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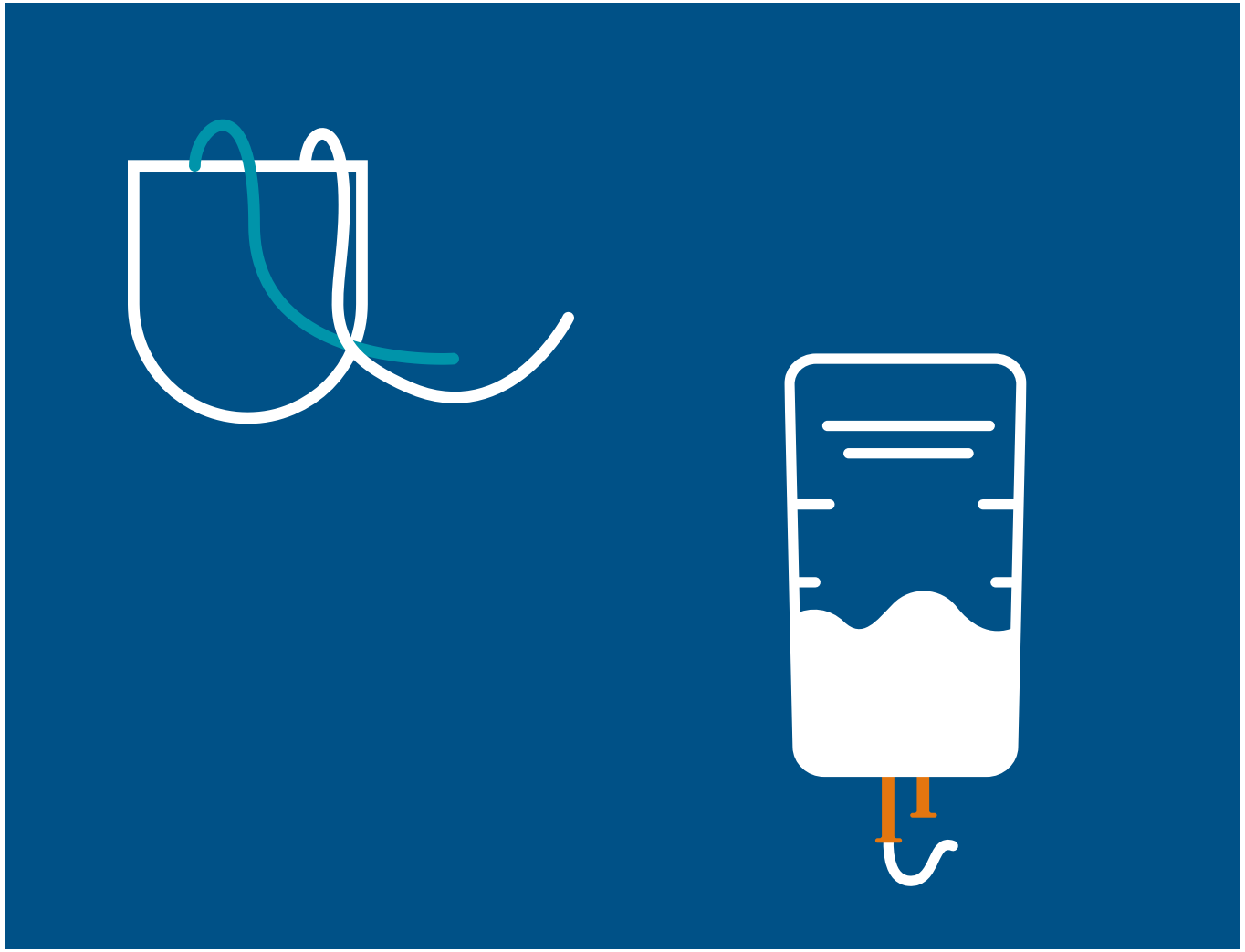

Pioneers in the treatment of fluid overload

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

January 2026

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.

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:

