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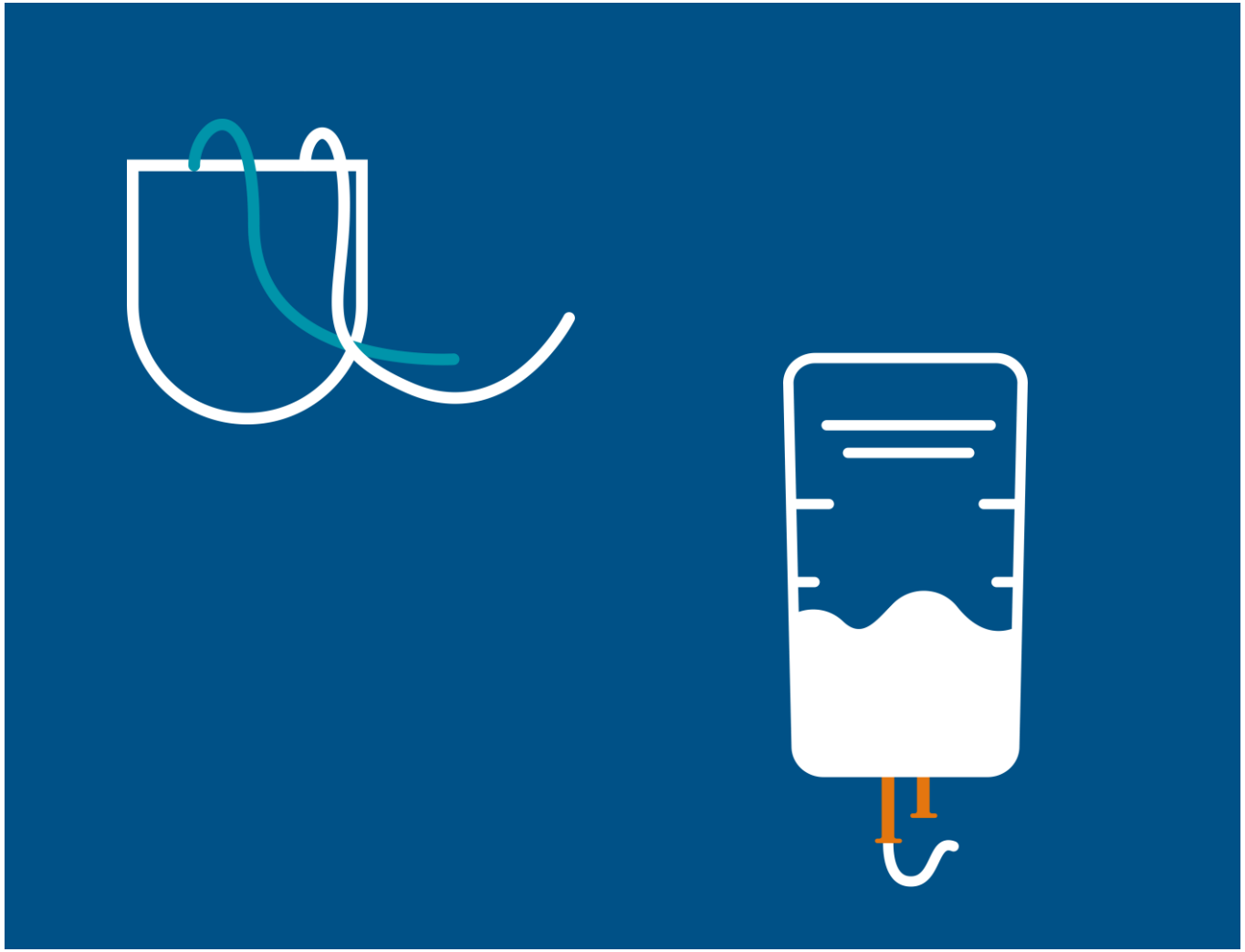

Pioneers in the treatment of fluid overload

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

June 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.

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.

Focus on alfapump commercialisation in the US

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

Primary Focus – alfapump US commercialisation

- US FDA approved device for recurrent & refractory ascites due to liver cirrhosis
- Potential to transform underserved $2 billion US market with forecast 9% CAGR
- PMA approval and FDA Breakthrough Device Designation
- US commercial launch planned for Q3 25 through speciality salesforce targeting US liver transplant centers

R&D Pipeline – DSR drug development program

- Targeting key unmet clinical needs in heart failure
- Cardiorenal syndrome & diuretic resistance market over $9 billion in US alone
- Clinical proof of concept published in *European Journal of Heart Failure*
- Intention to out-licence following completion of US phase I/IIa MOJAVE study
- Within 100% owned subsidiary (“DSR Co”); development to be funded through private financing of DSR Co

