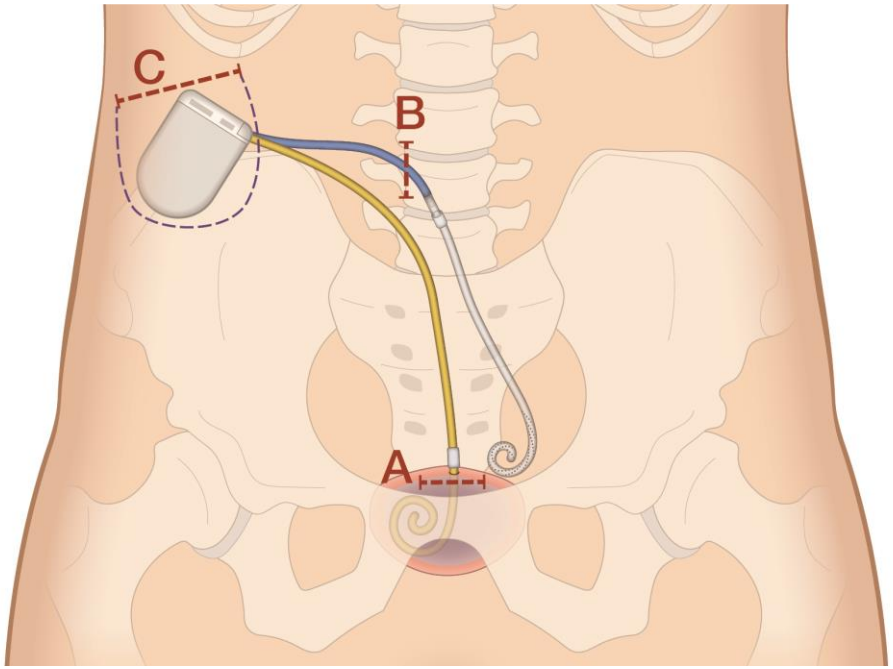
Chief Medical Officer

sequanamedical

Implant procedure

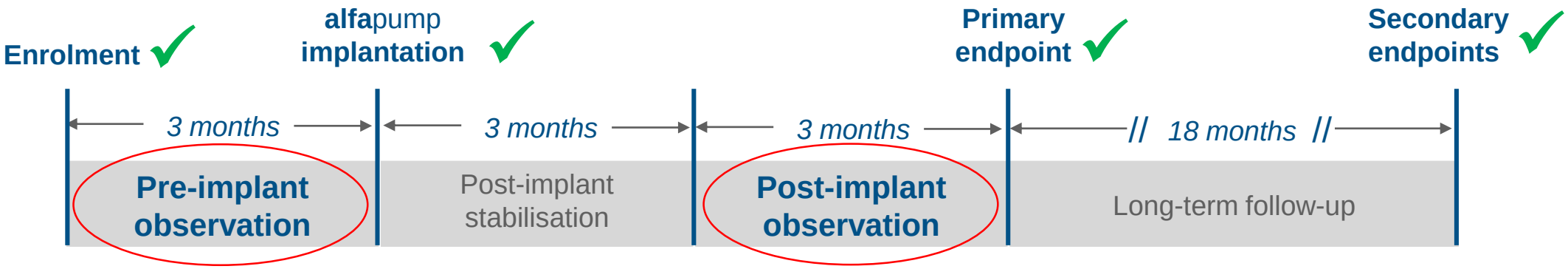
Percutaneous Procedure in 60 – 90 minutes

- Interventional Radiology (IR) procedure
- Straightforward procedure with short learning curve
  - Standard percutaneous techniques
  - Performed in standard IR suite – standard IR equipment
- Local or general anesthesia (patient/physician preference)
- Existing relationship between IR and Hepatologist from TIPS
- 1 – 2 days hospital stay
  - Post-implant follow up
  - Initial pump settings