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

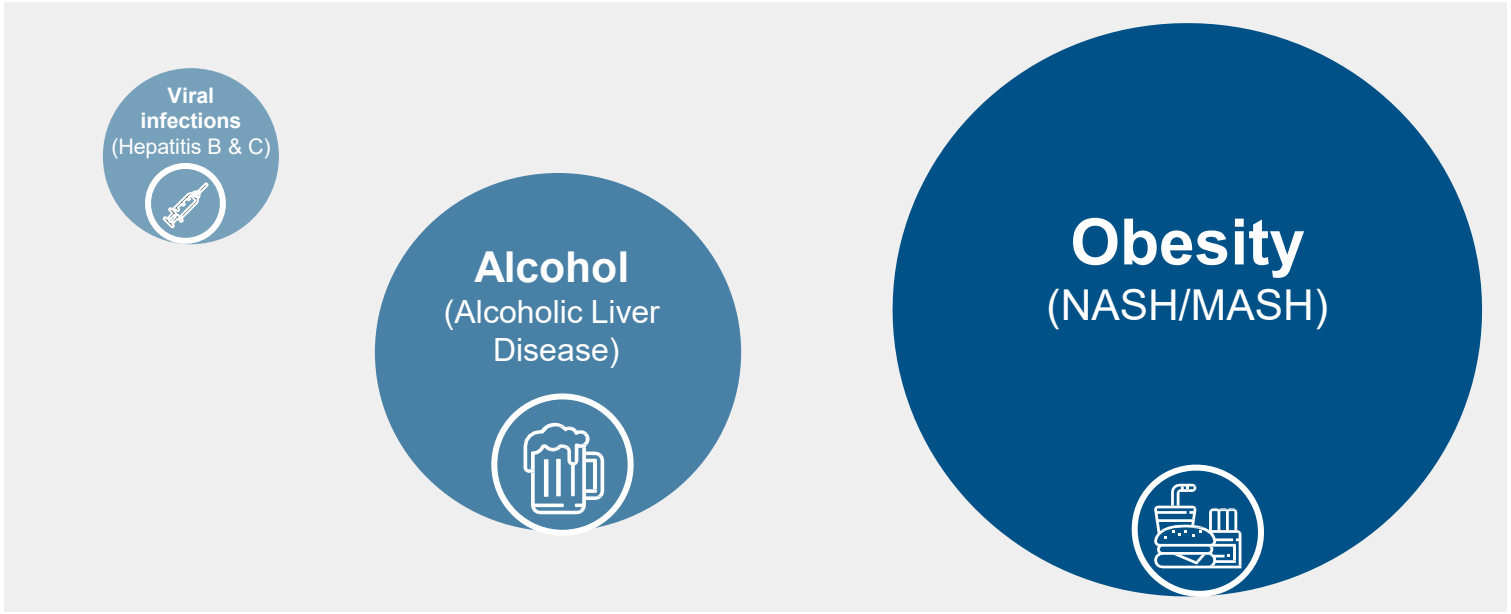
alfapump: FDA Approved, Transforming Neglected US Market

- $2 Billion Market Growing at 9% CAGR
- Differentiated Solution - Addressing Unmet Clinical Need
- Strong Clinical Evidence; FDA Approval and Breakthrough Designation
- Solid Reimbursement Position Supports $30K+ ASP
- Smart Direct Commercialisation Strategy
- Focused Strategy Supports Forecast Breakeven Below €55MM & High Profitability at €100MM

- Significant Upside Potential From DSR Pipeline Program for Diuretic-Resistant Heart Failure

Ascites – key complication of liver cirrhosis

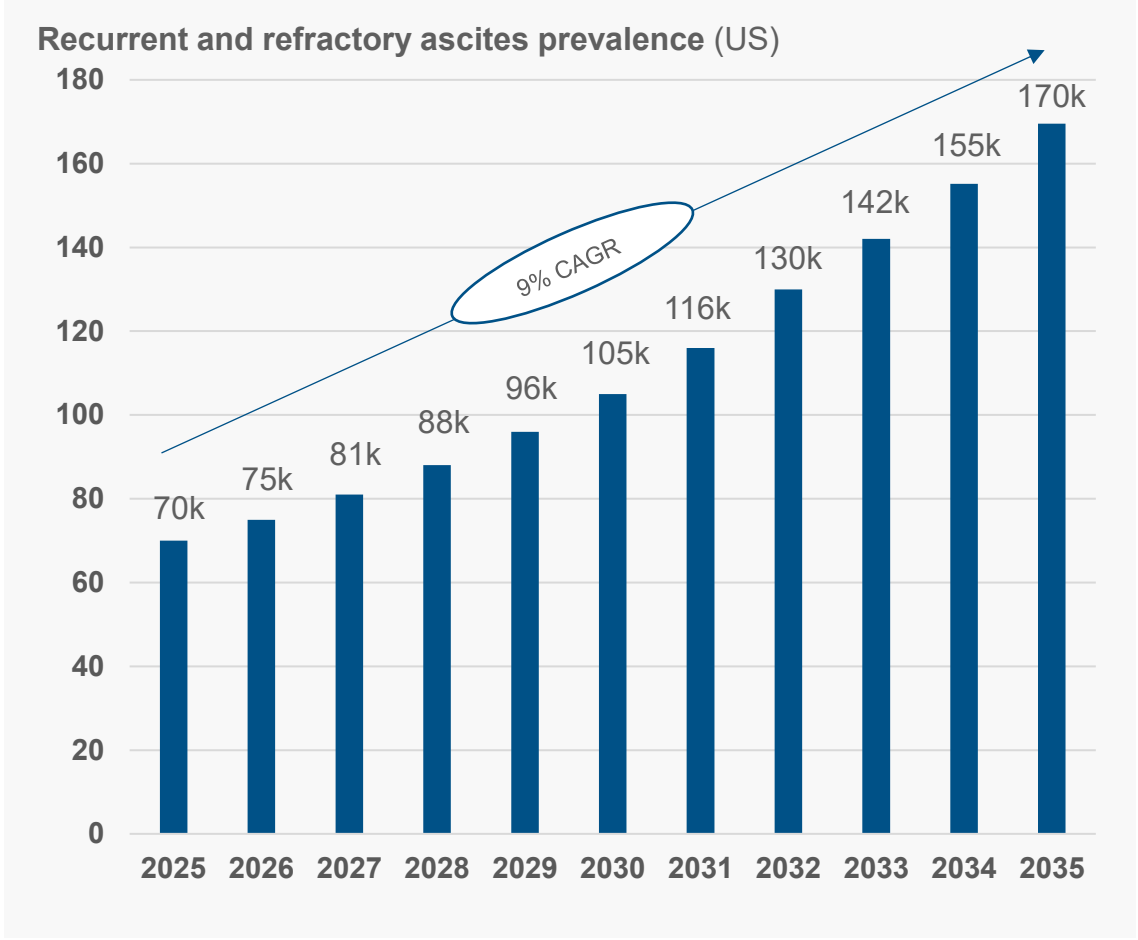
Painful build-up of fluid in the abdomen leading to severe clinical problems and quality of life impact



