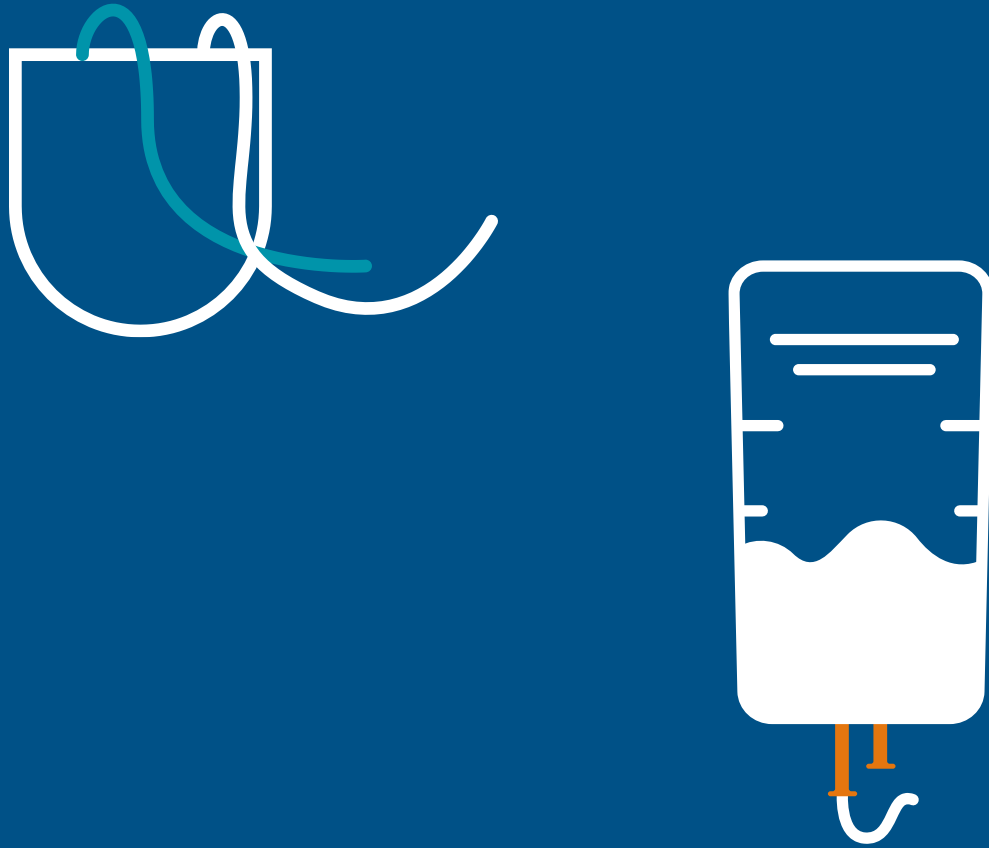


sequanamedical



Pioneers in the treatment of fluid overload

alfapump® - FDA approved
breakthrough device targeting
underserved \$2 billion US market

November 2025

Euronext: SEQUA.BR

Disclaimers

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- 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.

Important Safety Information:

- For important safety information regarding the alfapump® system, see <https://www.sequanamedical.com/wp-content/uploads/ISI.pdf>.
- 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

Note:

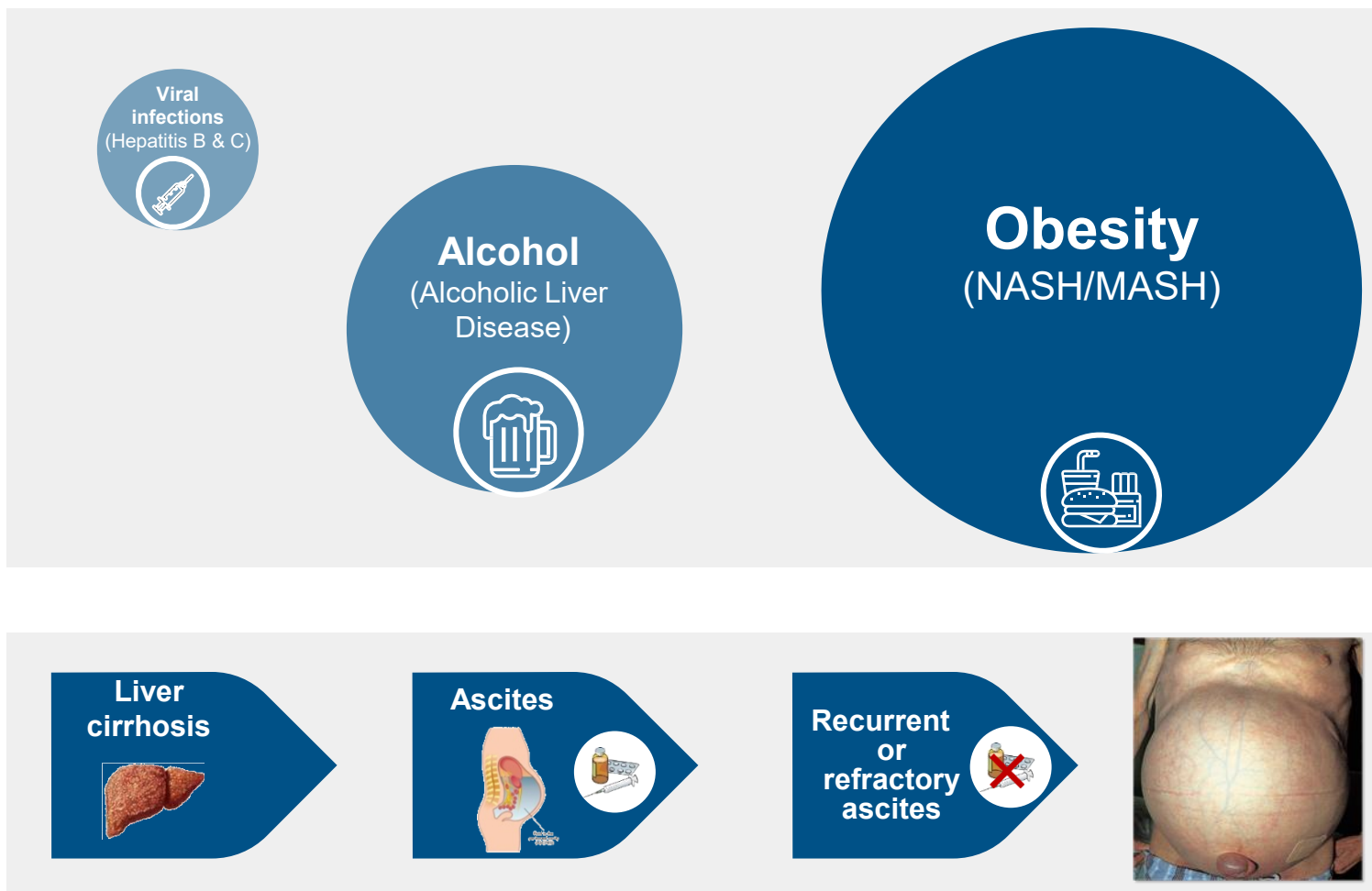
- alfapump® and DSR® are registered trademarks.

