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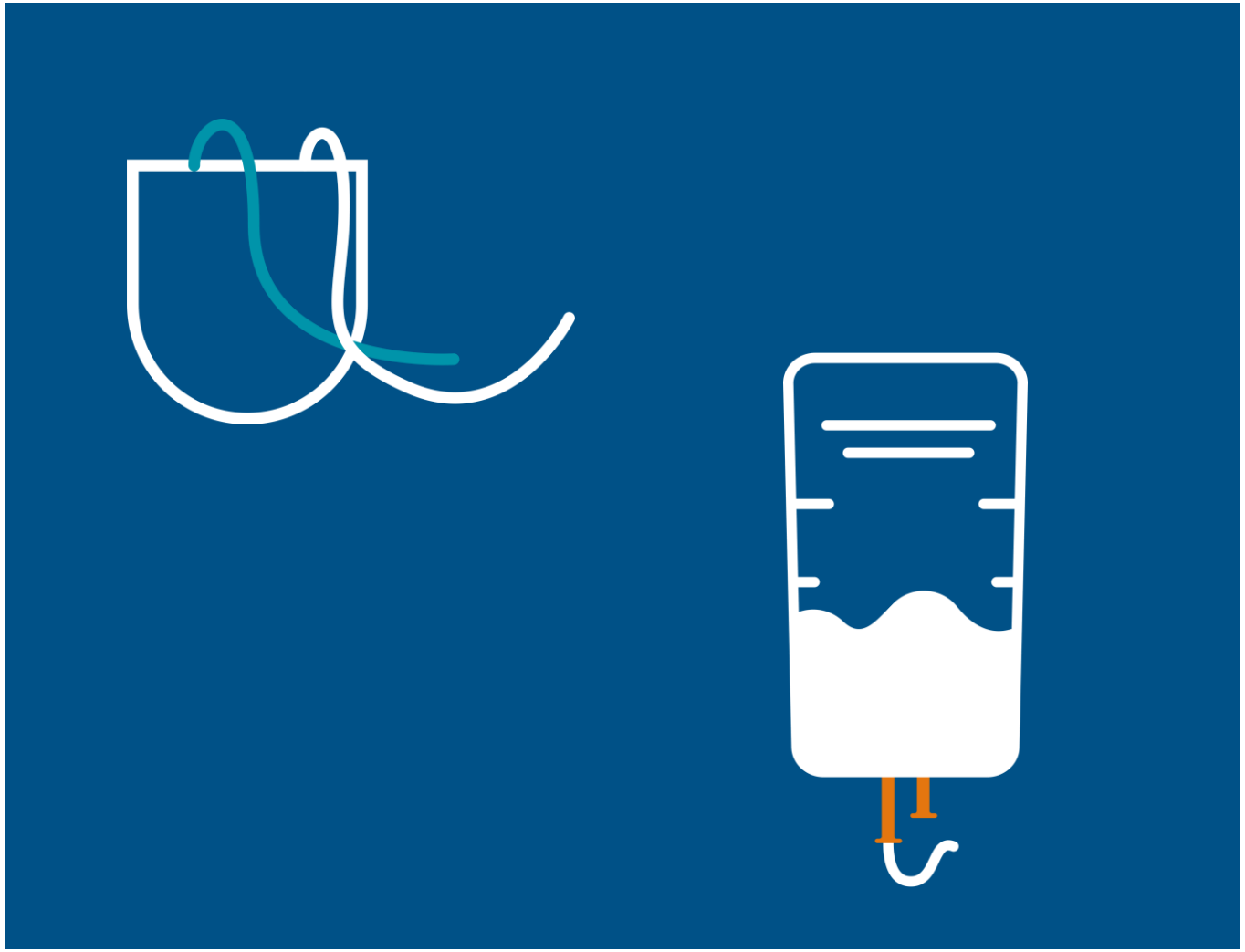

Pioneers in the treatment of fluid overload

alfapump approved by FDA for treatment of recurrent and refractory ascites due to liver cirrhosis

January 2025

Euronext: SEQUA.BR

Disclaimers

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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.

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- **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

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®

FDA Approved Breakthrough Device

Targeting $2 billion US Market for Treatment of Recurrent or Refractory Ascites Due to Liver Cirrhosis

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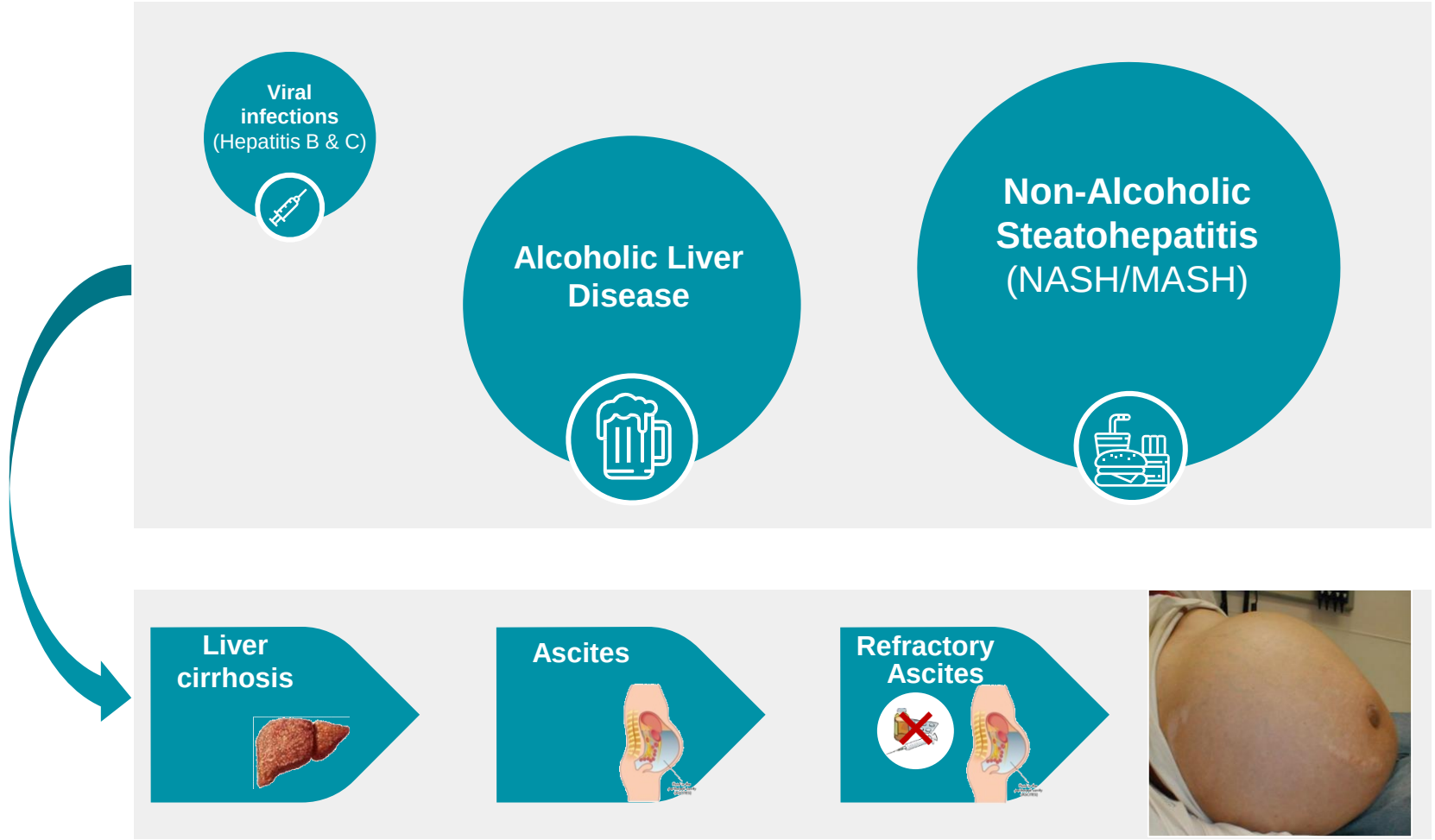
Refractory ascites – key complication of liver cirrhosis