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

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

Forecast to reach over $5 billion by 2035



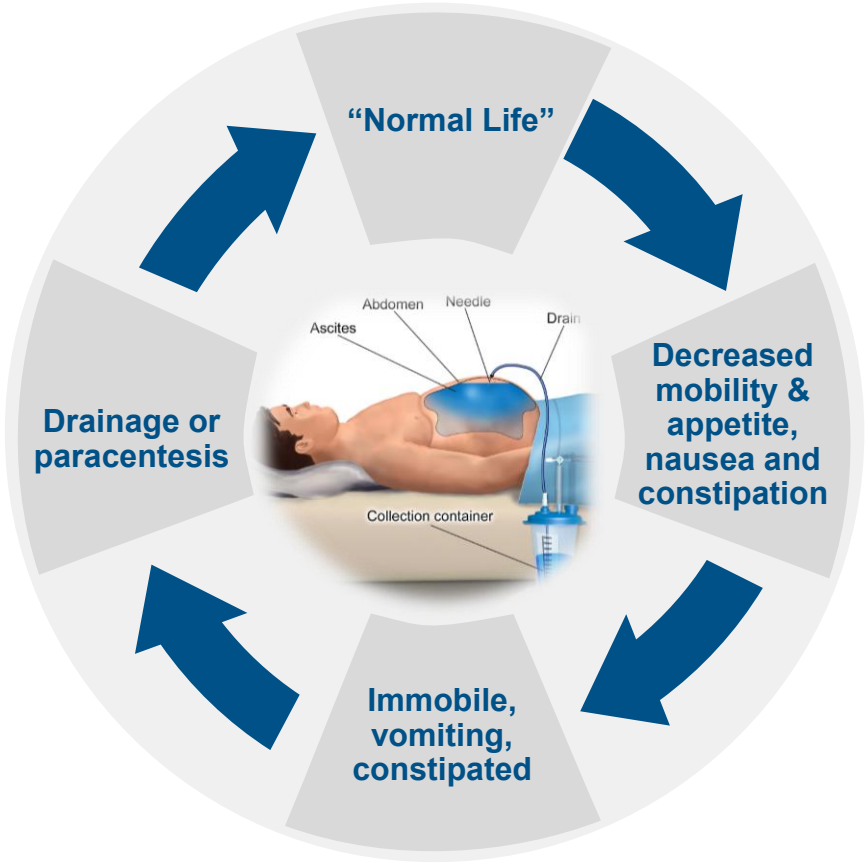
[1] Based on US market assessment conducted by highly experienced international consulting group, estimating 130,000 patients with recurrent or refractory ascites in US by 2032 and based on proposed price of $33k per alfapump;

Current treatments have clear clinical limitations

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

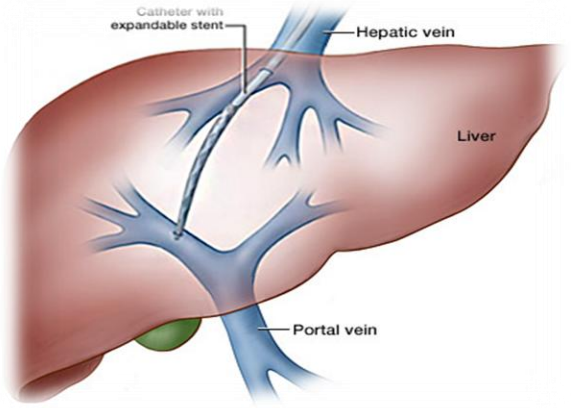
SoC: Paracentesis ("drainage")

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



TIPS ("bypass")