FDA Approved Device Transforming Large Neglected Market

- **Large Existing Market**
 - \$2 billion US market, growing at 9% CAGR
 - Long term growth driven by obesity and demand for better treatments
- **Differentiated Solution: alfapump® addresses unmet clinical need**
 - Physicians and patients want a better treatment option
- **Strong Clinical Evidence & FDA Approved**
 - 100% median reduction in therapeutic paracentesis plus important improvement in QoL
 - FDA PMA approved & Breakthrough Device Designation
- **Solid Reimbursement Position Supports \$30K+ ASP**
 - Coding/Payment: Strong position from existing DRG codes and NTAP
 - Coverage: High payor approval rate expected
- **Smart Commercial Strategy**
 - Focus on 90 Liver Transplant Centers
 - Limited competition creates wide open commercial opportunity
- **Significant upside potential from DSR pipeline program for diuretic-resistant HF**

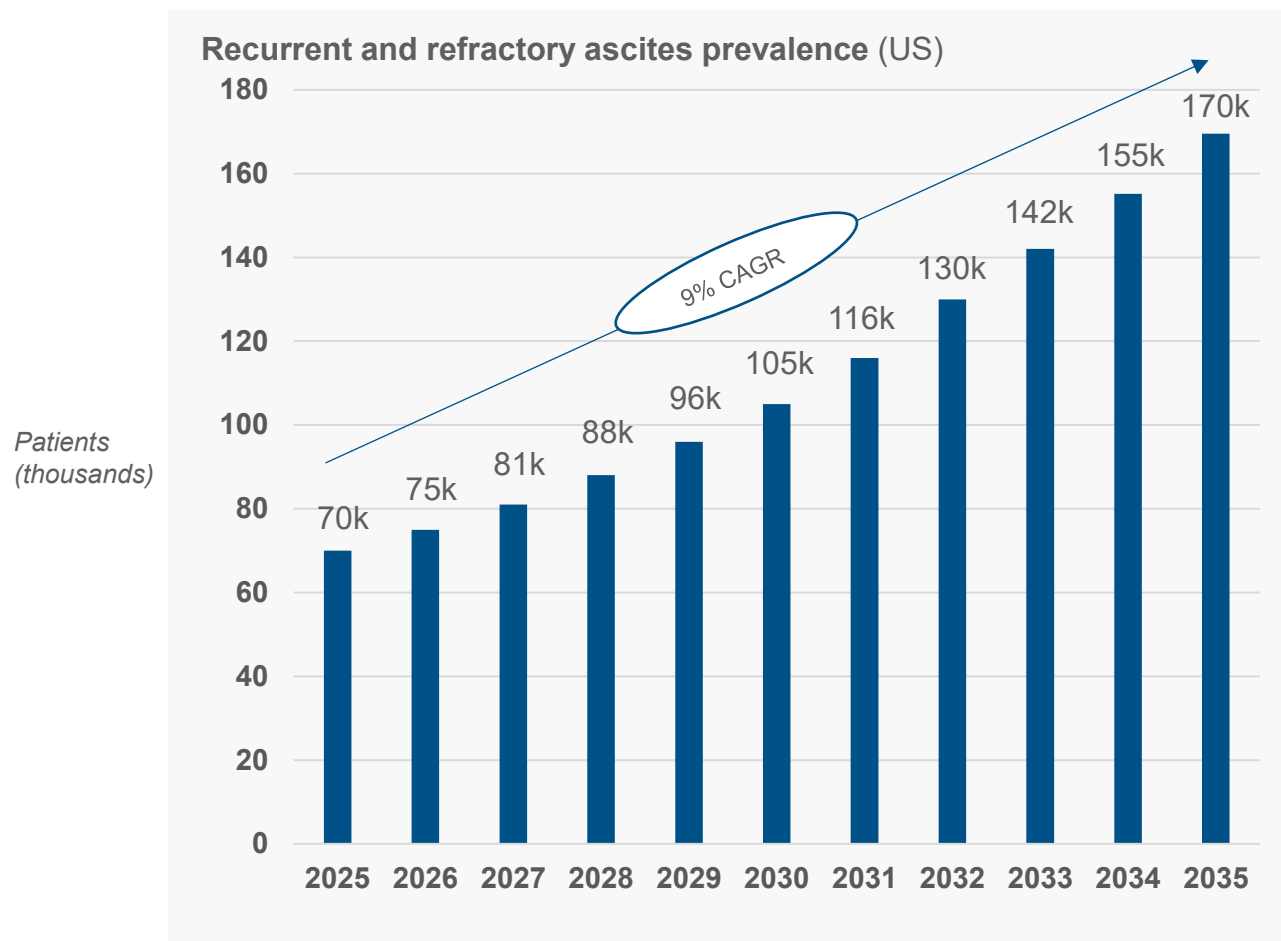
Ascites – key complication of liver cirrhosis

Painful build-up of fluid in the abdomen leading to severe clinical problems and quality of life impact



\$2 billion US market for alfapump and 9% CAGR⁽¹⁾

Forecast to reach over \$5 billion by 2035



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 \$33k per alfapump;