POSEIDON - Successful North American pivotal study

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

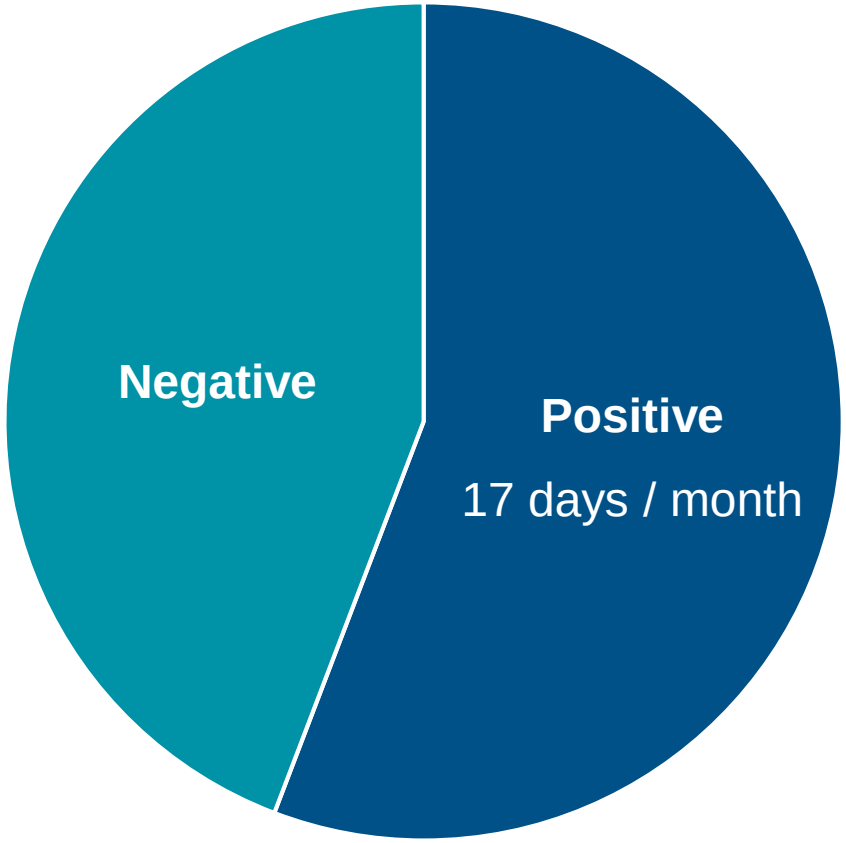


PERFORMANCE OUTCOMES	0 – 6 months	0 – 24 months
Therapeutic paracentesis / month	Median of 0.0	Median of 0.0
Freedom from LVP	90% of patients	80% of patients
Quality of Life: Change in SF-36 Physical Component score (higher is better)	+6.4 points(1)	+9.3 points(1)
Quality of Life: Change in AscitesQ score (lower is better)	-16.8 points(2)	-26.6 points(2)

Source: alfapump system SSED (summary of safety and effectiveness) PMA 230044
(1): Baseline 36.4: improvement exceeds minimally clinically important difference of 4.2 points / (2): Baseline 49.0

Impact on patient reported “Good Health Days”

In a true patient perspective



Pre-Implant (n=32)

Post-Implant (n=16)

Source: alfapump system SSED (summary of safety and effectiveness) PMA 230044
Good Health Day: Patient reported positive global assessment of health relative to their ascites symptoms and management Diary selection of good, very good or excellent on a 5-point Likert scale of poor, fair, good, very good and excellent

Primary safety endpoint through six months consistent with expected rate

Primary Safety Endpoint Through 6 months post implant	Events	Patients with Events N = 34* n (%)	95% CI
Primary safety endpoint	6	6 (18%)	(6.8, 34.5)
Open surgical re-intervention	0	0	(0.0, 10.3)
Pump explant without replacement due to related AE	6	6 (18%)	(6.8, 34.5)
Pump system related death	0	0	(0.0, 10.3)

Expected PSE rate: 15%

Source: alfapump system SSED (summary of safety and effectiveness) PMA 230044
**Per pre-specified imputation rules, patients with death or withdrawal due to unrelated cause (per CEC adjudication) are excluded from analysis (n = 6) leaving 34 evaluable mITT patients*

alfapump safety profile comparable to standard of care

Comparison for the six months post-implantation

Six month data[1]	NACSELD-III Registry Matched Patients	POSEIDON Pivotal Cohort[2]
Any Death or Hospitalization	**45.9% (17/37)**	56.8% (21/37)
Death	**10.8% (4/37)**	10.8% (4/37)
Hospitalization	**35.1% (13/37)**	45.9% (17/37)
Median # of hospitalizations (min, max)	**0 (0, 4)**	1 (0, 4)
Liver Transplant	**8.1% (3/40)**	5.4% (2/37)

NACSELD-III is a prospective cohort of outpatients with cirrhosis recruited from 10 centers across North America including patients with compensated and decompensated cirrhosis – study conducted contemporaneously with POSEIDON study