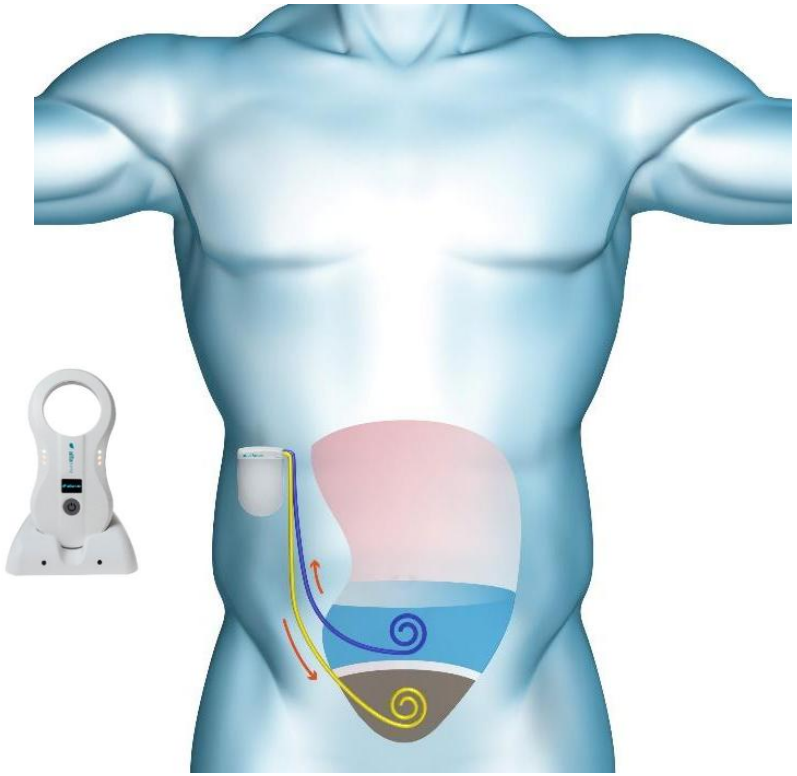
- Less than 40% of patients are eligible due to severe complications and contraindications [2]
- Patient concerns over cognitive impacts
- Limited efficacy in treating ascites [3]



[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*
SoC: *Standard of Care*

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)