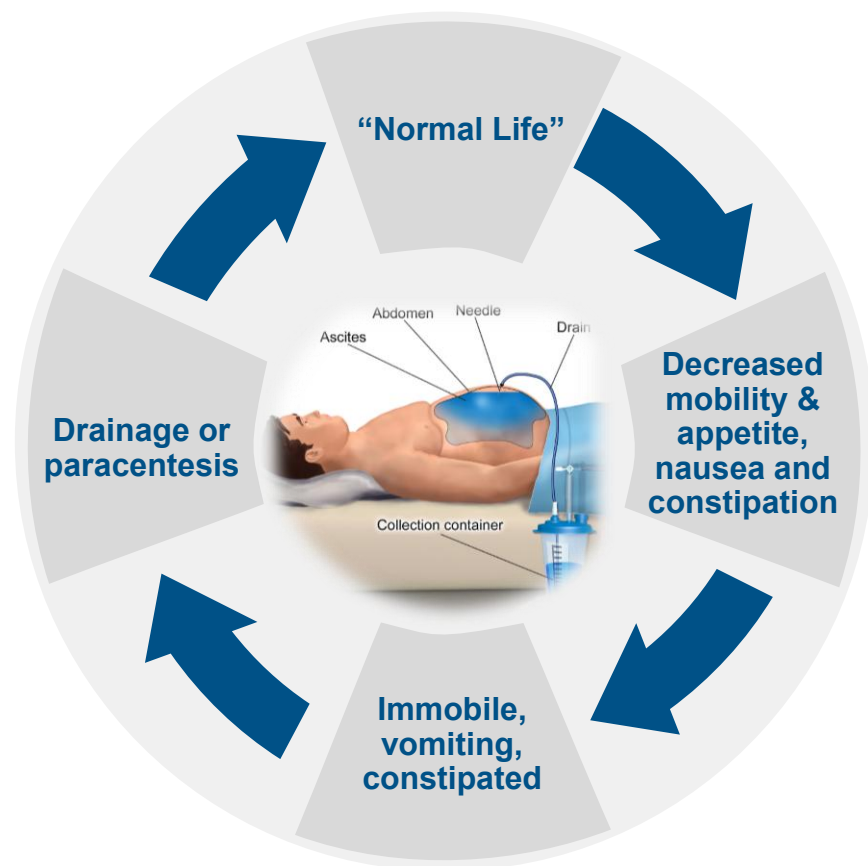


Current treatments have clear clinical limitations

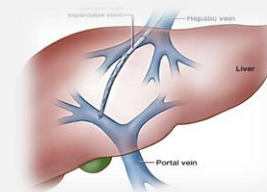
Drainage and TIPS are the main treatment options; alfapump is the only innovation, nothing in development

SoC: Paracentesis (“drainage”)

Painful, burdensome, short-term benefit, QoL impact⁽¹⁾



TIPS (“bypass”)



- Less than 40% of patients eligible (severe complications & contraindications)⁽²⁾
- Limited efficacy in treating ascites⁽³⁾

NASH Drugs



- Low responder rate
- Approved only for early-stage NASH (F2/3), before routine diagnosis
- Not approved for ascites

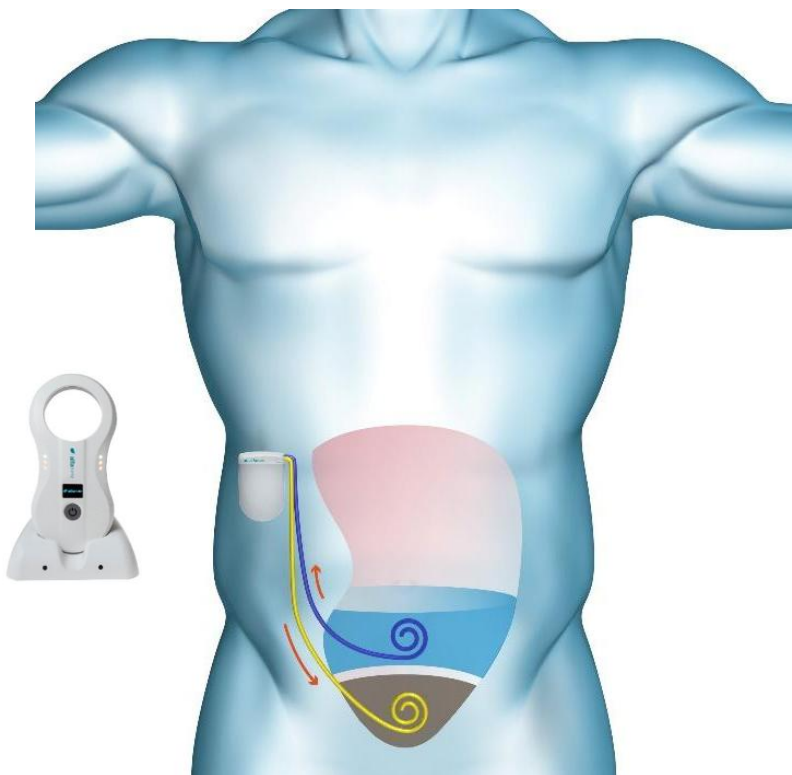
¹ Presentation of Dr. Rajiv Jalan at EASL in 2018, Large Volume Paracentesis (LVP) treatment cycle for refractory ascites

² Wong, F., Management of refractory ascites. Clin Mol Hepatol, 2023. 29(1): p. 16-32

³ Saab et al 2020

Proven step change in therapy, over 1,000 implanted

Automatic pumping of ascites from peritoneal cavity to the bladder where it is urinated away



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



PMA Approval from FDA⁽¹⁾



Breakthrough Device
Designation



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

FDA Approved⁽¹⁾ & US Launch Underway

Broad Indication for Use & No Post-Approval Study Supports Effective Commercialisation

*“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”
(FDA Approved Indication for Use)

Contraindications:

- i) **alfapump**® System is MRI unsafe, and
- ii) Hyperbaric oxygen therapy is contraindicated

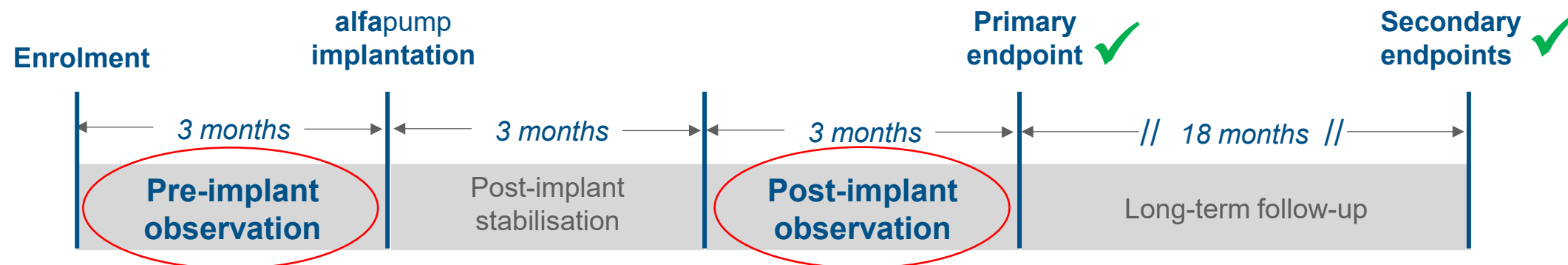
No FDA post-approval study requirements

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



Successful North American pivotal study (POSEIDON)