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



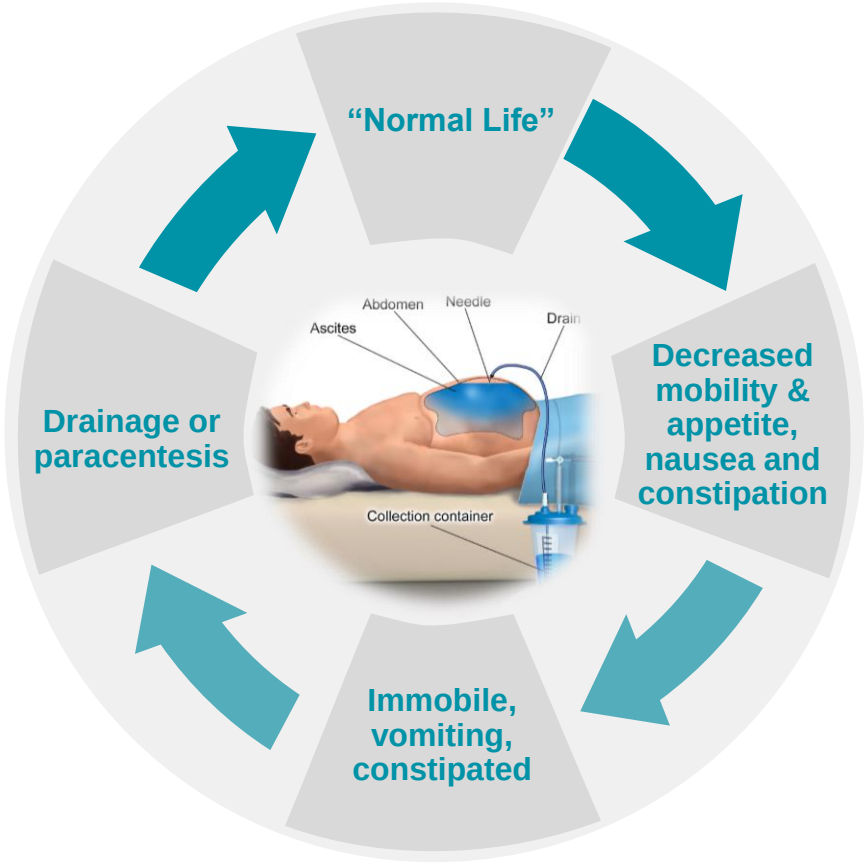
***NASH**: non-alcoholic steatohepatitis, also referred to as MASH (metabolic dysfunction-associated steatohepatitis) as per new fatty liver disease nomenclature (Hepatology, June 2023)*

SoC Virtually Unchanged for Thousands of Years

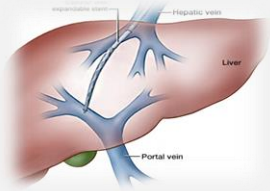
No new development apart from NASH/MASH drugs, which are not approved in late stage disease

SoC: Paracentesis ("drainage")

Painful, burdensome, short term benefit, QoL impact[1]



TIPS



- Severe Complications & Contraindications (less than 40% eligible)[2]
- Not always successful in treating ascites[3]

Permanent Catheter System

- External Catheter
- Risk for Infections / Blockage
- Limited use in US outside of palliative care