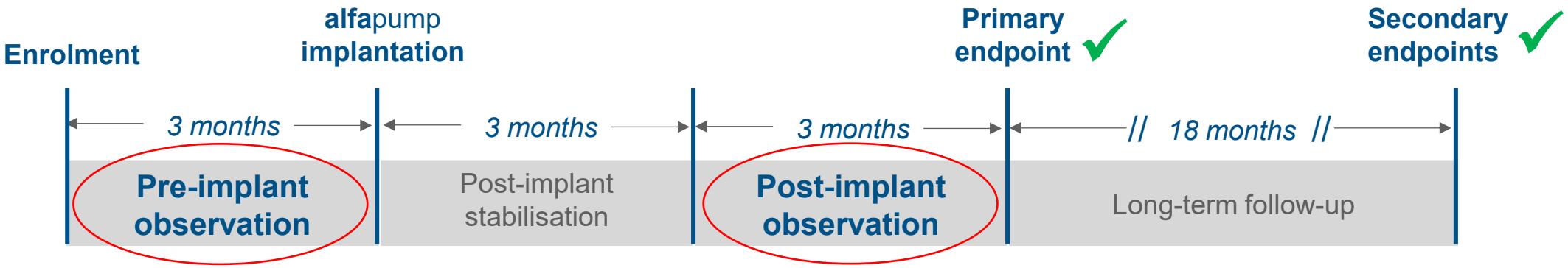
Breakthrough Device Designation

EASL The Home of Hepatology

(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

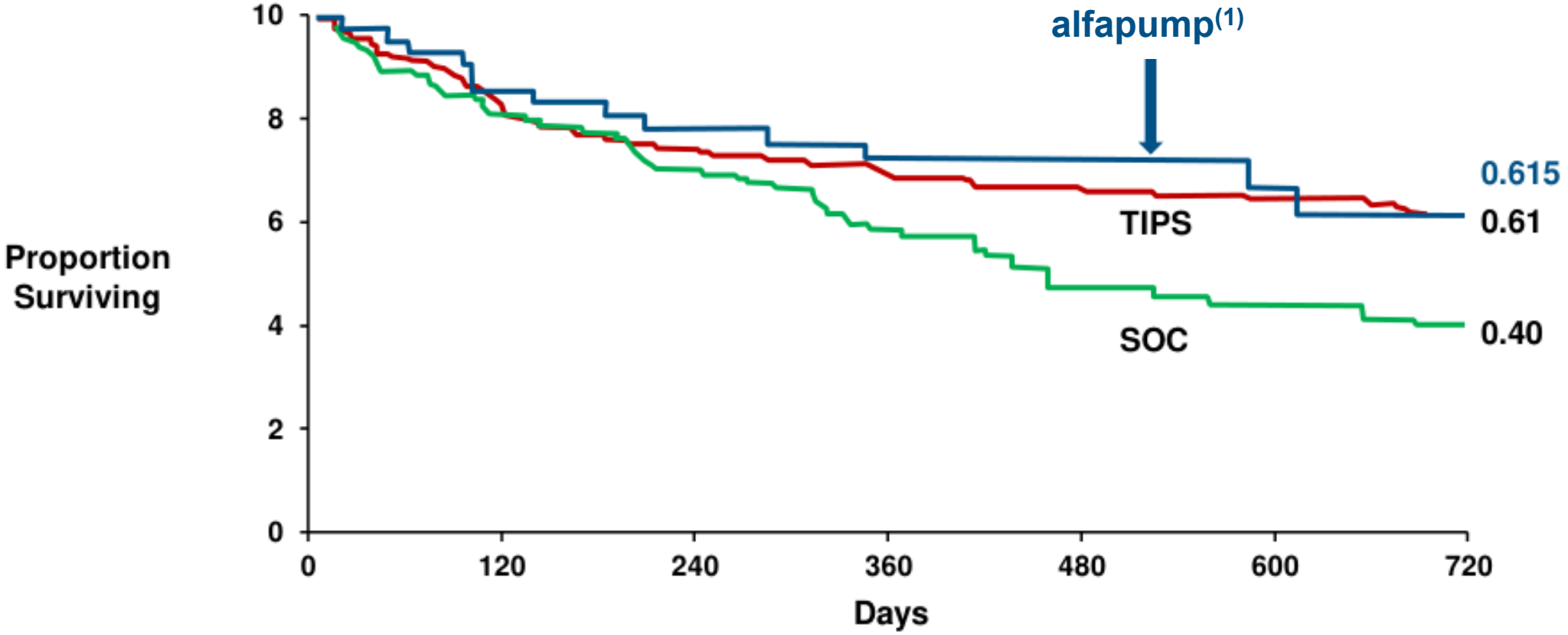


Impact on Paracentesis	0 – 6 months post-implant	0 – 24 months post-implant
Therapeutic paracentesis / month	100% median reduction	100% median reduction
Freedom from LVP	90% of patients	80% of patients
Quality of Life	**6 months post-implant**	**24 months post-implant**
• Change in AscitesQ score (lower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

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

(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)

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

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

*"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"

(FDA Approved Indication for Use)

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 **alfa**pump procedure*)
- **NTAP additional reimbursement approved** commencing October 1; up to $21K extra
- Target **alfa**pump ASP of **$30K+** (75% 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;*

Focused Strategy Supports Attractive Financial Model

Targeting breakeven below €55MM, and high profitability at €100MM

- **Anticipated breakeven at below €55MM**
  - 2,000 pumps
- **Driven by focused strategy & no commercial incumbent**
  - No significant investment in further trials planned
  - Cost-effective product development
  - Focused commercial investment
  - No established commercial player pushing back
- **Targeting high profitability at €100MM**
  - 3,600 pumps

		Monthly Implants / Center			
		2X	**4X**	**6X**	**8X**
No. of Centers	**10**	€7	€14	€20	€27
	20	€14	€27	€41	**€54**
	30	€20	€41	€61	€81
	40	€27	**€54**	€81	€108
	50	€34	€68	€102	€135
	60	€41	€81	€122	€162
	70	€47	€95	€142	€190
	80	**€54**	€108	€162	€217
	90	€61	€122	€183	€244
	100	€68	€135	€203	€271

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

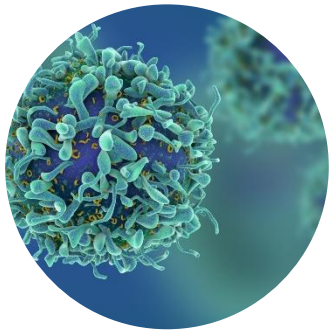
Breakthrough Device Designation: (granted to alfapump in 2019)

- 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)**

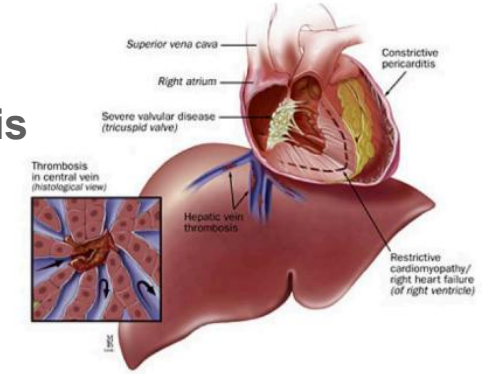
Potential market expansion(1)