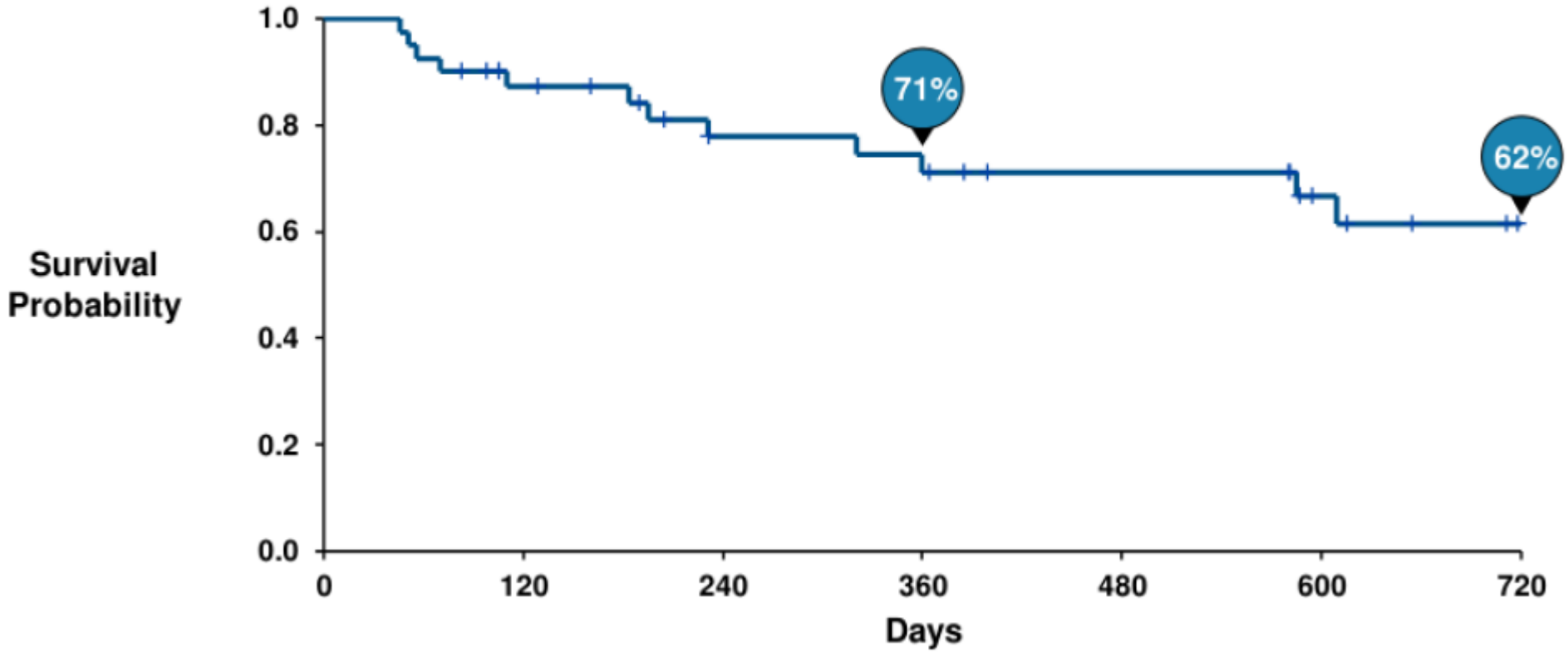
Source: alfapump system SSED (summary of safety and effectiveness) PMA 230044

(1) Deaths and serious adverse events (SAE) requiring hospitalization are presented hierarchically such that if a subject died and experienced an SAE requiring hospitalization, they are counted under "Death".
(2) POSEIDON data are derived from adverse event data