alfapump®

FDA Approved Breakthrough Device

Targeting Underserved $2 billion US Market

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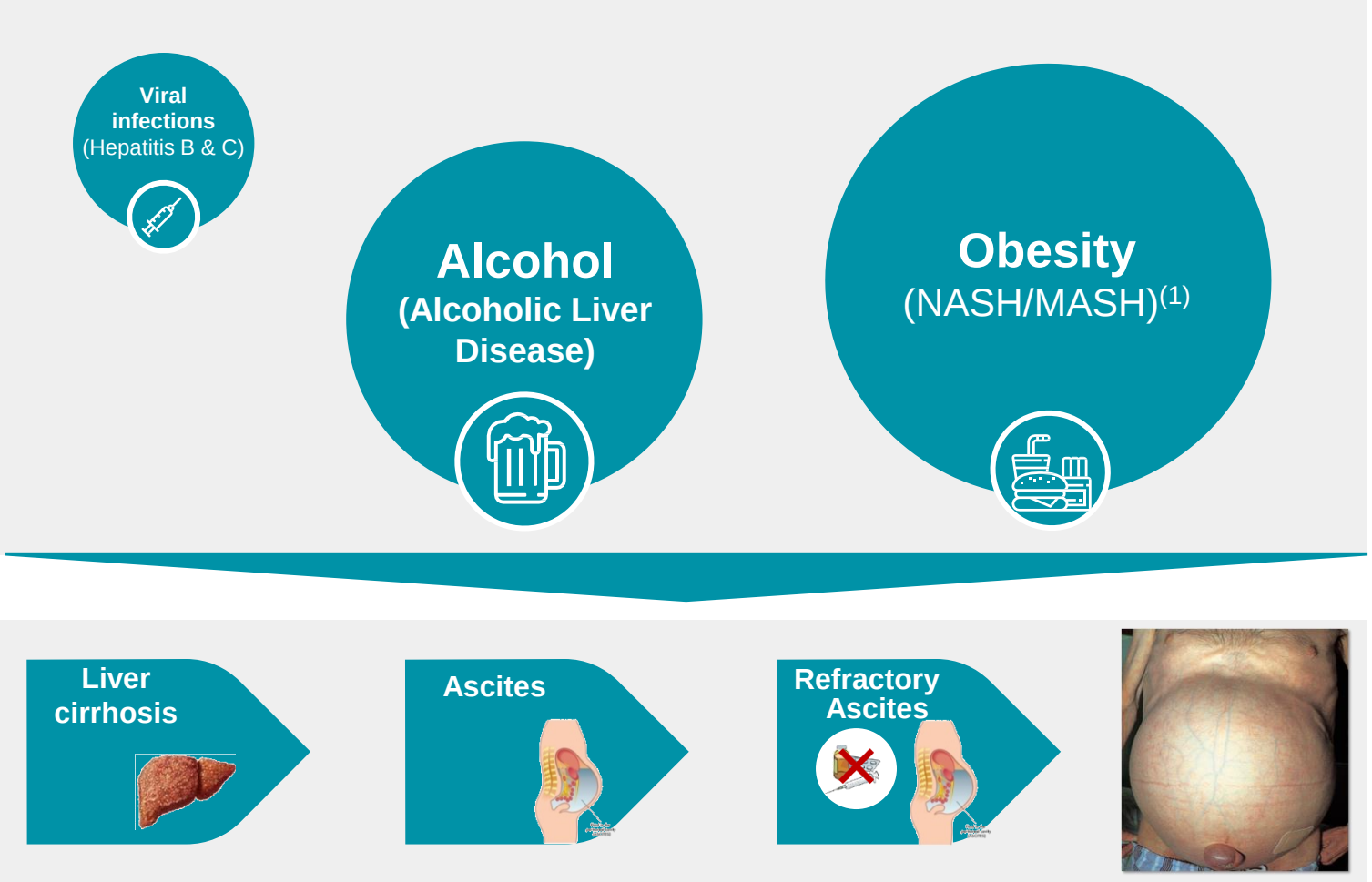
Refractory ascites – key complication of liver cirrhosis

MASH / NASH is driving strong growth in number of liver cirrhosis patients, and changing attitudes



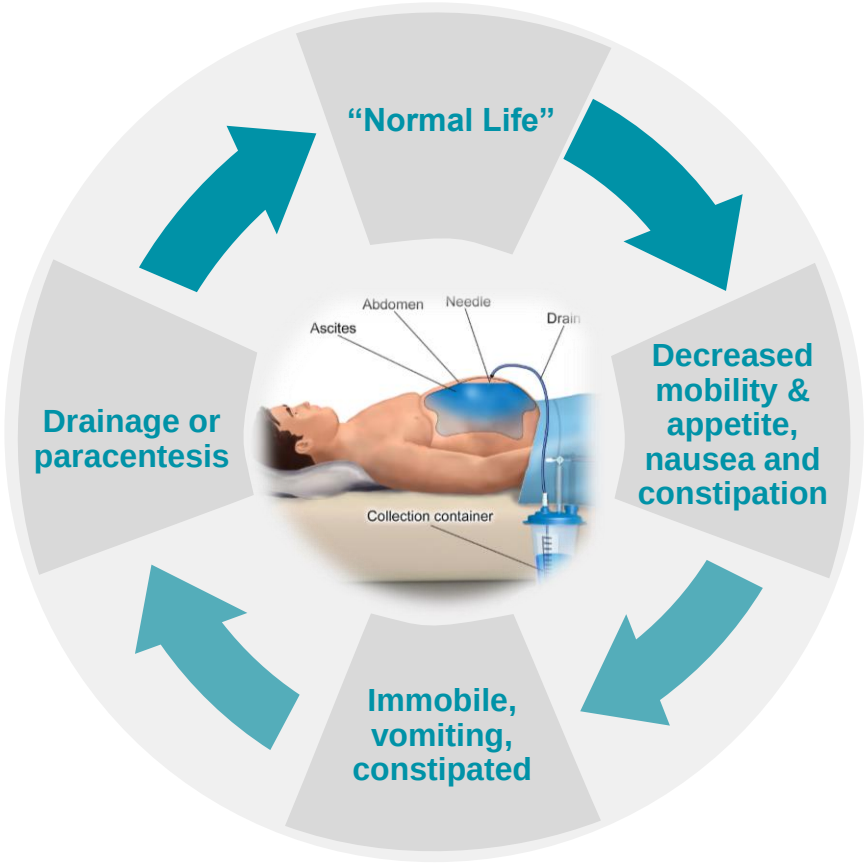
(1) Non-alcoholic / Metabolic dysfunction associated Steatohepatitis

SoC Virtually Unchanged for Thousands of Years

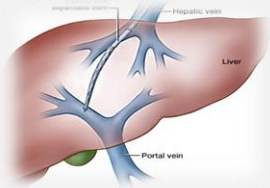
No medtech innovation foreseen; NASH/MASH drugs are not approved in liver cirrhosis

SoC: Paracentesis ("drainage")

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



TIPS



- Severe Complications & Contraindications (less than 40% eligible)[2]
- 45 – 63% efficacy in treating ascites[3]