Opportunities for Additional Indications in Other Significant Markets

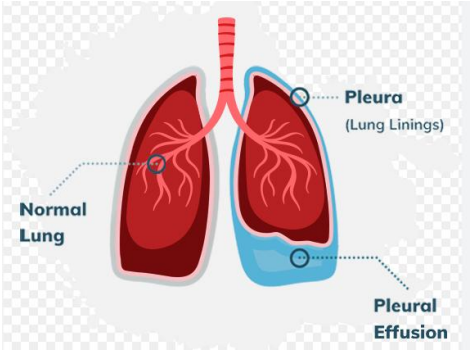
Malignant Ascites: Fluid in peritoneal cavity due to cancer



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

alfapump: FDA Approved, Transforming Neglected US Market

- **$2 Billion Market Growing at 9%**
  - Long term growth driven by obesity and demand for better treatments
  - Obesity is changing perceptions of cirrhosis amongst payors, providers, clinicians and patients
- **Differentiated Solution Addressing 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
- **Focused Strategy Supports Forecast Breakeven Below €55MM & High Profitability at €100MM**
- **Significant Upside Potential from DSR Pipeline Program for Diuretic-Resistant Heart Failure**

R&D Pipeline: DSR®

Clinical Proof-of-Concept Drug Program

Targeting Key Unmet Needs in Heart Failure

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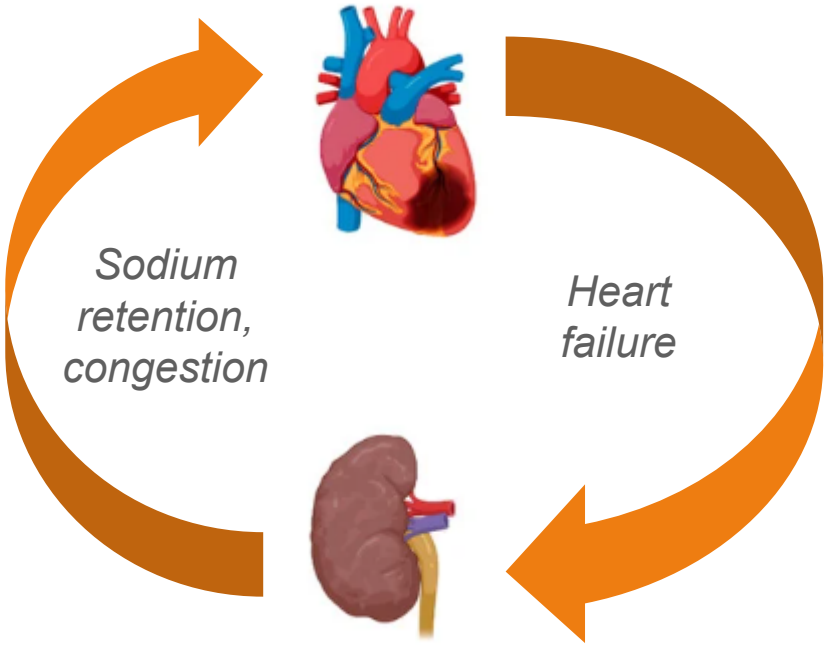
Cardiorenal Syndrome – key clinical challenge in HF

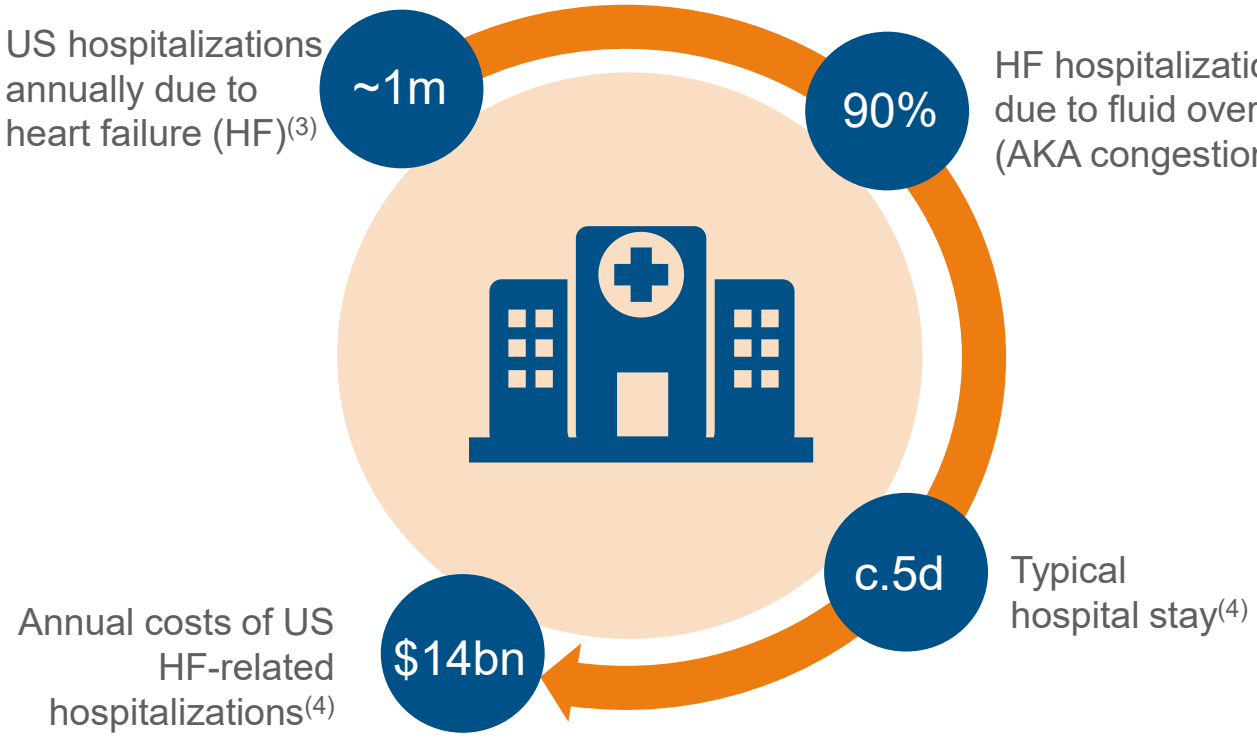
Unmet clinical need to tackle congestion for long enough, without damaging effect of loop diuretics