POSEIDON Overall Survival

Not a powered endpoint; Pre-specified per protocol analysis – Kaplan Meier

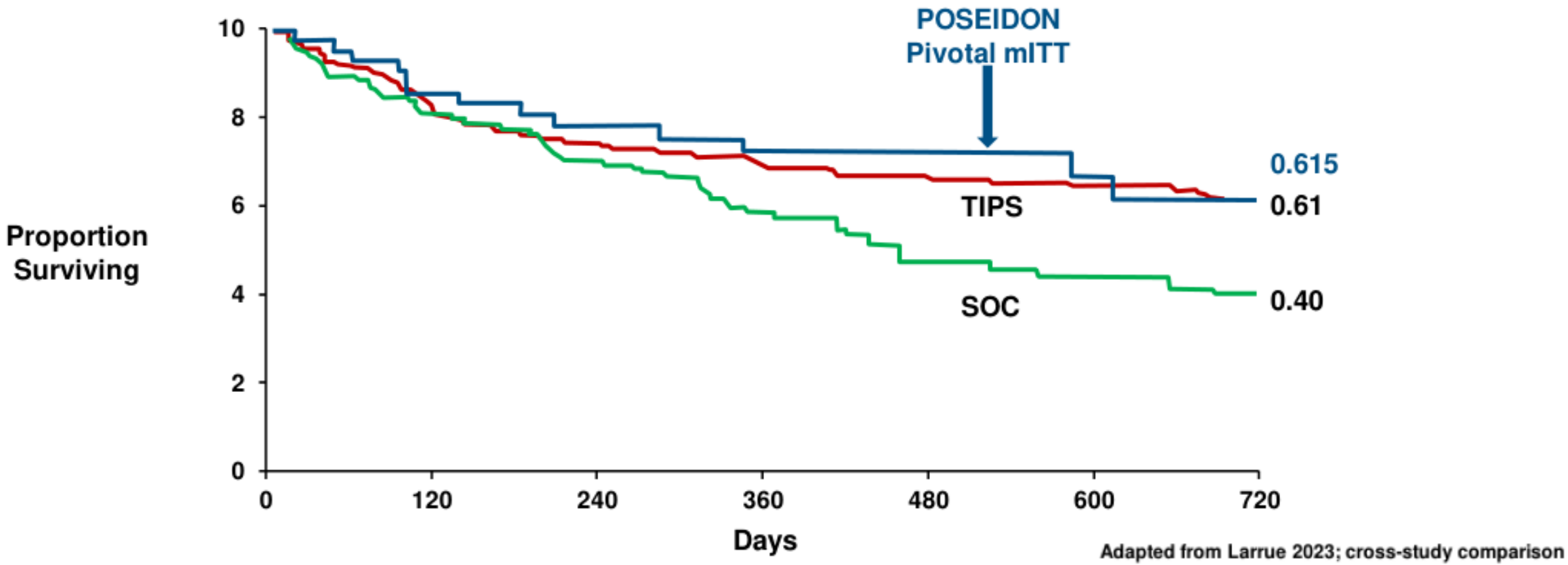
Long-Term Safety: Overall Survival



Source: POSEIDON clinical study report (data on file at Sequana Medical)

POSEIDON Overall Survival – favourable over SoC

Higher Than Expected in this Patient Population (compared to LVP), Comparable to TIPS



Source: POSEIDON clinical study report (data on file at Sequana Medical)

alfapump profile exceeding patient expectations

Patient preference study indicates compelling profile for alfapump based on POSEIDON outcomes

Risk tolerance (over 6 months)	Patient preference study Maximum acceptable risk	POSEIDON pivotal cohort Observed rate
Major surgery or death	>10%	0%
Minor procedure	>35%	20%
Serious infection or AKI resulting in hospitalization	>30%	22.5%

Desired benefits	Patient preference study	POSEIDON pivotal cohort
Reduction in paracentesis frequency	100%	100% (median)
Additional ascites good health days each month	10	>10 (mean)

Patient Preference Study indicates US patients are willing to tolerate risks beyond those observed for the alfapump in the POSEIDON study if the need for paracentesis is reduced and/or a positive impact on health days

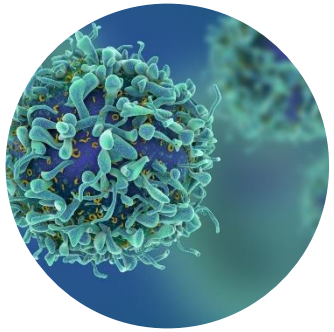
Source: alfapump system SSED (summary of safety and effectiveness) PMA 230044

Potential Market Expansion(1)

sequanamedical

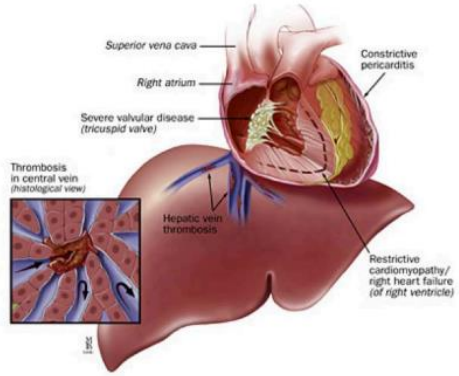
Opportunities for Additional Indications in Other Significant Markets