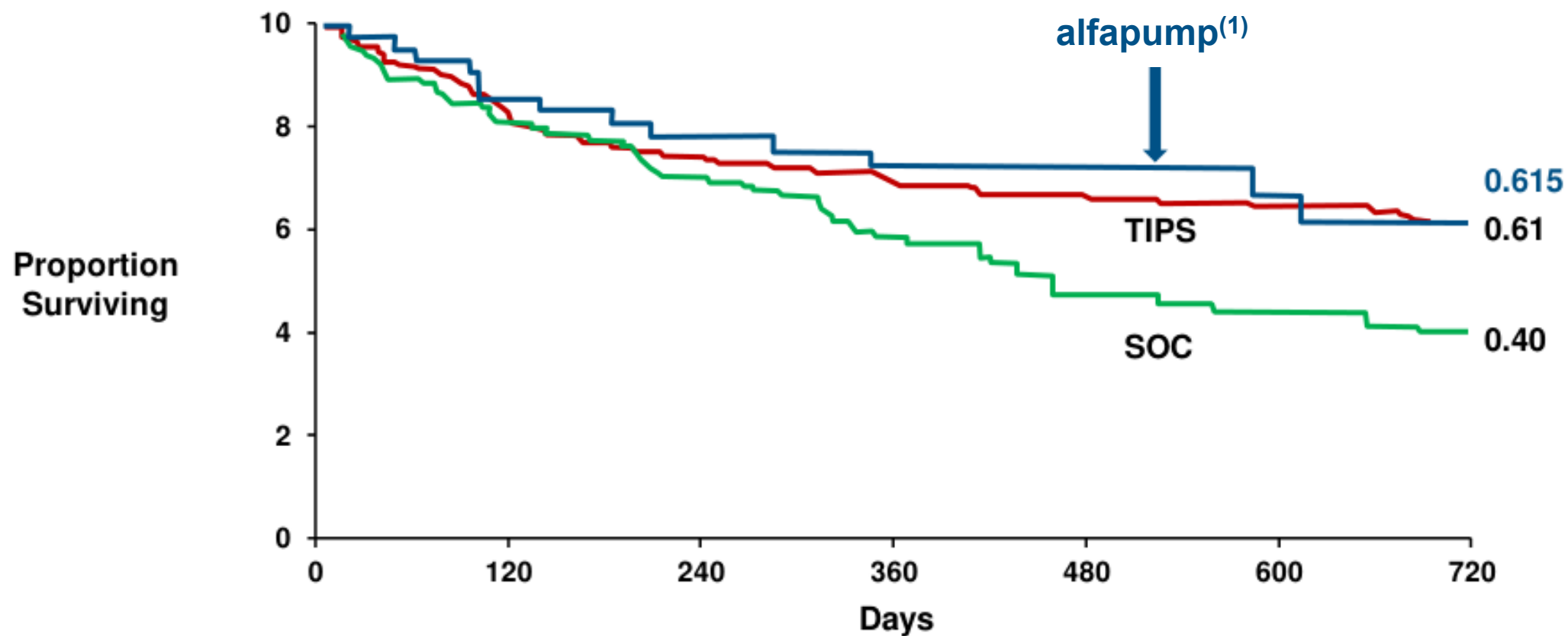
100% median reduction in therapeutic paracentesis plus important improvement in QoL



Impact on Paracentesis	0 – 6 months post-implant	0 – 24 months post-implant
Therapeutic paracentesis / month	100% median reduction	100% median reduction
Freedom from LVP	90% of patients	80% of patients
Quality of Life	6 months post-implant	24 months post-implant
• Change in AscitesQ score (lower is better)	-16.8 points	-26.6 points
• Change in SF-36 Physical Component score (higher is better)	+6.4 points	+9.3 points

POSEIDON: Overall Survival favourable over SoC

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



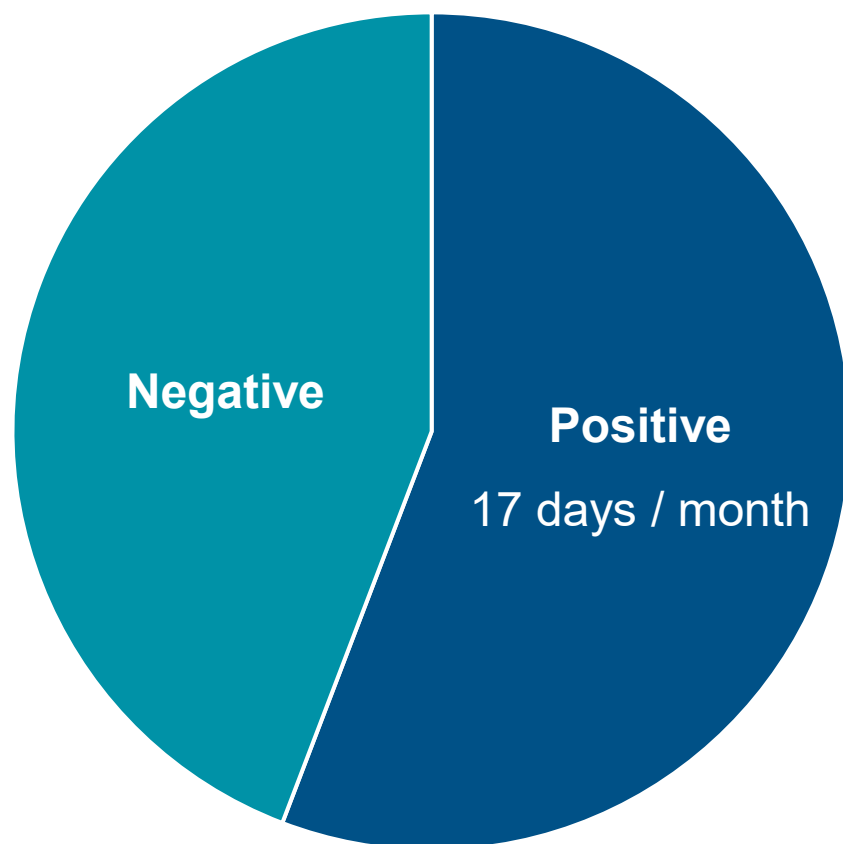
Adapted from Larrue 2023; cross-study comparison

(1): Alfapump data from POSEIDON Pivotal Cohort mITT

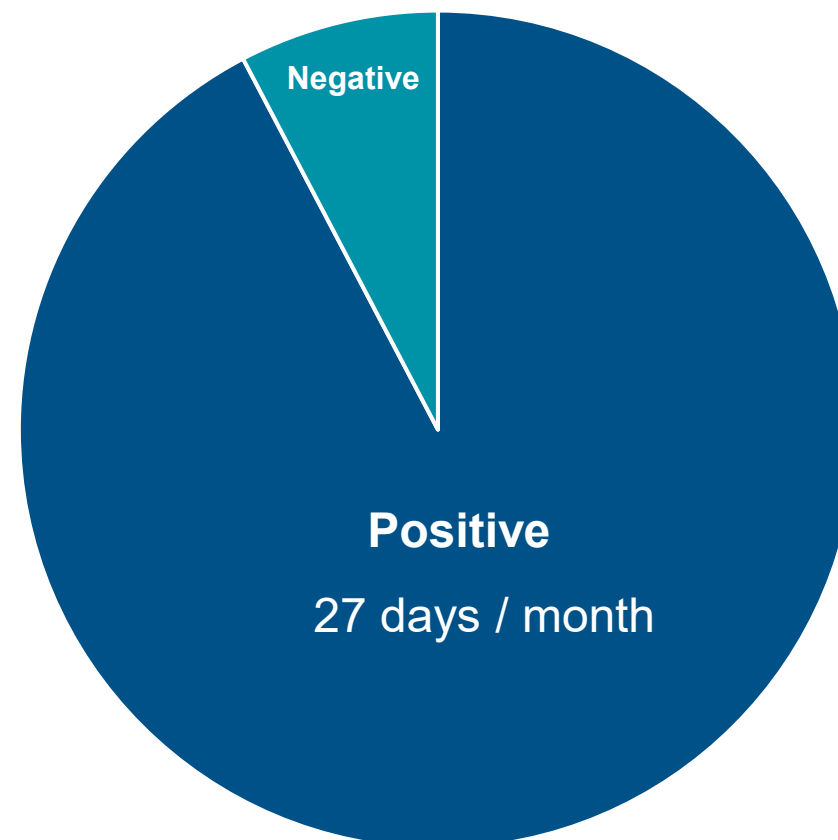
Source: POSEIDON data from POSEIDON clinical study report (data on file at Sequana Medical)