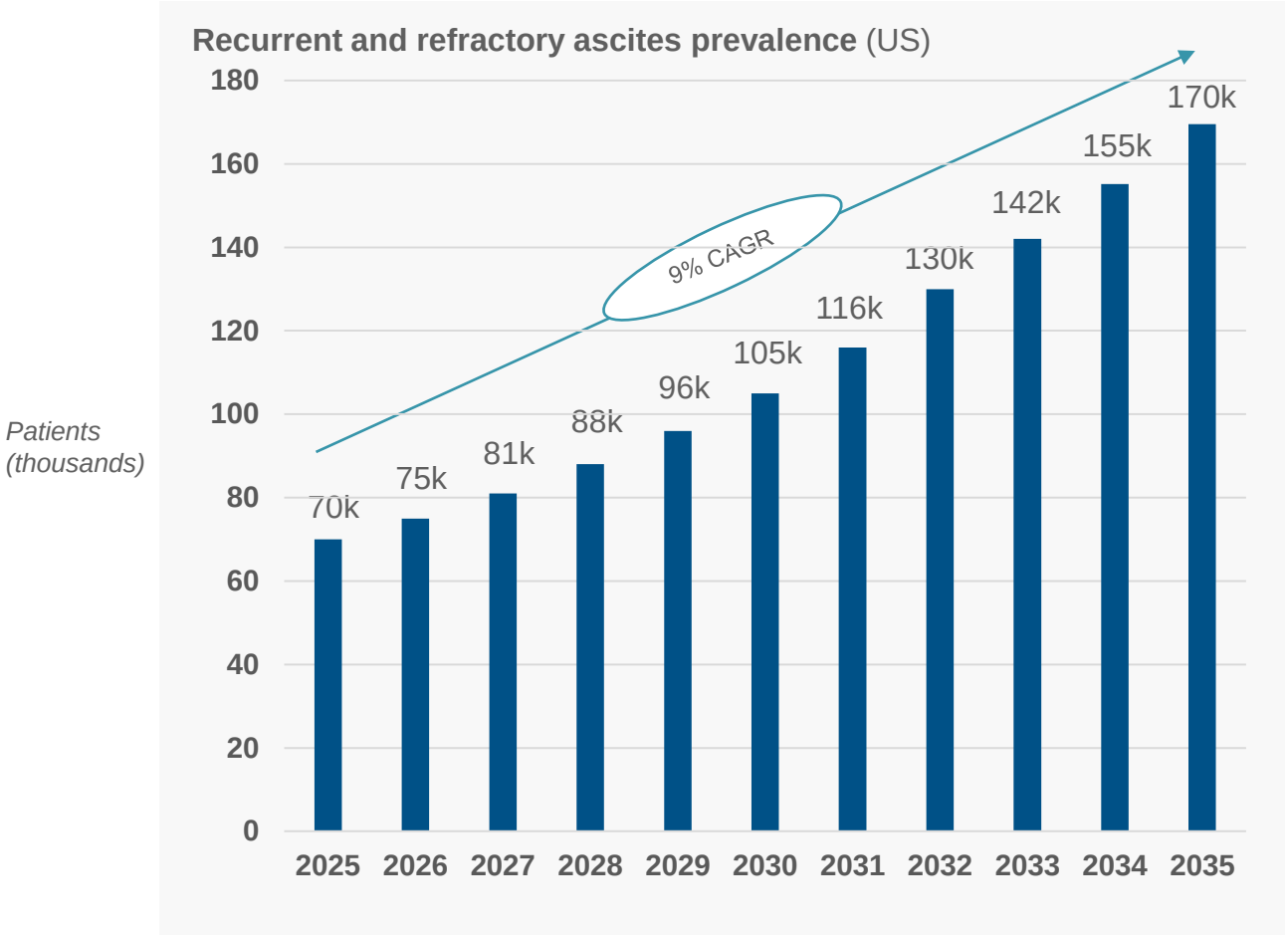
NASH Drugs

- 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] 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*

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

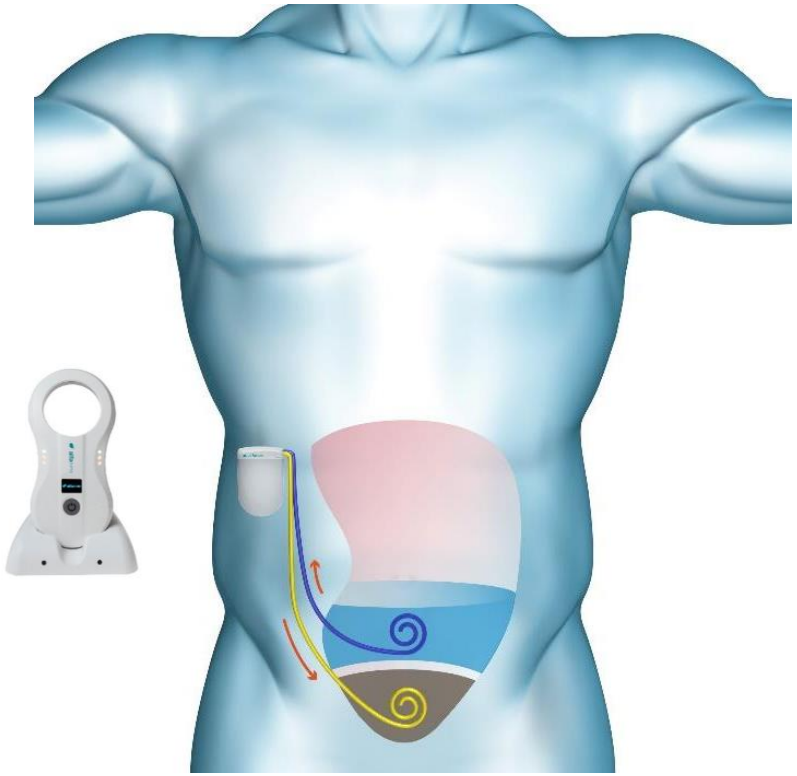
Forecast to reach over $5 billion by 2035 – with strong barriers to entry for new competition



[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;*

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 Q3 25

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

*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.