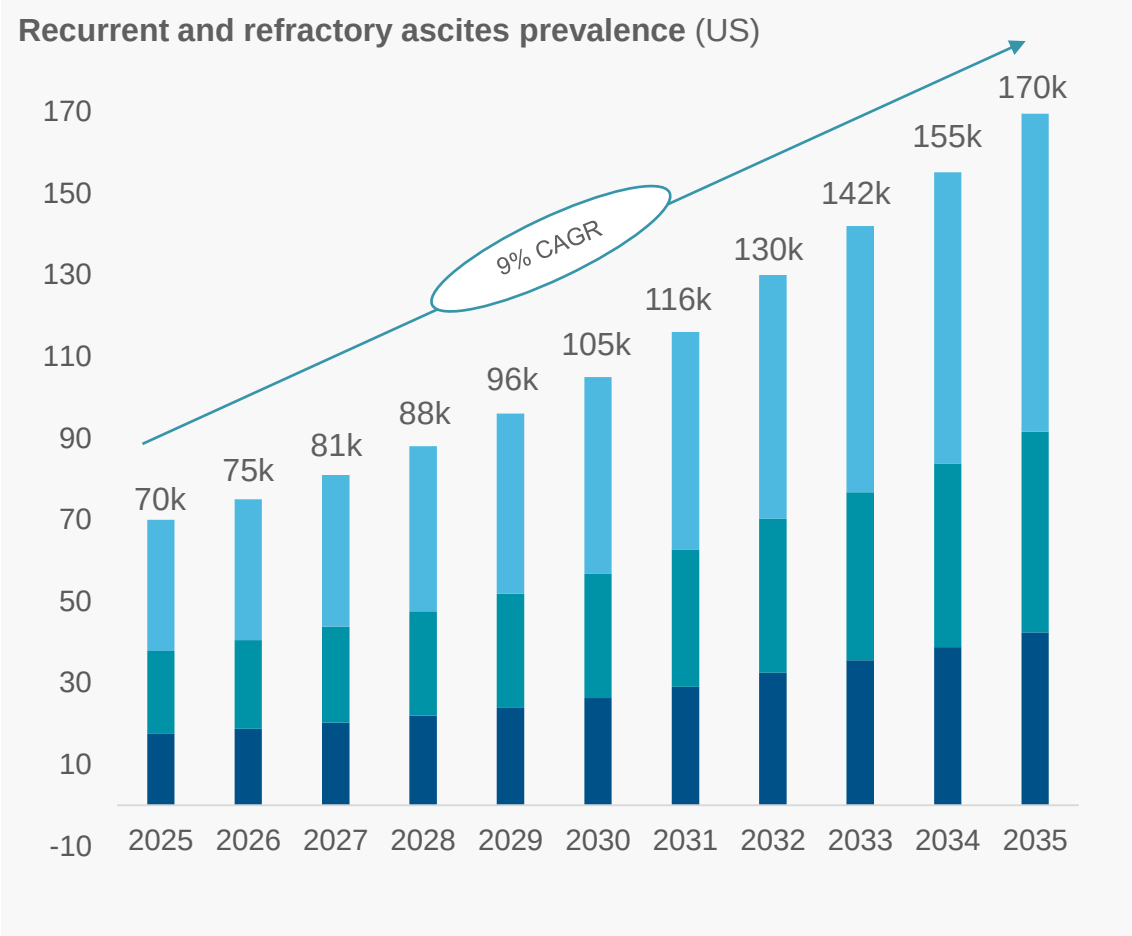
NASH Drugs

- Low responder rate
- Approved only for early stage NASH (F2/3), before routine diagnosis

[1] *Presentation of Dr. Rajiv Jalan at EASL in 2018, Large Volume Paracentesis (LVP) treatment cycle for refractory ascites*
[2] 45 – 63% efficacy (Wong, F., *Management of refractory ascites.* Clin Mol Hepatol, 2023. **29**(1): p. 16-32
[3] *Saab et al 2020*
SoC: *Standard of Care;* ***TIPS:*** *Transjugular Intrahepatic Portosystemic Shunt*

$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

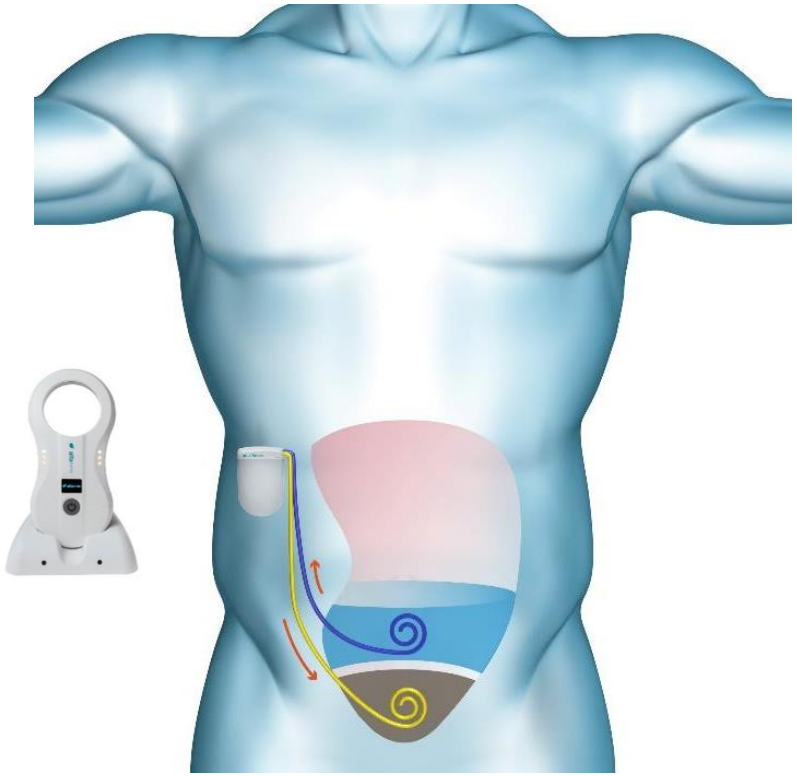
Prioritisation Factors:

- **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

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

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

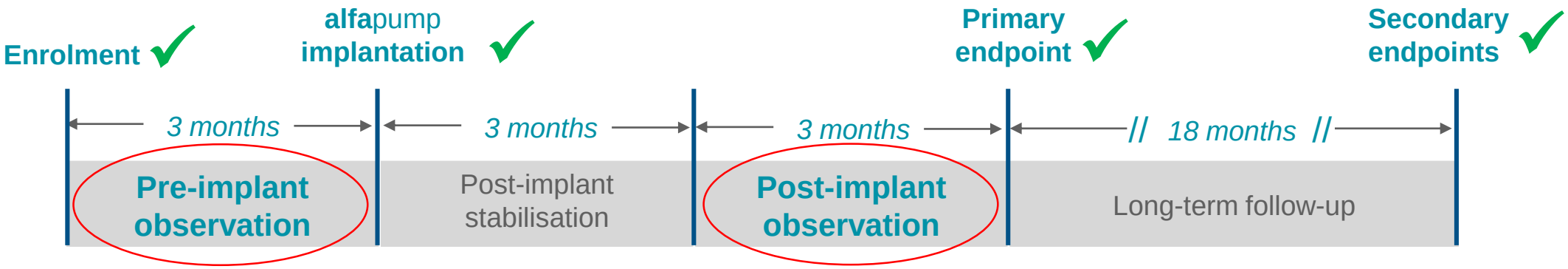
No post approval study requirements

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

POSEIDON - Successful North American pivotal study

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

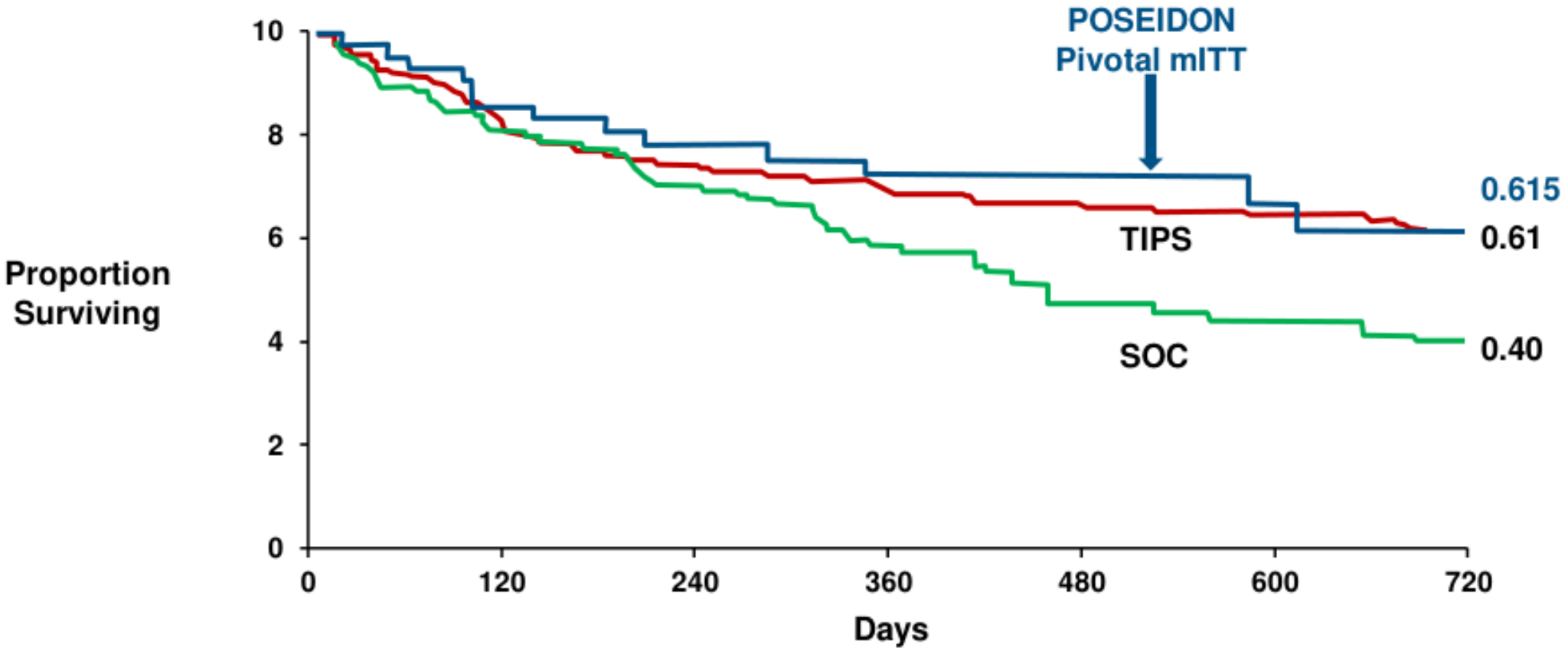


	0 – 6 months	0 – 24 months
Therapeutic paracentesis / month	Median of 0.0	Median of 0.0
Freedom from LVP	90% of patients	80% of patients
Quality of Life: Change in AscitesQ score (lower is better)	-16.8 points	-26.6 points
Quality of Life: Change in SF-36 Physical Component score (higher is better)	+6.4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

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

POSEIDON Overall Survival – favourable over SoC

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



Adapted from Larrue 2023; cross-study comparison

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

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

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%

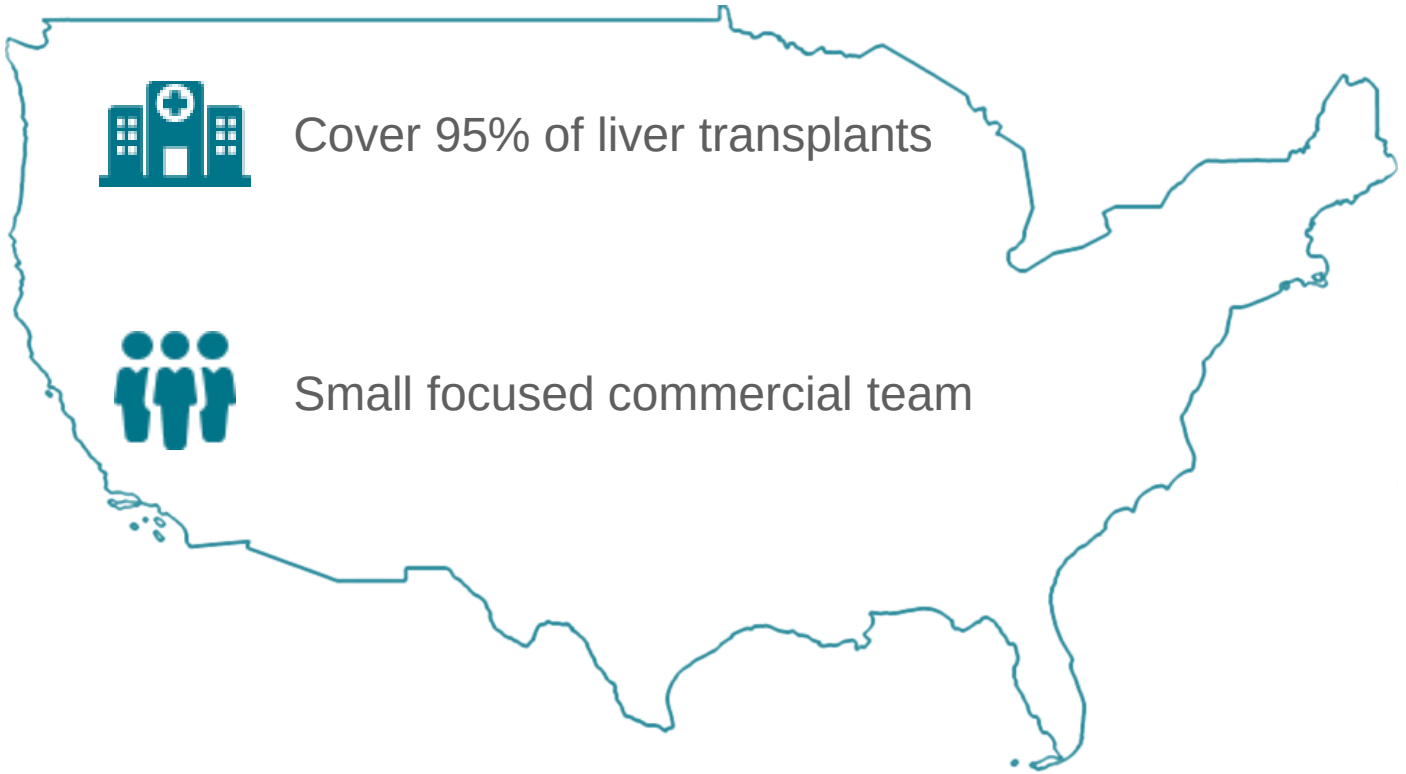
Desired benefits	Patient preference study	POSEIDON pivotal cohort
Reduction in paracentesis frequency	100%	100% (median)
Additional ascites good health days each month	10	>10 (mean)