Malignant Ascites (secondary to cancer)



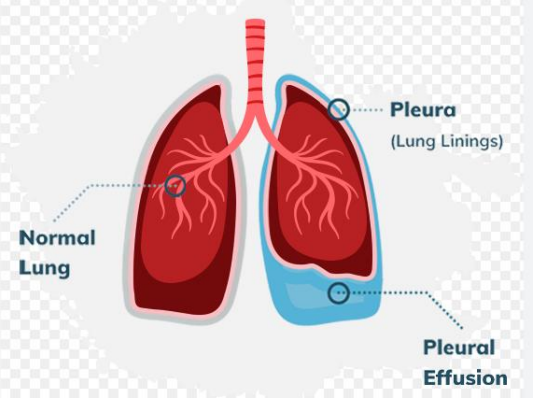
- Breast and ovarian cancer have longest survival with ascites(2)
- Severe impact on quality of life
- Positive clinical experience in Europe(3)

Cardiac Ascites



- Secondary to Congestive Cardiac Failure
- Presents very similar to ascites due to liver cirrhosis

Pleural Effusion



- Fluid in the chest cavity, secondary to cancer, heart failure or pneumonia or hepatic hydrothorax
- Initial positive experience from KOLs(4)

1: Not included in current US indication for use for alfapump
2::Ayantunde & S. L. Parsons. Annals of Oncology 2007
3: Fotopoulou et al; BMC Palliat Care . 2019 Dec 5;18(1):109
4 Tiwari et al; ACG Case Reports Journal 11(6):p e01372, June 2024

What the POSEIDON data means for US patients and physicians & Experiences from the POSEIDON study

Dr Pagadala,

Methodist Dallas Medical Center

sequanamedical

Effectiveness demonstrated in POSEIDON

Impact on patients – caregivers – physicians / hospital

Both Primary and Key Secondary Effectiveness Endpoints Related to Paracentesis Were Achieved

Co-Primary Endpoint	Achieved	Summary	P-value
Reduction in Median Number of Therapeutic Paracentesis / Month (N = 40)	✓	**100% reduction**	**p<0.001**
% of Patients with ≥ 50% Reduction in Therapeutic Paracentesis (N = 40)	✓	**77% of patients**	**p<0.001**

Secondary Endpoint	Achieved	Summary	P-value
Reduction in average monthly number of LVP (>5.0L) (N = 26)	✓	**Reduced by 2.2** (2.3 → 0.1)	**p<0.001**
Reduction in cumulative volume of ascitic fluid removed by needle paracentesis in 3 months (N = 26)	✓	**Reduced by 51.4L** (54.2 → 2.8)	**p<0.001**

Source: POSEIDON clinical study report (data on file at Sequana Medical)

Impact on Quality of Life

Patient Perspective beyond numbers as outcome of a Questionnaire

Secondary Endpoint: SF-36 Physical Component Summary Score Improved (QoL)

Secondary Endpoint	Achieved	Summary	P-value
Improvement in SF-36 Physical Component Summary Score (N = 26)	✓	**Improved by 6.4 points** (36.4 → 42.8)	**p<0.001**

Minimum clinically important difference (MCID) = 4.2

Secondary Endpoint: Ascites-Q Score Improved (QoL)

Secondary Endpoint	Achieved	Summary	P-value
Improvement in Ascites-Q score (N = 26)	✓	**Improved by 16.8 points** (49.0 → 32.2)	**p<0.001**

Source: POSEIDON clinical study report (data on file at Sequana Medical)

Safety - Complications

As expected for this patient population – manageable

Frequency of Major Adverse Events Aligns wit Those Reported in Population with Cirrhosis

	Pre-Implant (Day -90 to -1)		Stabilization (Day 0 to 90)		Post-Implant (Day 91 to 180)	
	Patients N = 40		Patients N = 40		Patients N = 40	
	n	%	n	%	n	%
Major Adverse Events (MAEs)	**3**	**8%**	**6**	**15%**	**4**	**10%**
AKI > stage 2 or hepatorenal syndrome	**0**	**0**	**2**	**5%**	**2**	**5%**
AKI > stage 2	*0*	*0*	*1*	*3%*	*1*	*3%*
Hepatorenal syndrome	*0*	*0*	*1*	*3%*	*1*	*3%*
Hepatic encephalopathy > stage 2	**2**	**5%**	**4**	**10%**	**1**	**3%**
Spontaneous bacterial peritonitis	**1**	**3%**	**2**	**5%**	**1**	**3%**
Recurrent / refractory infection related to alfapump System, procedure, or therapy (as adjudicated by CEC)	**0**	**0**	**2**	**5%**	**1**	**3%**