POSEIDON: 10 additional “Good Health Days” / month

What it really means to the patient



Before alfapump (n=32)



With alfapump (n=16)

Smart US commercial strategy underway

Initial Focus on Non-TIPS market, and Transplant Centers

Non-TIPS Market

- Majority of the market
- Clear unmet needs
- Limited competition / low entry barriers
- Platform for expansion into entire market

Transplant Centers

- 90 centers cover 90% of liver transplants
- Small focused commercial team
- Centers experienced with novel therapies
- Expand their range of treatments options

Solid reimbursement supports \$30K+ ASP

NTAP and granted hospital procedure codes support \$33K ASP

Coding & Payment – Strong position from existing DRG codes and NTAP

- Hospital reimbursement codes granted (existing DRG's for **alfapump** procedure*)
- **NTAP additional reimbursement approved** commencing October 1; up to \$21K extra
- Target **alfapump** ASP of **\$30K+** (80% gross margin)
- Physician CPT III codes granted

Coverage – Case-by-Case Based on High Medical Need

- High payer approval rate expected: focus on sophisticated hospitals & high medical need
- 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;

Compelling commercial opportunity

Potential to disrupt the non-TIPS market with little pushback expected

Physicians Are Looking for Better Options for their Non-TIPS patients

- When TIPS is i) not an option, ii) has failed or iii) when patient is concerned about cognitive risk
- Potential to drive additional attractive procedures, and streamline patient care

Mainstream Patients Want High Quality Life Without Constant Concern of Drainage

- Ascites accumulation is a problem between drainages, not just for the procedure
- Ascites accumulation is not always predictable, making planning hard & a constant concern
- Patients often travel long distances for drainage, placing heavy burden on them and caregivers

Non-TIPS market is Majority of Patients & Open for New Entrant

- Paracentesis is not commercially attractive to product or service providers – low margin, burdensome
- Time and effort is not attractive to hospitals or clinicians
- Unplanned visits by patients to ER are disruptive to hospital planning, expensive, and frequent

Positioned for sustainable market leadership

PMA & Breakthrough Device Designation Creates Major Barriers to Entry for Followers

IP: Granted US patent protection through 2036

PMA: (granted to alfapump system)

- Does not create 510(k) pathway; requires ownership of data so our data & studies cannot be referenced by a competitor
- **Significant time, resource & cost barrier for new entrants to conduct new studies**
- Study recruitment for new unapproved product likely to be harder now alfapump has US approval

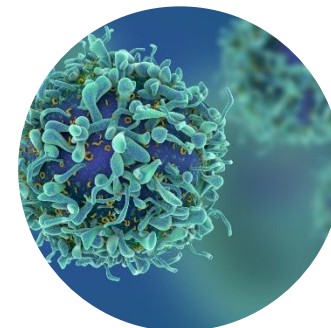
Breakthrough Device Designation: (granted to alfapump in 2019)

- Medical devices that provide for more effective treatment of irreversibly debilitating 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 the alfapump is approved, competitors likely face greater challenge to obtain breakthrough designation and resulting benefits in trial design (time and duration)**

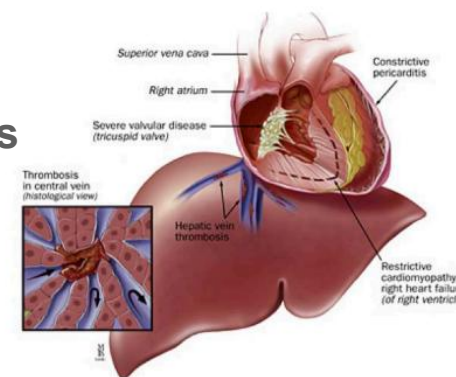
Potential market expansion⁽¹⁾

Opportunities for Additional Indications in Other Significant Markets

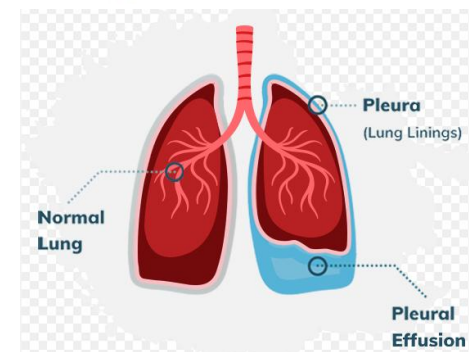
Malignant Ascites: Fluid in peritoneal cavity due to cancer



Cardiac Ascites: Very similar presentation to liver cirrhosis



Pleural Effusion: Fluid in the chest cavity



1: Not included in current US indication for use for alfapump system

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

Highly experienced leadership team

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

Senior Leadership Team:



Ian Crosbie
Chief Executive Officer



Kirsten Van Bockstaele
Chief Financial Officer



Martijn Blom
Chief Commercial Officer



Gijs Klarenbeek
Chief Medical Officer



Dragomir Lakic
VP Manufacturing



Timur Resch
Global VP QM/QA/RA



Mark Singer
Head of US Commercial



Andreas Wirth
VP Engineering

Board of Directors:



Pierre Chauvineau
Chairman
Prev. Cameron Health
(acquired by Boston Scientific)



Alex Clyde
Prev. Corp. SVP Global
Health Economics, Policy &
Reimbursement, Medtronic



Wim Ottevaere
Prev. Ablynx CFO
(acquired by Sanofi)