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

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

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)

Strong pricing with derisked reimbursement

Breakthrough device designation and high gross margin

Coding – Strong position from existing DRG codes and Breakthrough Designation

- Existing US hospital DRG payment for **alfa**pump procedure*
- Target **alfa**pump ASP of **$30K** (80% gross margin)
- Breakthrough designation enables higher payments via NTAP
- 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, 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;*

Potential Market Expansion[1]

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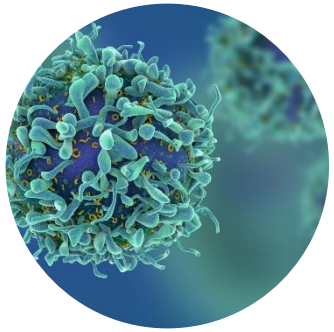
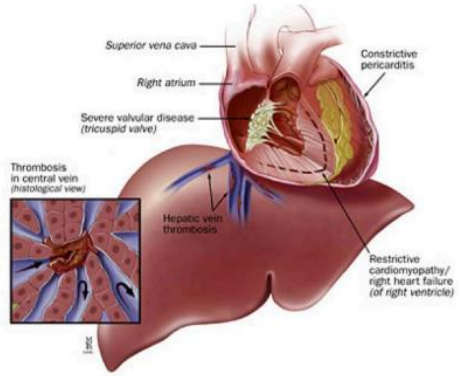
Opportunities for Additional Indications in Other Significant Markets

Malignant Ascites (secondary to cancer)



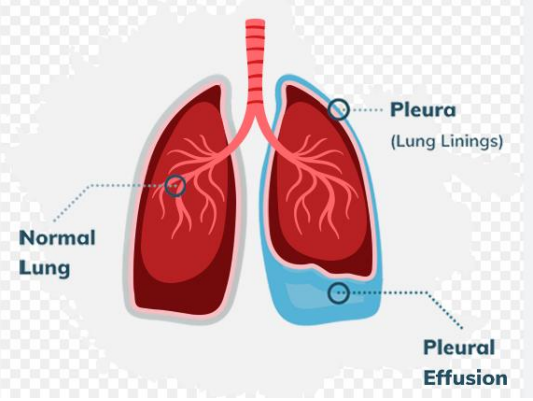
- Breast and ovarian cancer have longest survival with ascites[2]
- Severe impact on quality of life
- Positive clinical experience in Europe[3]

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

DSR®

Disease-modifying heart failure drug therapy tackling cardiorenal syndrome (CRS)

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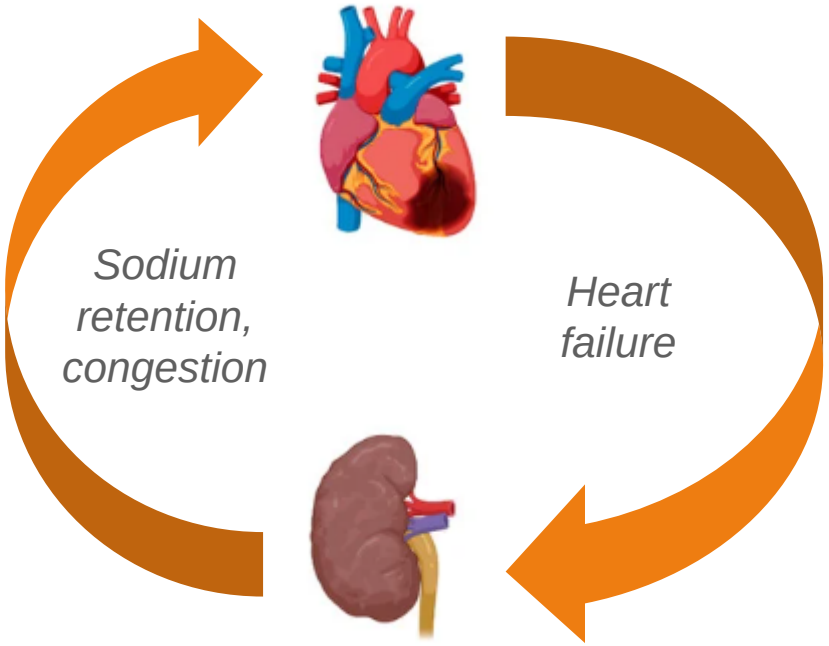
Cardiorenal Syndrome – key clinical challenge in HF