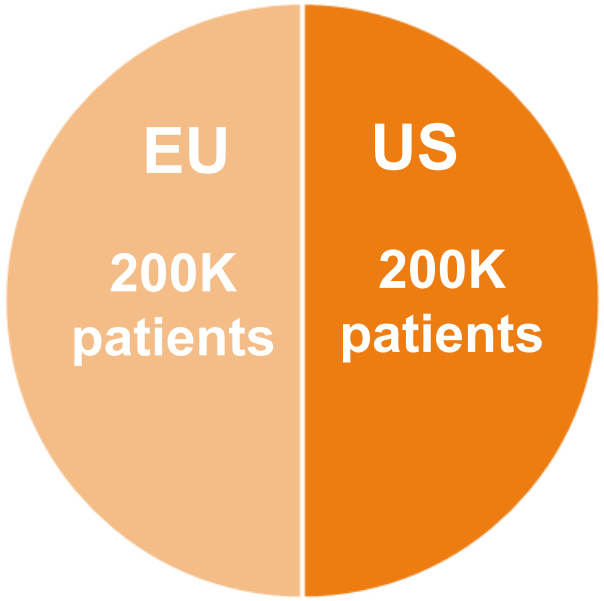
- Heart and kidneys are a closely linked, dependent system
- Poor cardiac output leads to retention of sodium by kidneys, increasing fluid volume to maintain homeostasis
- Additional load exacerbates heart failure "doom loop"
- Loop diuretics are mainstay of decongestion therapy BUT exacerbate many of 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





>$9 Bn

DSR addressable market in **US**(5)

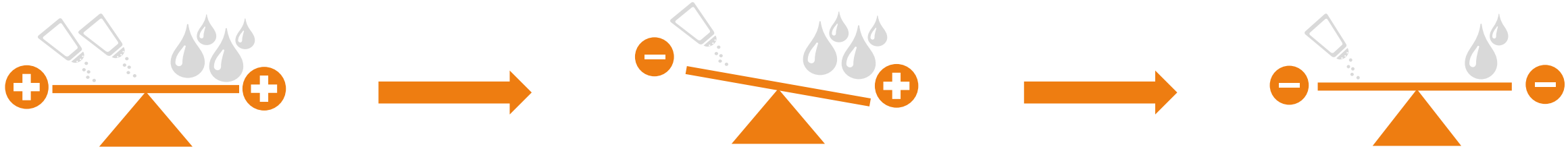
40% of heart failure patients on IV loop diuretics have a poor response(1)

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

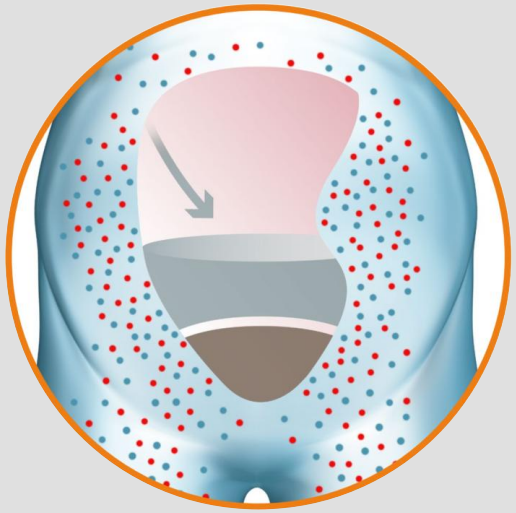
(1): Testani, Circ Heart Failure, 2014 & 2016; (2): Ross et al. (2010); (3): Costanzo et al., J. Am. Coll., 2007; (4): Urbich et al. (2020); (5) based on 3 hospitalisations / year at $15k / admission