Jackie Fielding
Prev. VP UK / Ireland,
Medtronic



Rudy Dekeyser
EQT, head of Health
Economic Funds



Ids van der Weij
Partners in Equity,
Managing Partner



Ian Crosbie
Chief Executive Officer



FDA Approved Device Transforming Large Neglected Market

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R&D Pipeline: DSR®

Clinical Proof-of-Concept Drug Program

Targeting Key Unmet Needs in Heart Failure



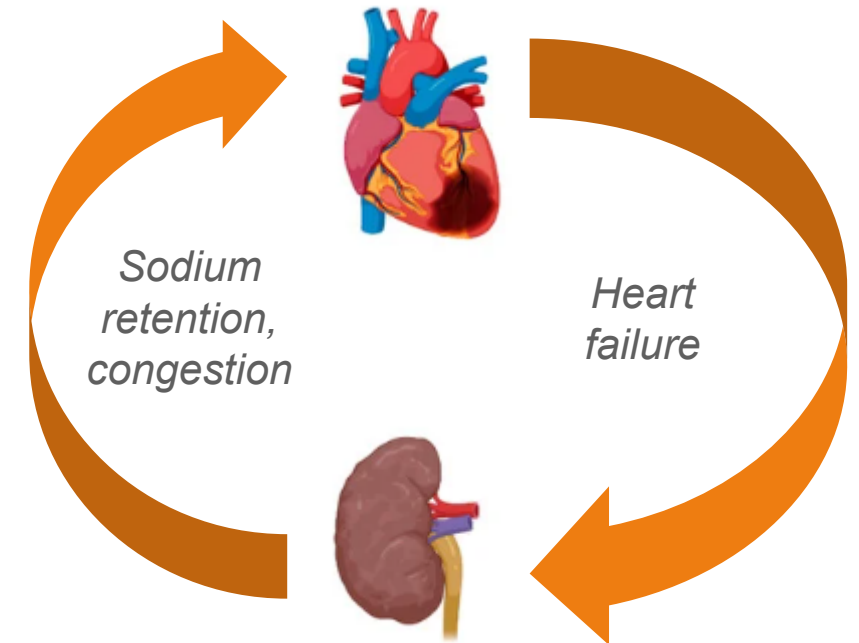
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Cardiorenal Syndrome – key clinical challenge in HF

Unmet clinical need to tackle congestion for long enough, without damaging effect of loop diuretics

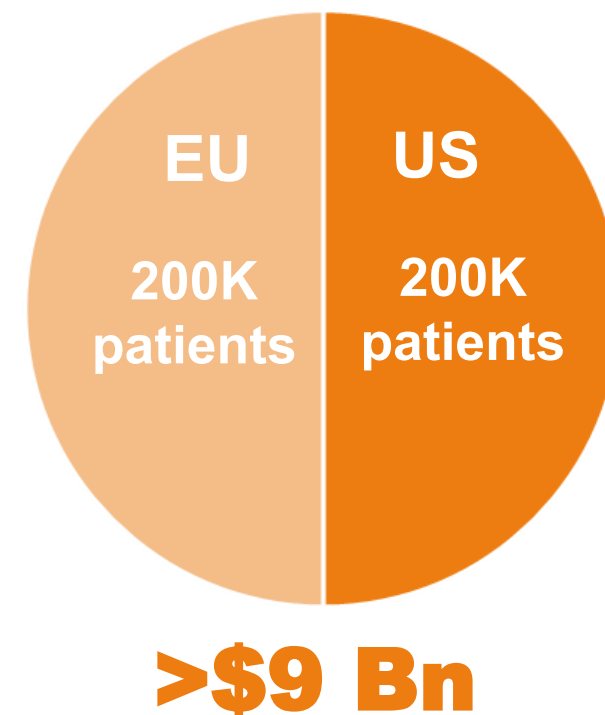
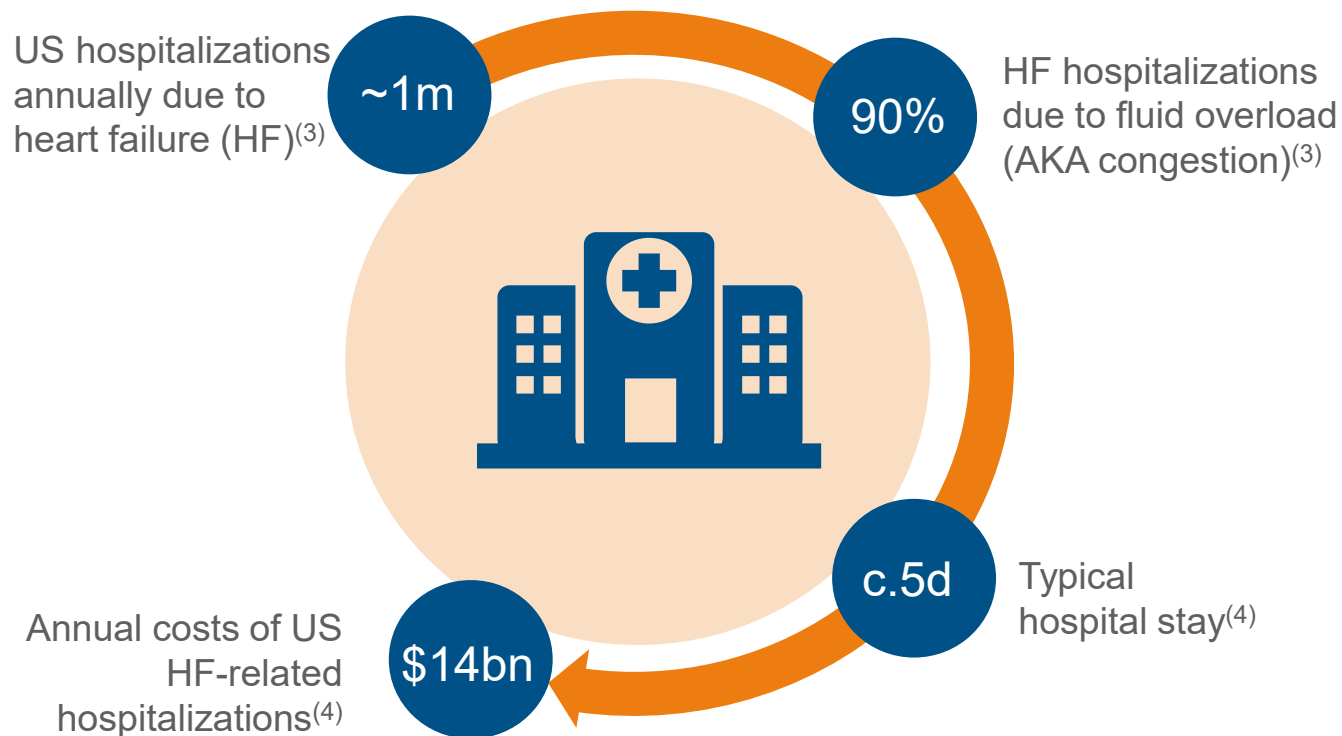
- Heart and kidneys are a closely linked, dependent system
- Poor cardiac output leads to retention of sodium by kidneys, increasing fluid volume to maintain homeostasis
- Additional load exacerbates heart failure “doom loop”
- Loop diuretics are mainstay of decongestion therapy BUT exacerbate many of the core mechanisms thought to underly CRS, worsening diuretic-resistance and CRS – including direct damage to kidney
- Objective is to develop potent therapy to reduce congestion, relieve load on heart and allow kidney recovery