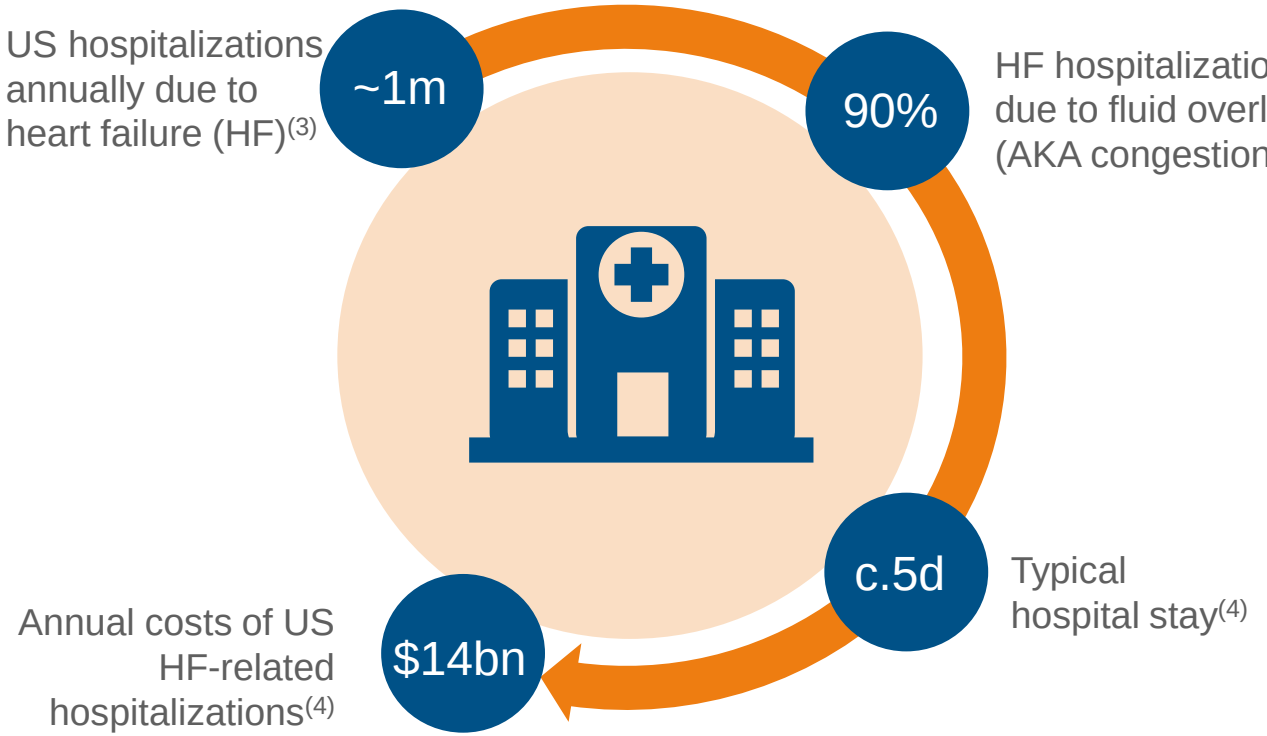
Clear need for options to tackle congestion for long enough, without the problems of loop diuretics

- Combined, and self-reinforcing dysfunction of heart and kidneys with hypothesised complex and interconnected mechanisms
- Clinical profile of self-reinforcing negative feedback cycle that is challenging to break
- Loop diuretics are mainstay of decongestion therapy BUT exacerbate many of the core mechanisms thought to underly CRS, worsening diuretic resistance and CRS



Congestion is key driver of morbidity & hospitalization

Diuretic-resistance in heart failure is common; no “super-diuretics” in development



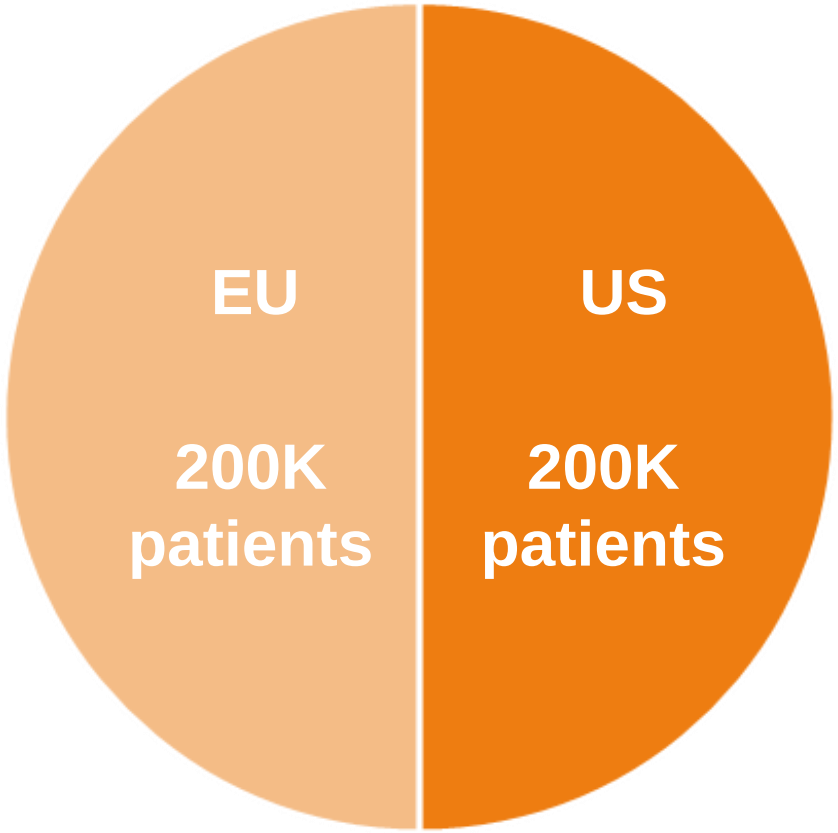
40% of heart failure patients on IV loop diuretics have a poor response(1)

24% re-admission rate at 30 days(2)

Source 1: Testani, Circ Heart Failure, 2014 & 2016; Source 2: Ross et al. (2010); Source 3: Costanzo et al., J. Am. Coll., 2007; Source 4: Urbich et al. (2020)

Multi-billion commercial opportunity

~400K chronically congested HF patients hospitalized per year in the US and EU ("frequent flyers")



$45K

US annual HF hospitalization cost per patient

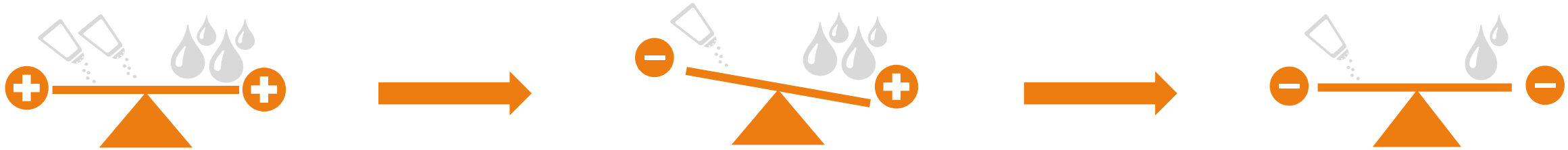
>$9 Bn

DSR addressable market in **US**

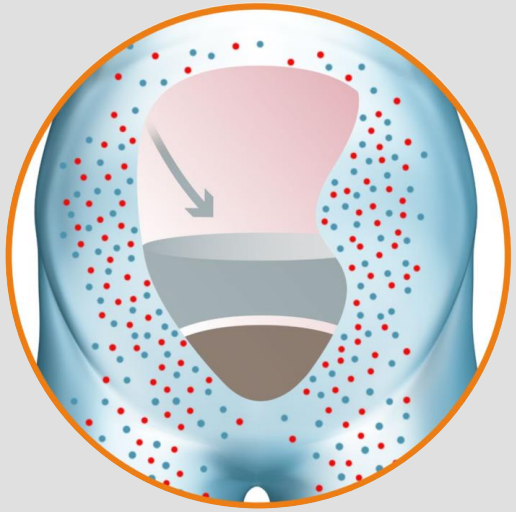
Potential for premium DSR pricing through reduced hospitalization and improved survival