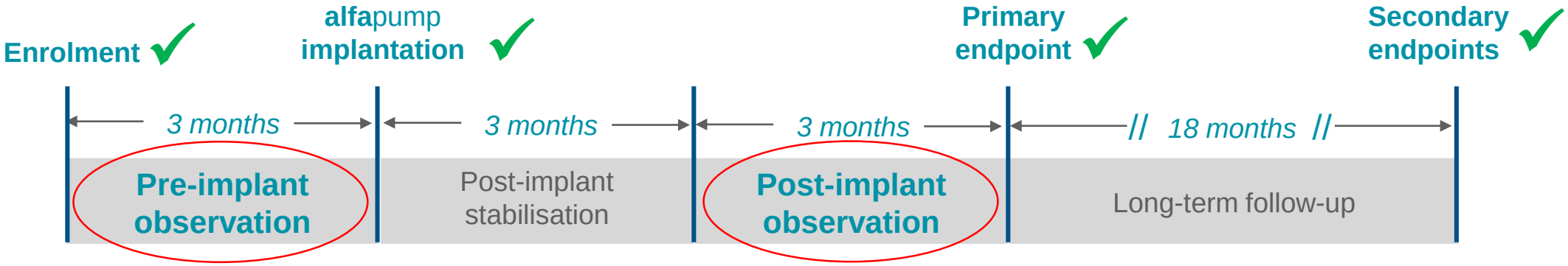
Contraindications:
i) **alfa**pump® System is MRI unsafe, and
ii) Hyperbaric oxygen therapy is contraindicated

No post approval study required by FDA

(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

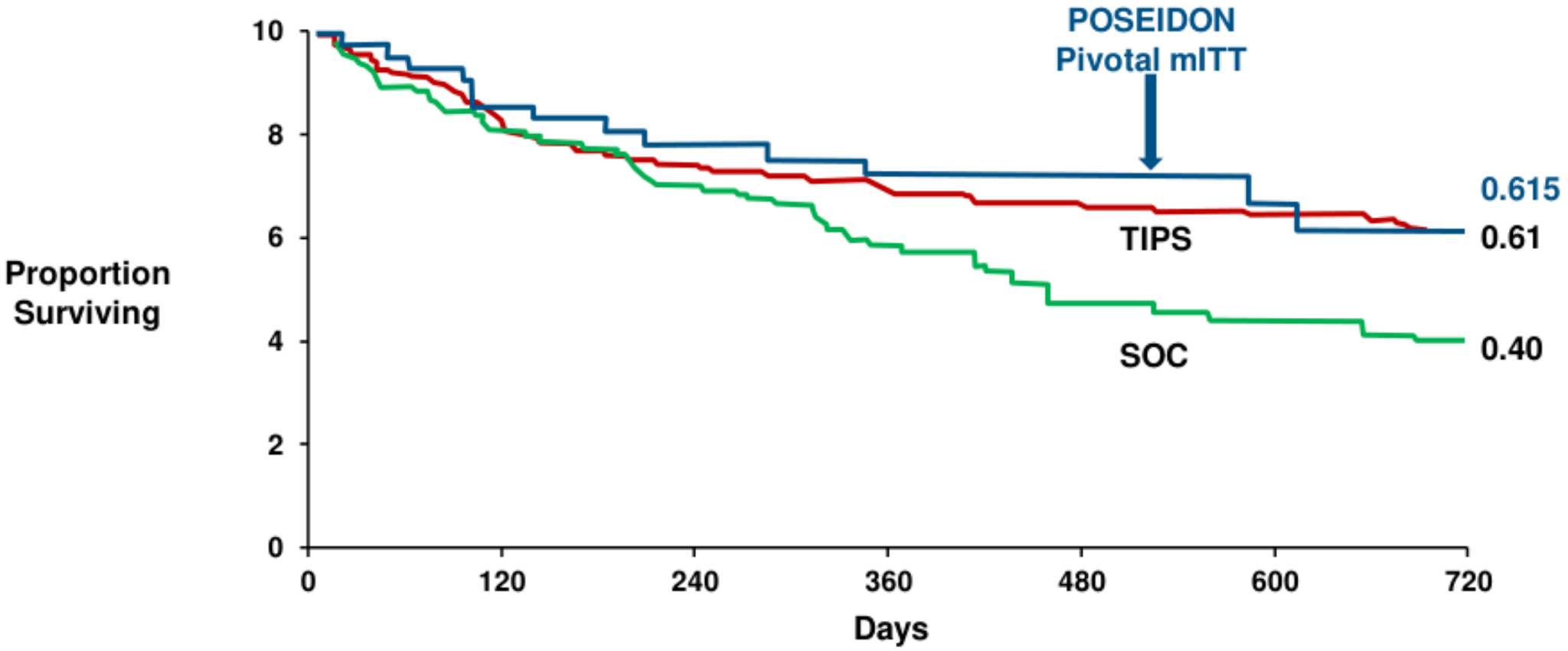


Impact on Paracentesis	0 – 6 months post-implant	0 – 24 months post-implant
Therapeutic paracentesis / month	Median of 0.0	Median of 0.0
Freedom from LVP	90% of patients	80% of patients
Quality of Life	**6 months post-implant**	**24 months post-implant**
• Change in AscitesQ score (lower is better)	-16.8 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

Source: POSEIDON data from POSEIDON clinical study report (data on file at Sequana Medical)
Note: The data in this chart is combined from different studies and does not represent a single prospective study

POSEIDON: robust safety profile

In line with expectations for this patient population and comparable to standard of care

Primary safety endpoint data in line with expectations (0 - 6 months)

- No unanticipated adverse device effects
- MAE rate comparable to baseline, and aligns with general decompensated liver cirrhosis population
- 6 primary safety events (3 explants due to skin erosion & 3 explants due to moderate bladder discomfort)
- Safety profile comparable to SoC(1)

Robust safety profile despite disease progression (7 - 12 months)

- Maintained stable kidney function
- 2 pumps explanted (1 patient with UTI and 1 patient with wound dehiscence)

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

(1) based on matched cohort analysis to contemporary registry of North American cirrhosis patients (NACSELD3)

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%

Based upon observed outcomes in POSEIDON pivotal cohort:

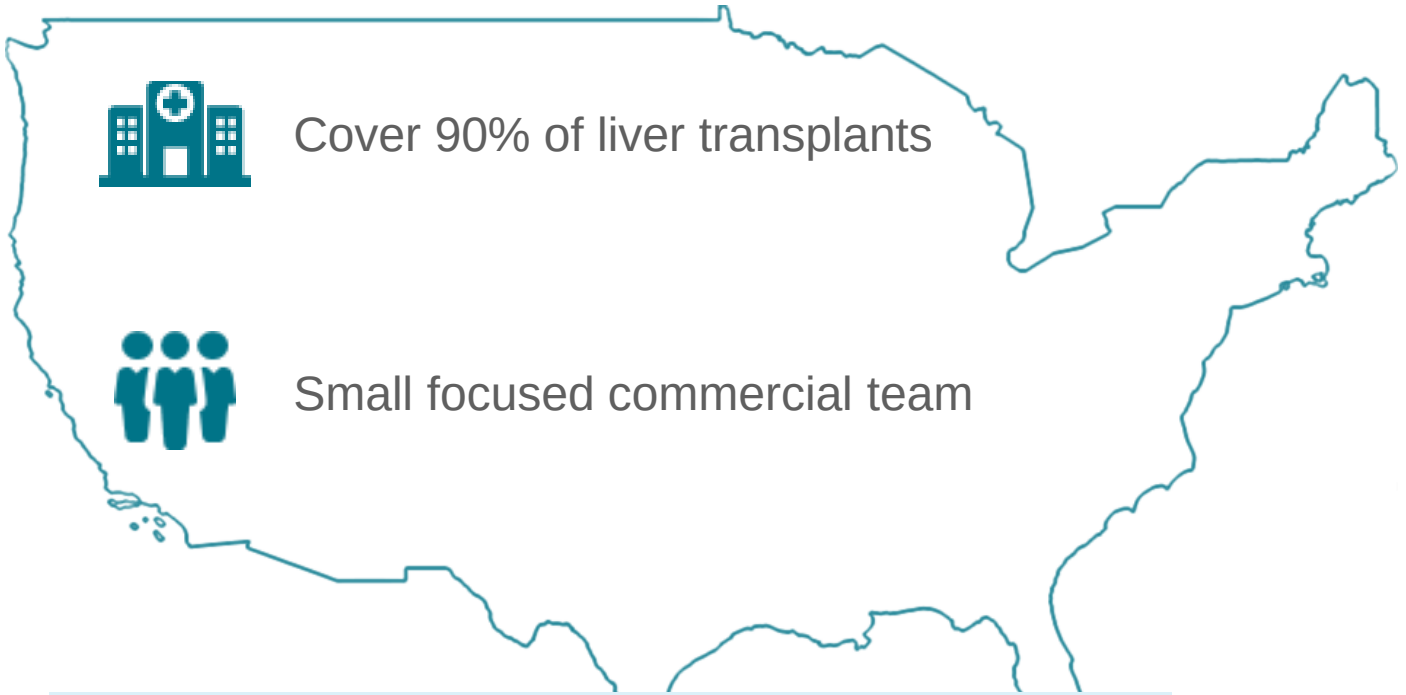
- 100% median reduction in therapeutic paracentesis
- 10 additional ascites good health days / month

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

Direct salesforce targeting 90 liver transplant centers

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



- **Commercial sales planned to start mid Q3**
- **Initial launch this year at six centers**
- **Full launch planned to start Q2 2026**

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

Attractive pricing based on derisked reimbursement

Breakthrough device designation and high gross margin

Coding – Strong position from existing DRG codes and Breakthrough Designation

- Hospital reimbursement codes granted - existing DRG's for **alfa**pump procedure*
- Breakthrough designation enables higher payments via NTAP
- Target **alfa**pump ASP of **$33K** (80% gross margin)
- Physician CPT III reimbursement codes granted

Coverage – Case by Case Based on High Medical Need

- High success rate potential due to our focus on sophisticated hospitals & high medical need
- New Federal Regulation enforces rapid decision making

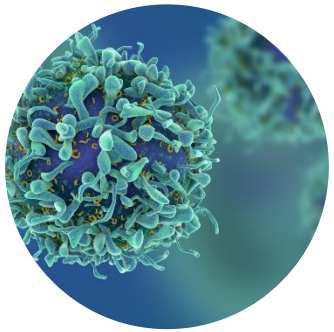
On the basis of existing ICD-10 codes issued for the **alfapump, the likely DRG coding will be 423 "OTHER HEPATOBILIARY OR PANCREAS O.R. PROCEDURES",*

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

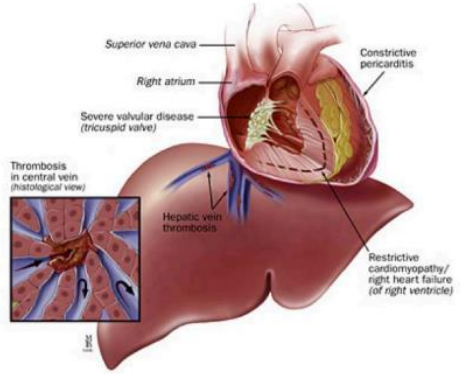
Potential Market Expansion[1]

Opportunities for Additional Indications in Other Significant Markets

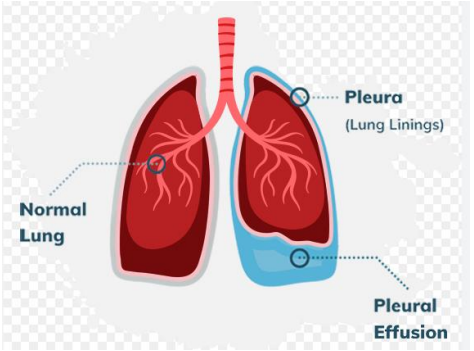
Malignant Ascites: Fluid in peritoneal cavity due to cancer



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

R&D Pipeline: DSR®

Clinical Proof-of-Concept for Disease-Modifying Drug Program Targeting Key Unmet Needs in Heart Failure