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⁾**

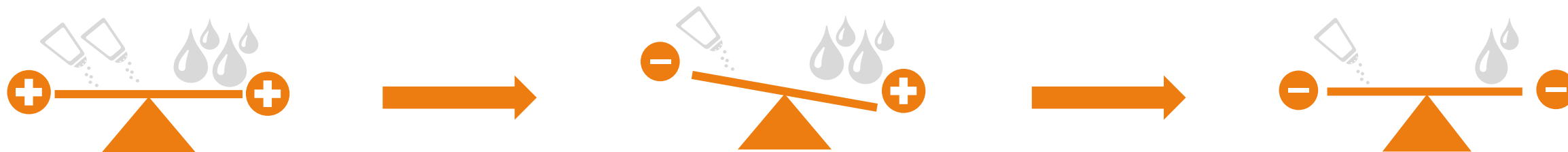
24% re-admission rate at 30 days⁽²⁾

DSR addressable market
in US⁽⁵⁾

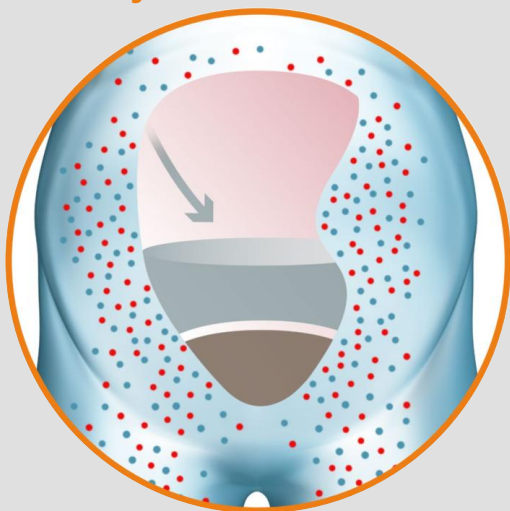


DSR targets key driver of congestion – Sodium overload

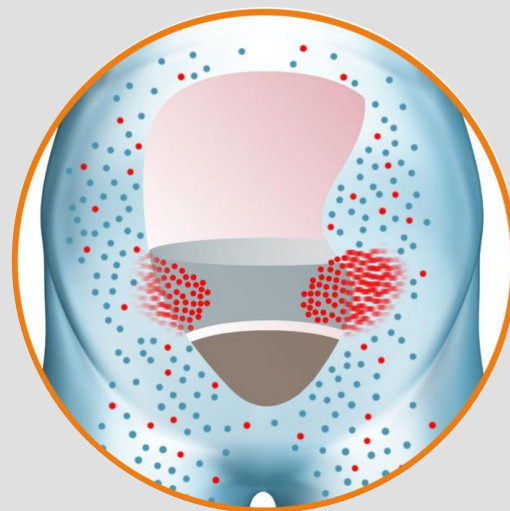
Validated by RED DESERT, SAHARA & MOJAVE clinical studies, with peer-reviewed publication



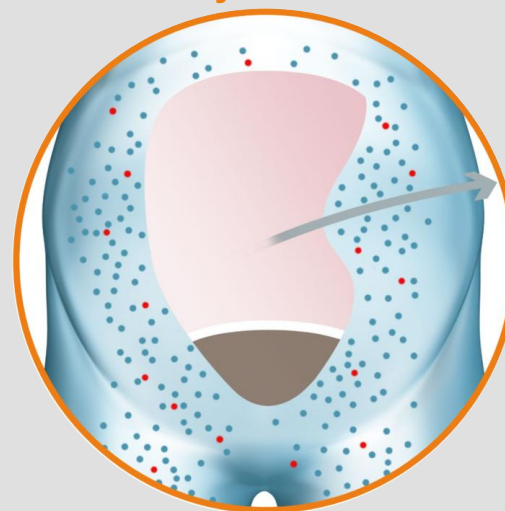
1 Sodium-free DSR product administered to peritoneal cavity



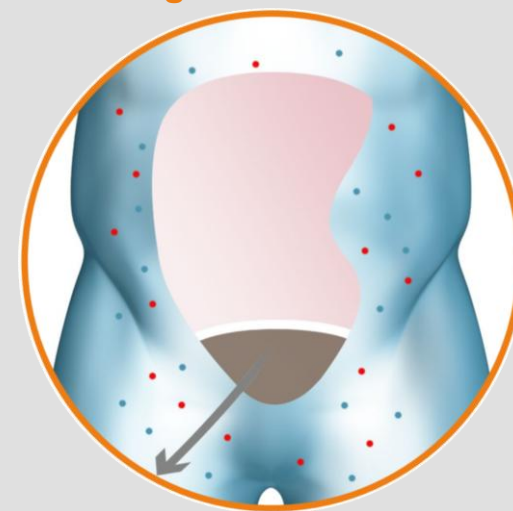
2 Sodium diffuses from body into DSR product



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, Japan & China*



Clinical proof of concept in cardiorenal syndrome

Strong results from RED DESERT (n = 8) and SAHARA (n = 10) clinical studies – published in EJHF

- ✓ Safe, rapid and effective elimination of excess fluid and maintenance of fluid balance
- ✓ Restores normal response of kidneys to diuretics
- ✓ Long lasting reduction in loop diuretic needs
- ✓ Improvement in kidney function

Delivering improved clinical outcomes

- ✓ No congestion-related 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

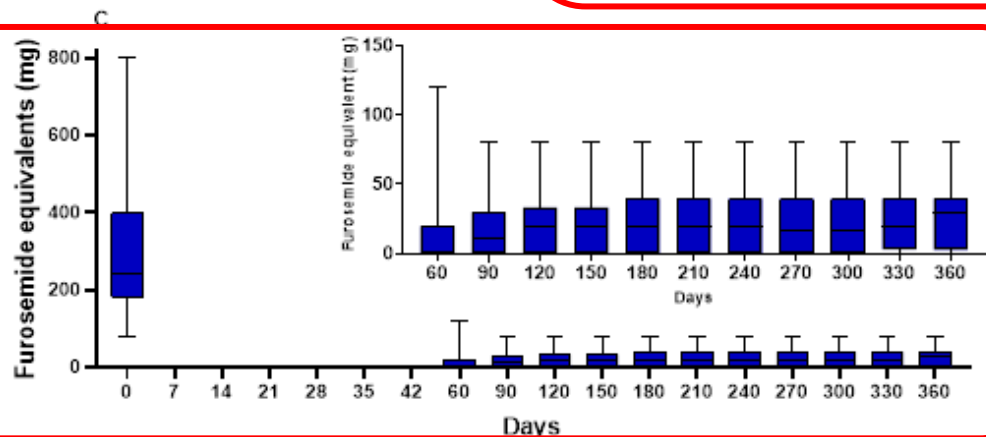
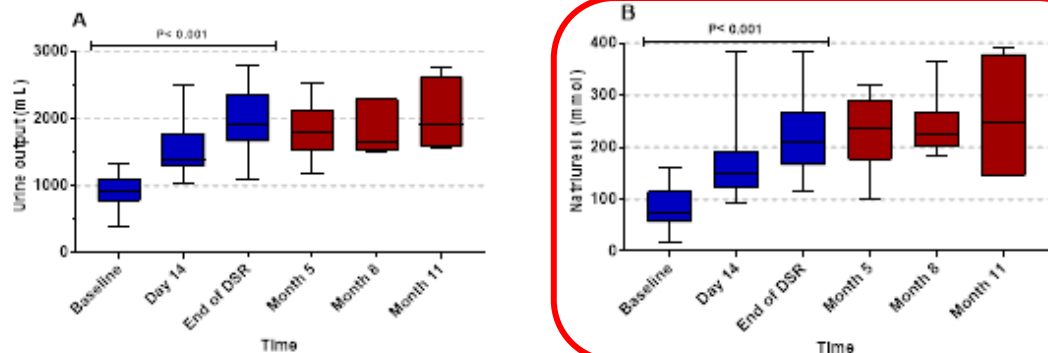
NYHA: New York Heart Association classification (data collected outside study protocols of RED DESERT and SAHARA)