DSR (Direct Sodium Removal) targets key driver

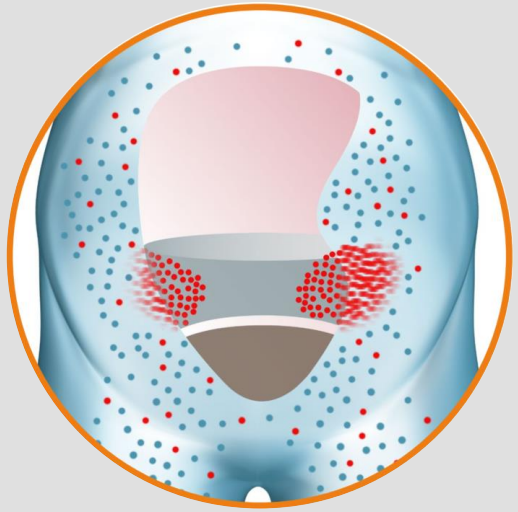
Validated by RED DESERT, SAHARA & MOJAVE clinical studies, with peer-reviewed publication



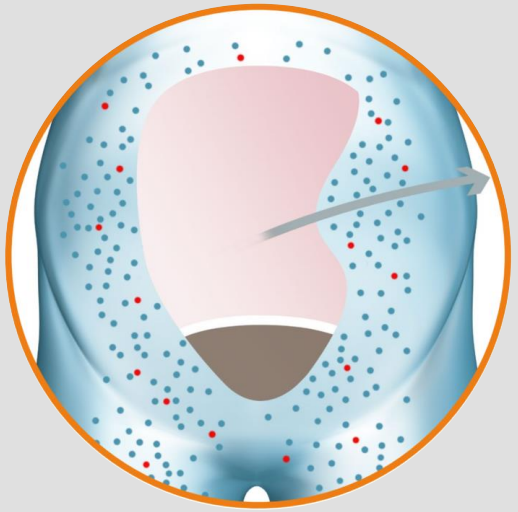
1 Sodium-free DSR product administered to peritoneal cavity



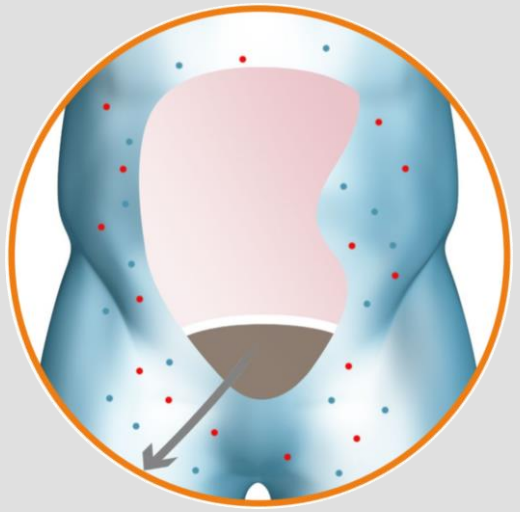
2 Sodium diffuses from body into DSR product



3 DSR product + extracted sodium & water removed from body



4 Body eliminates free water to restore sodium balance, reducing the fluid overload



- water
- sodium

Fundamental patents to reduce fluid overload in heart failure patients granted in US, Europe & China

Clinical proof of concept in cardiorenal sydrome

Rapid and effective decongestion PLUS improvement in cardio-renal status

Strong results from RED DESERT (N = 8) and SAHARA (n = 10) clinical studies

- ✓ Replacement of loop diuretics; safe, rapid and effective decongestion and maintenance of euvolemia
- ✓ Normalization of renal diuretic-response & long lasting reduction in loop diuretic needs post-DSR
- ✓ Improvement in renal function

Delivering improved clinical outcomes

- ✓ No congestion-related heart failure re-hospitalizations
- ✓ One class improvement of NYHA status
- ✓ Over 75% reduction in predicted one-year mortality*

"This data is truly revolutionary, representing really the first and only novel therapeutic approach to treat diuretic resistance and cardiorenal syndrome in heart failure."

Dr. Testani, Yale

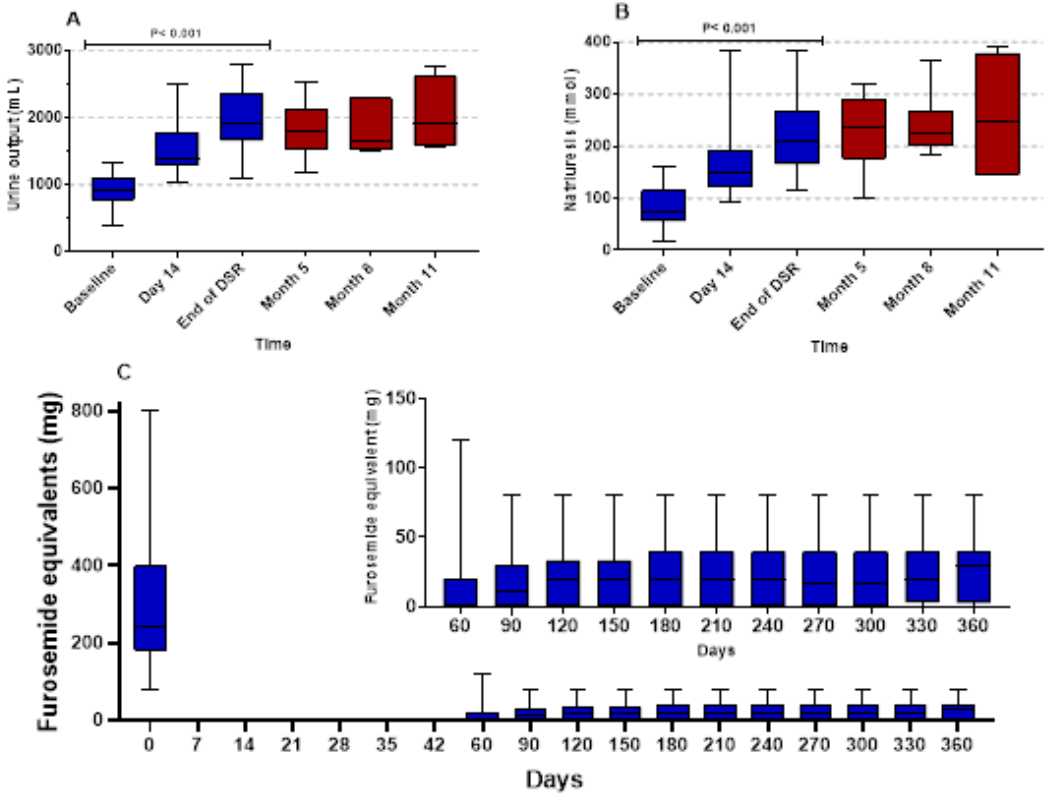
** Based on Seattle Heart Failure Model*