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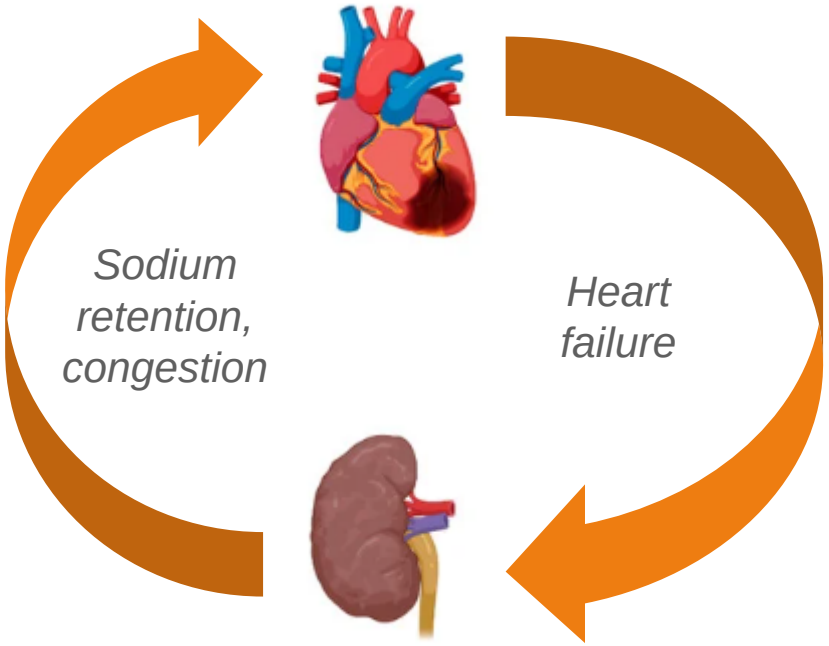
Cardiorenal Syndrome – key clinical challenge in HF

Unmet clinical need to tackle congestion for long enough, without the problems of loop diuretics

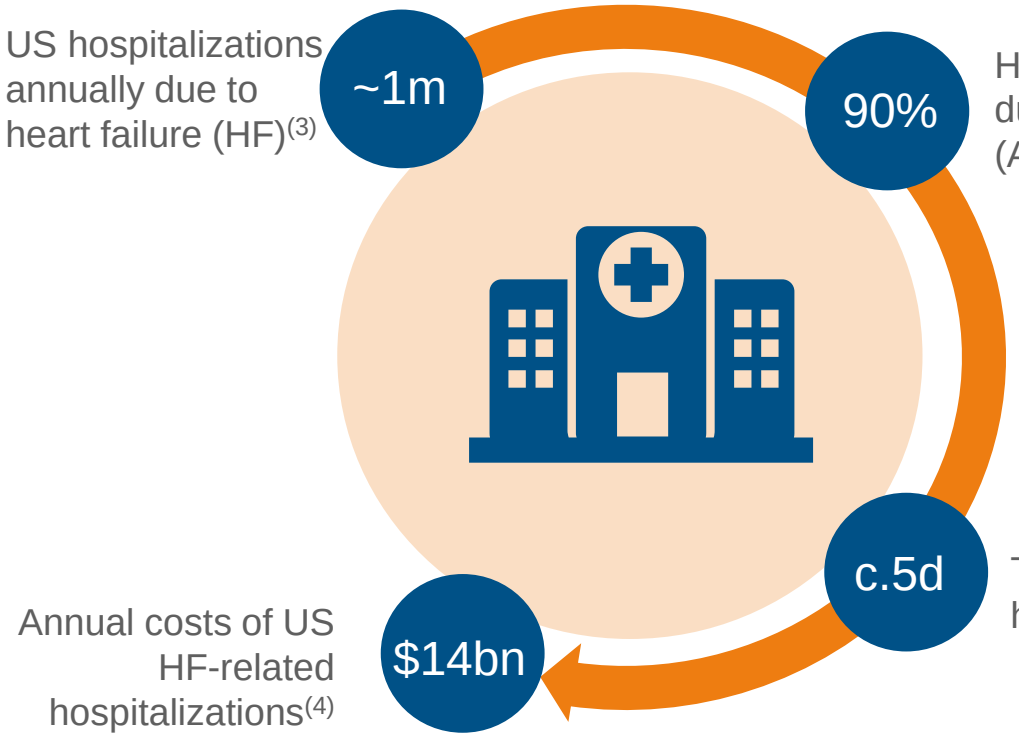
- Combined, and self-reinforcing negative feedback dysfunction of heart and kidneys with hypothesised complex and interconnected mechanisms

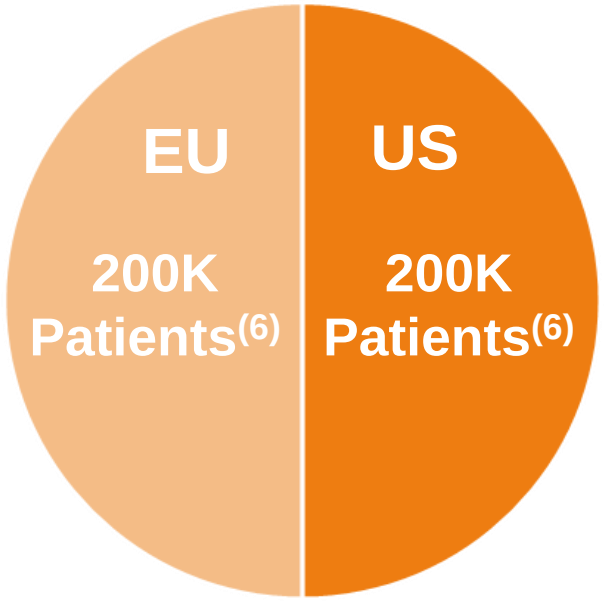
- Loop diuretics are mainstay of decongestion therapy BUT exacerbate many of the core mechanisms thought to underly CRS, worsening diuretic resistance and CRS



Congestion is key driver of morbidity & hospitalization

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





>$9 Bn

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

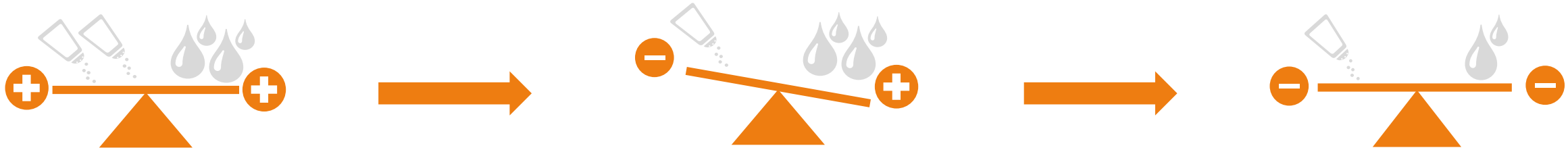
40% of heart failure patients on IV loop diuretics have a poor response(1)