Source: POSEIDON clinical study report (data on file at Sequana Medical)

Center Experience

From POSEIDON clinical study

- Build alfapump Team

- Collaboration between departments
  - Hepatology
  - Interventional Radiology
  - Other Medical and Paramedical Staff

- Learning curve
  - Implantation – early post-implant period
  - Long term follow up

US Market Opportunity & Commercial Roll-Out Plans

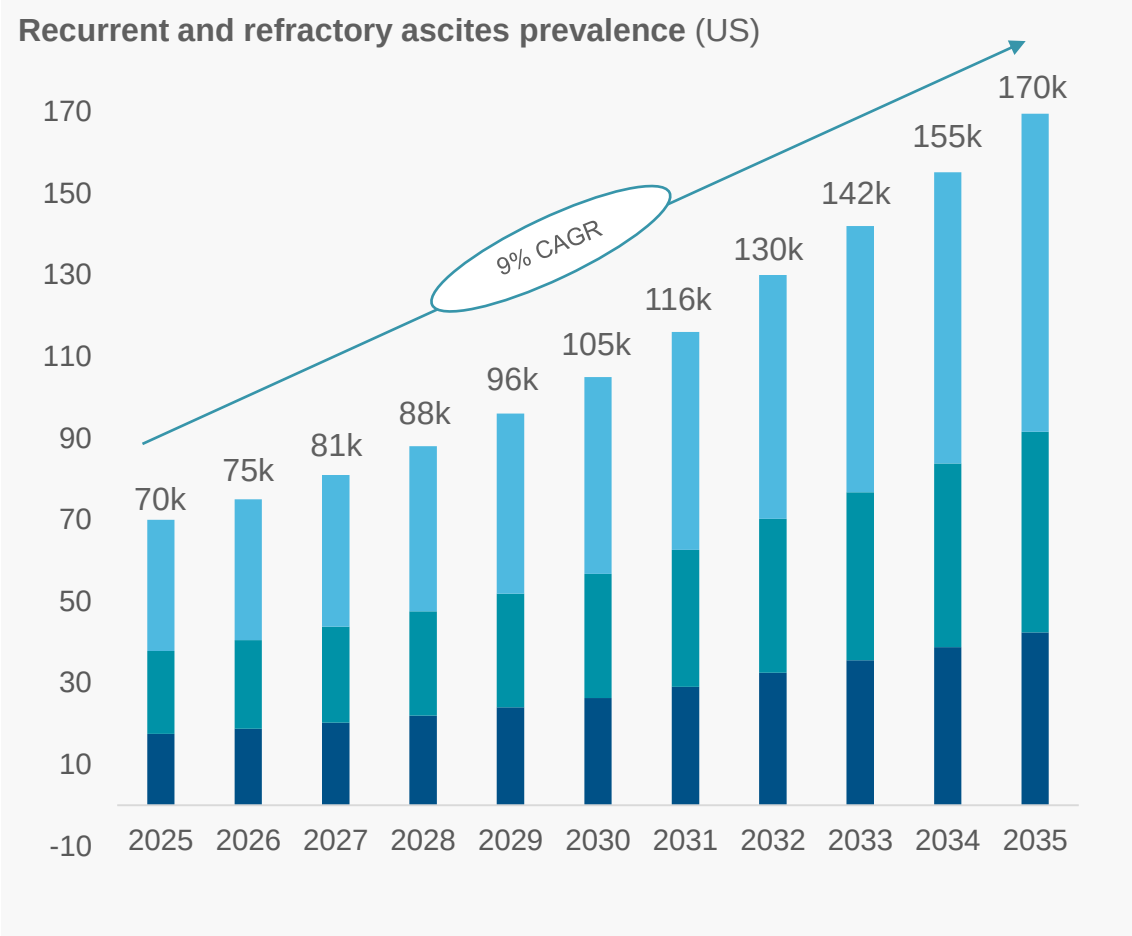
Martijn Blom,

Chief Commercial Officer

sequanamedical

$2bn US market for alfapump in 2025; 9% CAGR[1]

$500 million Priority One market with highly attractive dynamics for the alfapump