***NYHA**: New York Heart Association classification (data collected outside study protocols of RED DESERT and SAHARA)*

Improvement in diuretic response and renal function

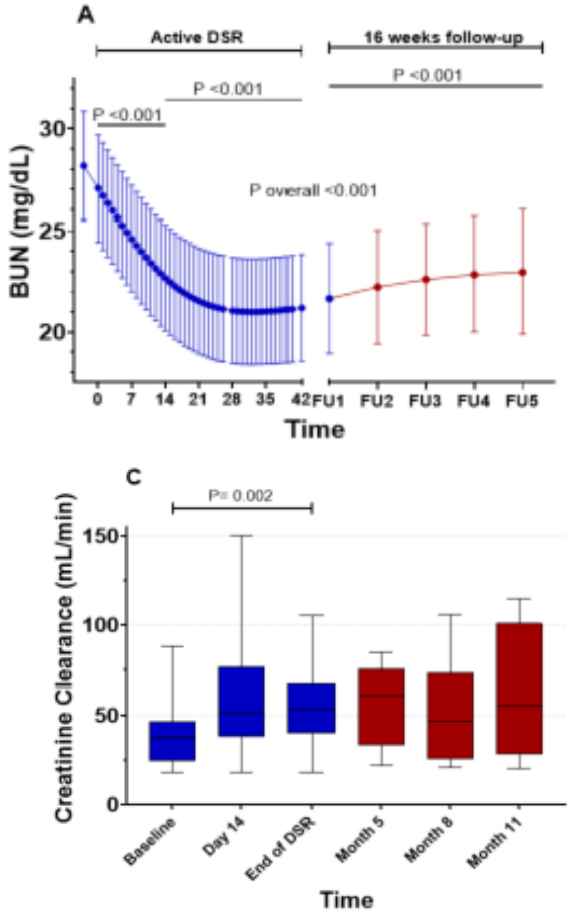
Normalization of diuretic-response with dramatic durable reduction in LD needs post-DSR therapy

Cumulative 6-hour urine output and urinary sodium excretion
following an intravenous 40mg dose of furosemide



Oral loop diuretic dose over the first year of follow-up
(in furosemide equivs: 1mg oral bumetanide = 20mg oral torsemide = 80mg oral furosemide)

Blood urea nitrogen (BUN) and creatinine clearance



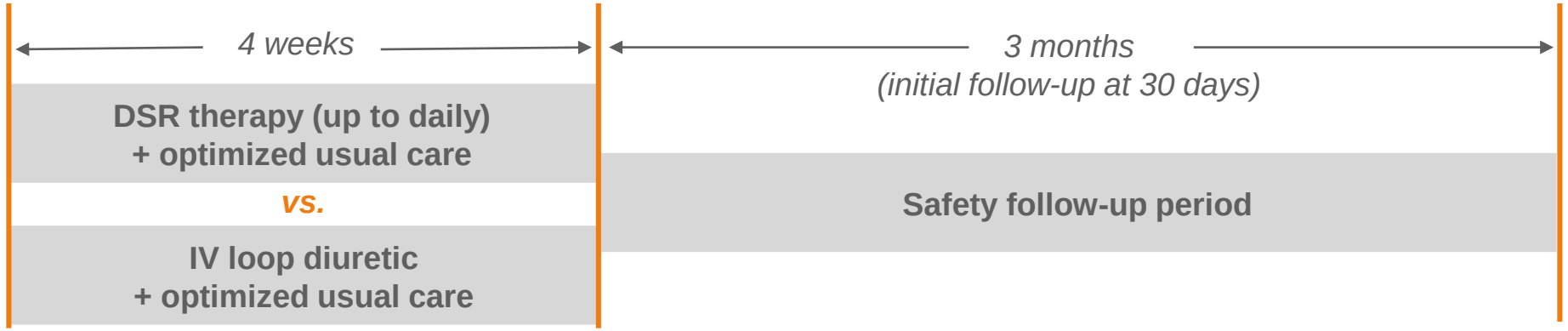
Published in European Journal of Heart Failure, May 2024

Blue bars *indicate data from both RED DESERT and SAHARA, and* ***red bars*** *indicate data only from SAHARA.*

LD*: Loop Diuretics*

MOJAVE: Phase 1/2a randomized controlled US study

Seeking to replicate RED DESERT and SAHARA positive results in US patients



Non-randomized (n=3)	Randomized cohort (n=30, DSR=20, control=10)

DSMB Approval Received to Proceed to Randomized Cohort

Positive Results from Patients in Non-randomized Cohort (n = 3)

- Safe, well tolerated and maintenance of euvolemia without loop diuretics
- Virtual elimination of loop diuretics three months post-DSR therapy
- Dramatic improvement in diuretic response*

Innovating DSR Access to Expand Market Opportunity

Four weeks of outpatient therapy targeting long term benefit

Treatment Overview

- Expected to be 2-3x per week, for 4 weeks
- DSR infused at doctors office / outpatient, ~30 minutes session
- After dwell (12 – 24 hours as directed), patient drains at home

PD catheter is fastest US regulatory route (drug-only)

- Well understood access path with existing US approvals

Subcutaneous Port is next step, expected to improve physician and patient acceptable

- Enhanced patient convenience and reduced infection risk
- Can remain implanted once therapy complete, ready for future use

Highly experienced leadership team

Derisking US commercial roll-out, and leveraging extensive board experience

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