DSR targets key driver of congestion – Sodium overload

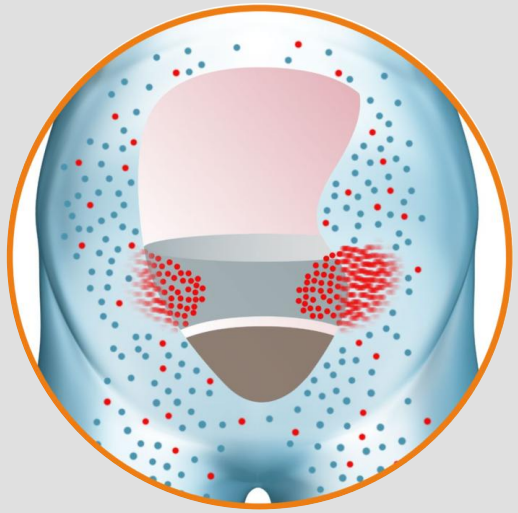
Validated by RED DESERT, SAHARA & MOJAVE clinical studies, with peer-reviewed publication



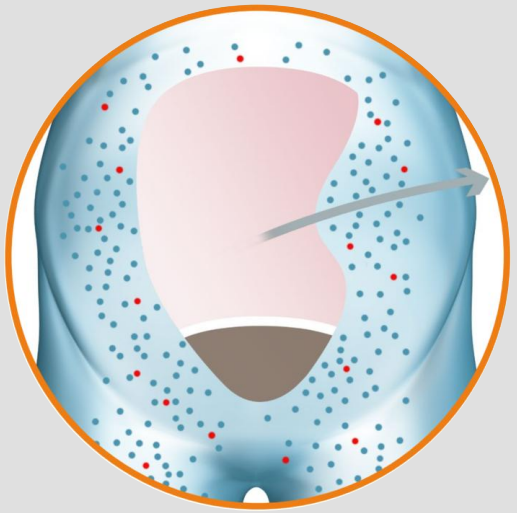
1 Sodium-free DSR product administered to peritoneal cavity



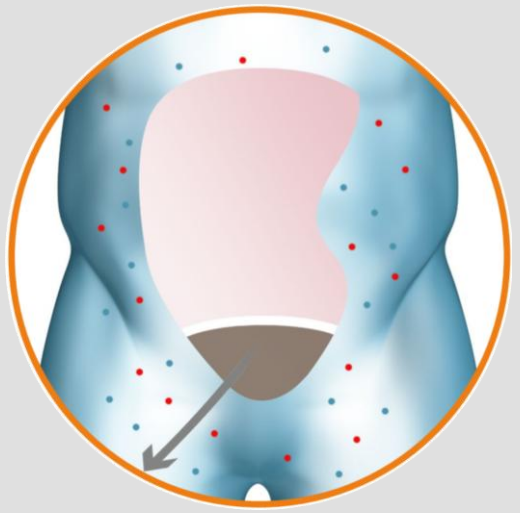
2 Sodium diffuses from body into DSR product



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 sydrome

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."

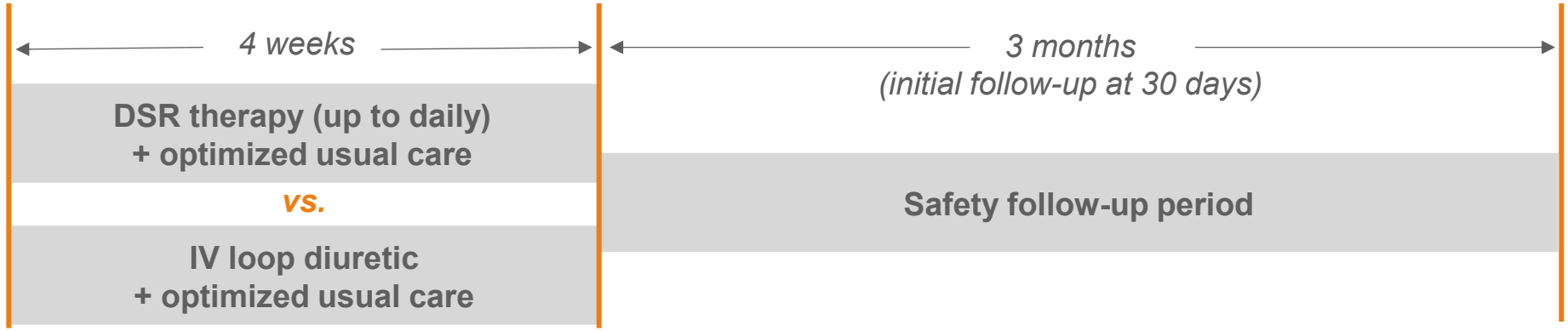
Dr. Testani, Yale

** Based on Seattle Heart Failure Model*

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

Phase 1/2a randomized controlled US study Underway

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