Priority 3[2]
3-5 paracenteses / year

Priority 2[2]
6-11 paracenteses / year

Priority 1[2]
12+ paracenteses / year

Prioritisation Factors:

- **Impact on patient QOL**
- **Current cost to payors**
- **Burden on hospital resources**
- **Likelihood to be TIPS exclusions or TIPS failures**

[1] Based on US market assessment conducted by highly experienced international consulting group, estimating 130,000 patients with recurrent or refractory ascites in US by 2032 and based on proposed price of $30k per alfapump;
[2] Based on US and Canada market assessment by 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

Attractive pricing with derisked reimbursement

Existing DRG & CPT III codes - NTAP and TCET benefit from Breakthrough Device Designation

Coding – Strong position from existing DRG codes and Breakthrough Designation

- Existing US hospital DRG payment for **alfa**pump procedure*
- Breakthrough designation enables higher payments via NTAP (applied for, and expected in 10/25)
- Supports **alfa**pump ASP of **$30K** (80% gross margin)
- CPT III codes granted

Coverage – Prior Approval from Specialist Centers With High Medical Need

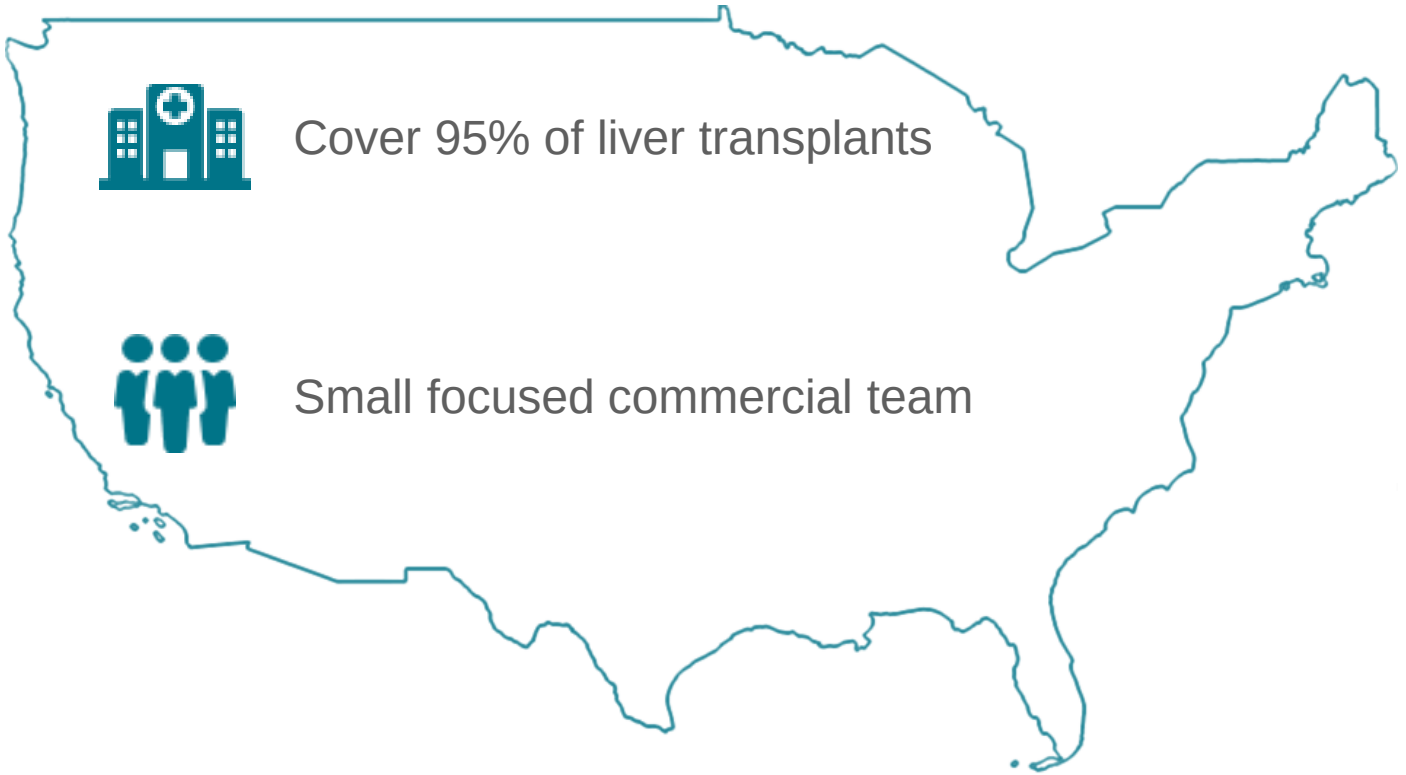
- High pre-approval potential from targeted hospitals
- New Federal Regulation enforces rapid decision making