Breakthrough in kidney response and LD requirement

Published in European Journal of Heart Failure, May 2024

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)



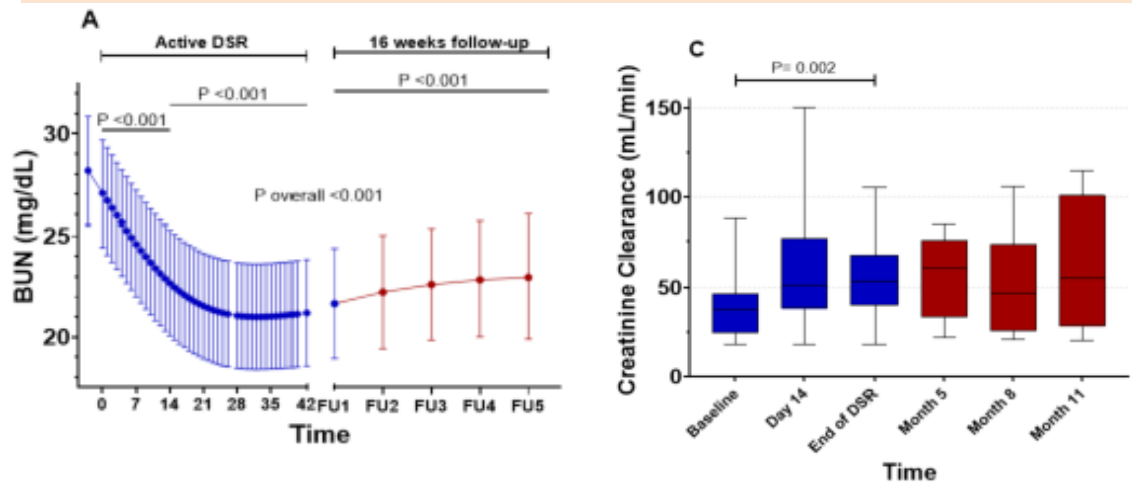
European Journal of Heart Failure (2024)
doi:10.1002/ehf.3196

RESEARCH ARTICLE

Serial direct sodium removal in patients with heart failure and diuretic resistance

Veena S. Rao^{1*}, Juan B. Ivey-Miranda^{1,2}, Zachary L. Cox^{3,4}, Julieta Moreno-Villagomez^{1,5}, Daniela Ramos-Mastache⁵, Daniel Neville¹, Natasha Balkcom¹, Jennifer L. Asher⁶, Lavanya Bellumkonda¹, Tamar Bigvava⁷, Tamaz Shaburishvili^{7*}, Jozef Bartunek⁸, F. Perry Wilson^{9,10}, Fredrick Finkelstein⁹, Christopher Maulion¹, Jeffrey M. Turner⁹, and Jeffrey M. Testani^{1*}

Blood urea nitrogen (BUN) and creatinine clearance

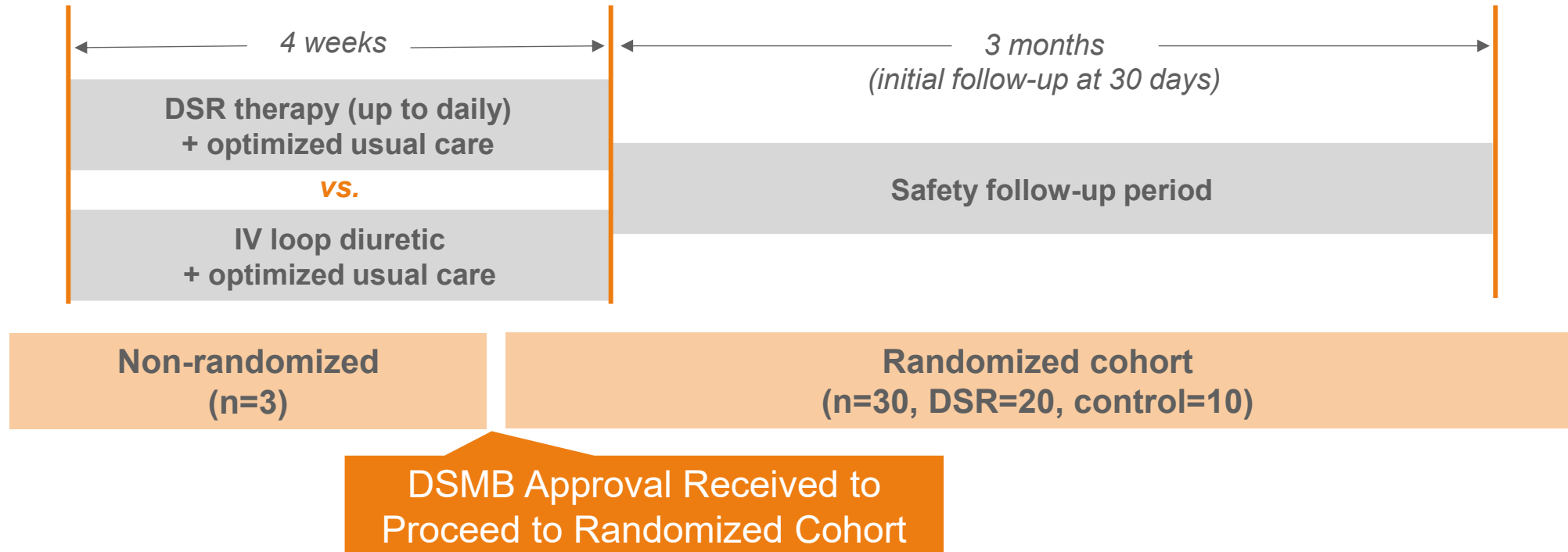


Blue bars indicate data from both RED DESERT and SAHARA, and red bars indicate data only from SAHARA.



MOJAVE: Phase 1/2a randomized controlled US study

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



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