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

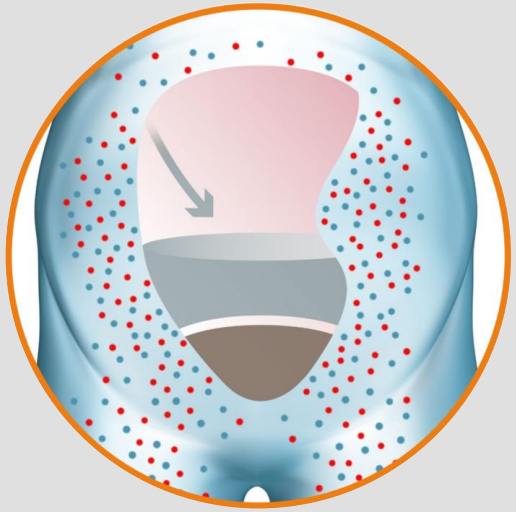
(1): Testani, Circ Heart Failure, 2014 & 2016; (2): Ross et al. (2010); (3): Costanzo et al., J. Am. Coll., 2007; (4): Urbich et al. (2020); (5) based on 3 hospitalisations / year at $15k / admission (management estimate) (6) management estimates

DSR (Direct Sodium Removal) targets key driver

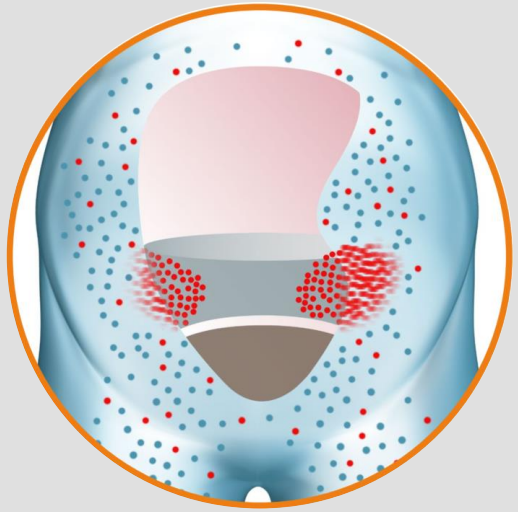
Validated by RED DESERT, SAHARA & MOJAVE clinical studies, with peer-reviewed publication



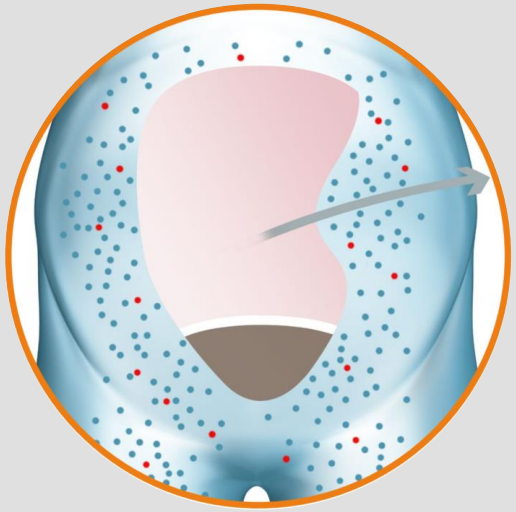
1 Sodium-free DSR product administered to peritoneal cavity



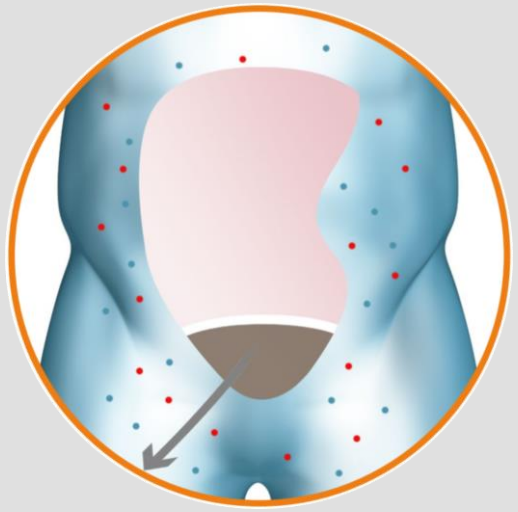
2 Sodium diffuses from body into DSR product



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, 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 euvolemia
- ✓ Normalization of response 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*

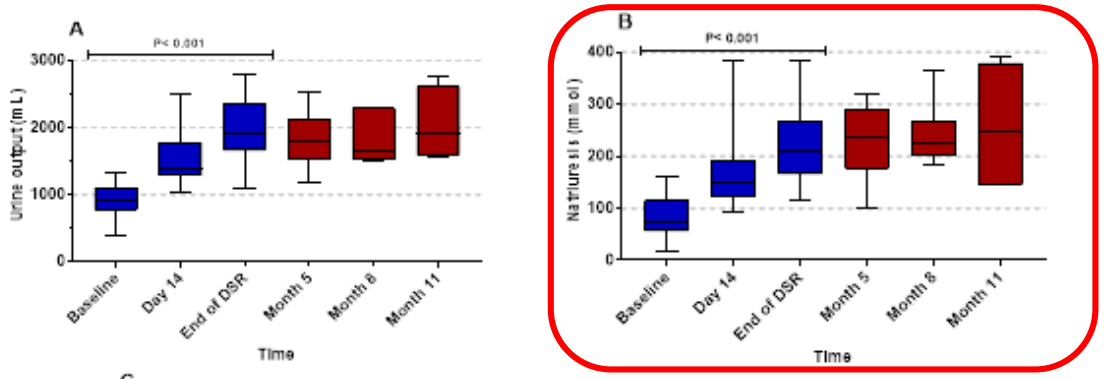
***NYHA**: New York Heart Association classification (data collected outside study protocols of RED DESERT and SAHARA)*