On the basis of existing ICD-10 codes issued for the **alfapump (OW1G3J6 & OJH80YZ), the likely DRG coding will be 423 "OTHER HEPATOBILIARY OR PANCREAS O.R. PROCEDURES",*

***DRG:** Diagnosis Related Group; **NTAP:** New Technology Add-On Payment; **CPT:** Current Procedural Terminology;*

US – Go direct to 90 liver transplant centers

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



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

Commercial Roll-Out – Focus on High Quality Outcomes

Driven by product availability, recruitment / training of Sequana team and onboarding of new sites

- **“Soft Commercial Launch”: H2 2025 – Q1 2026**
  - Limited initial production availability of key supplier; forecasting 80-100 systems available
  - Targeting up to seven centers – sites identified and preparations underway
  - Training of Sequana implanting team
  - Training of centers and refining “onboarding” activities (contracting, training etc)
  - Optimising the process for Full Commercial Launch

- **“Full Commercial Launch”: Q2 2026 onwards**
  - Full production availability planned
  - Growth driven by:
    - Increasing penetration of existing centers (ie more implants / quarter)
    - Addition of ~5 new centers every quarter, targeting all 90 transplant centers by end of 2030
  - Addition of new centers requires recruitment and training of Sequana implanting team, and new centers to be onboarded

PMA & Breakthrough Device Designation Are Key

Combination creates real challenges to entry of competing products

PMA: (granted to alfapump system in 2024)

- Evaluation of safety and efficacy of Class III devices; most stringent regulatory category – technical, non-clinical and clinical components
- Requires collection of data so our data & studies cannot be referenced by a competitor & does not create a 510(k) pathway
- **Significant time, resource & cost barrier for any new entrants to conduct new studies**
- Recruiting for study with unapproved product likely to be harder now alfapump has US approval

Breakthrough Device Designation: (granted to alfapump system in 2019)

- Medical devices [and device-led combination products] that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions
- Expedites the development and review of devices, incl. pre/postmarket balance of data collection, and efficient and flexible clinical study design – POSEIDON study design was major advantage
- **Now alfapump is approved, can a competitor obtain breakthrough device designation and resulting benefits in trial design?** if not, will they likely require longer and more complex studies?

Wrap-Up

Ian Crosbie,
CEO

sequanamedical

Highly experienced leadership team

Supported by committed shareholders

Executive team:

Ian Crosbie
Chief Executive Officer

Kirsten Van Bockstaele
Chief Financial Officer

Gijs Klarenbeek
Chief Medical Officer

Martijn Blom
Chief Commercial Officer

Dragomir Lakic
VP Manufacturing

Timur Resch
Global VP QM/QA/RA

Andreas Wirth
VP Engineering

Board of Directors:

Pierre Chauvineau
Chairman

Alex Clyde
Director

Wim Ottevaere
Director

Jackie Fielding
Director

Rudy Dekeyser
Director

Ids van der Weij
Director

Ian Crosbie
Chief Executive Officer

alfapump – highly attractive US opportunity

US PMA approval in large and growing market with attractive dynamics and direct specialty sales model

- **Recurrent and Refractory Liver Ascites** - $2 billion market with 9% CAGR driven by MASH/NASH & alcoholic liver disease
- **Potential to Transform Underserved Market** – Clear unmet clinical needs from standard of care that is not defended by commercial player, and no competitive devices in development
- **Strong Clinical Message** – POSEIDON pivotal study clearly met efficacy and safety end points
- **Derisked Reimbursement** – Existing coding, together with NTAP and focus on specialist centers
- **Direct Specialty Sales Model Launching H2 2025** - Small specialty salesforce focused on liver transplant centers
- **Positive Market Feedback** – Clear need for improved treatment options from clinicians & patients
- **Platform for Sustained Market Leadership** – Real long term barriers to direct competitors from PMA and FDA Breakthrough Device Designation, plus granted IP and extensive know-how
- **Established and Experienced Leadership** – Derisking scale-up & commercial rollout

Q&A

sequanamedical

Thank You

IR@sequanamedical.com
T: +32 (0)9 496 17 27

sequanamedical