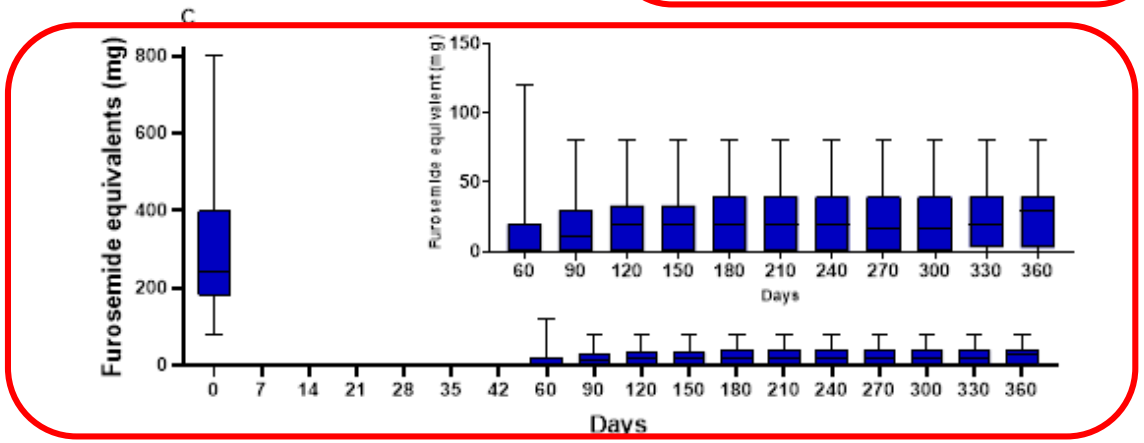
Breakthrough in kidney response and LD requirement

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

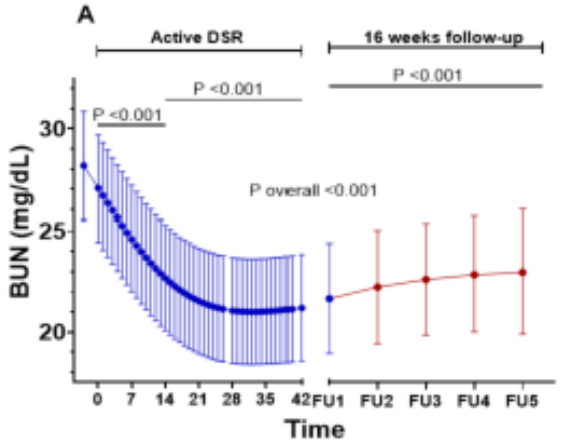
(in furosemide equivs: 1mg oral bumetanide = 20mg oral torsemide = 80mg oral furosemide)

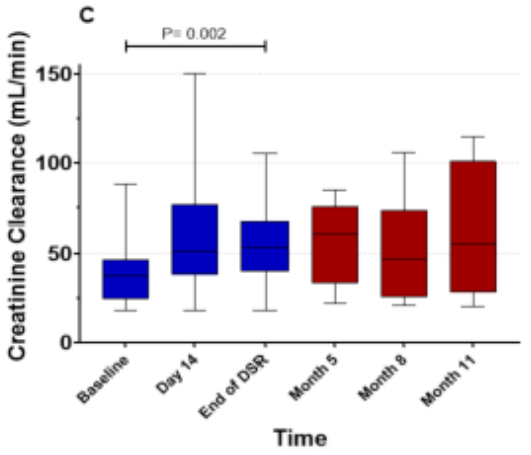
ESC European Society of Cardiology
European Journal of Heart Failure (2024)
doi:10.1002/ejhf.3196
RESEARCH ARTICLE

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-Mastache[5], Daniel Neville[1], Natasha Balkcom[1], Jennifer L. Asher[6], Lavanya Bellumkonda[1], Tamar Bigvava[7], Tamaz Shaburishvili[7]*, Jozef Bartunek[8], F. Perry Wilson[9,10], Fredrick Finkelstein[9], Christopher Maulion[1], Jeffrey M. Turner[9], and Jeffrey M. Testani[1]*

Blood urea nitrogen (BUN) and creatinine clearance



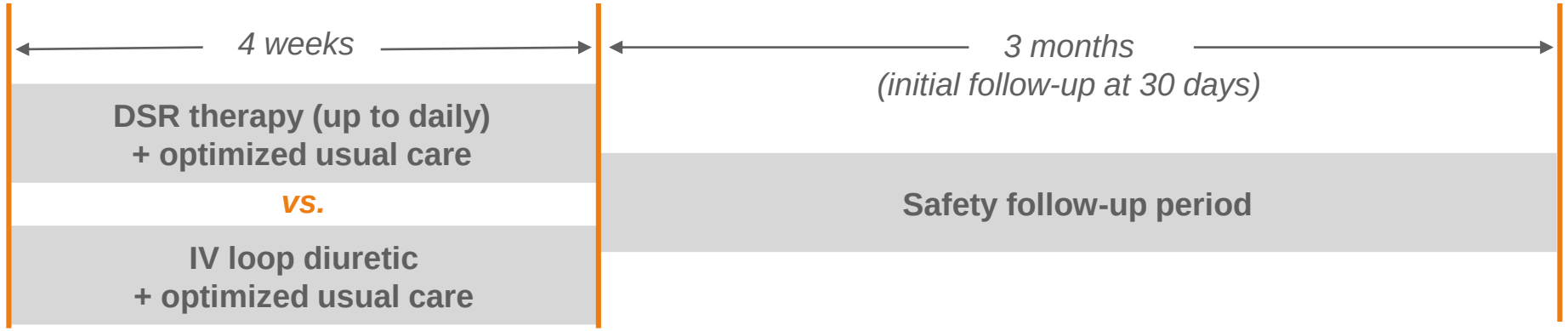


Blue bars *indicate data from both RED DESERT and SAHARA, and* ***red bars*** *indicate data only from SAHARA.*

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

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:

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Alex Clyde
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Rudy Dekeyser
Director

Ids van der Weij
Director

Ian Crosbie
Chief Executive Officer