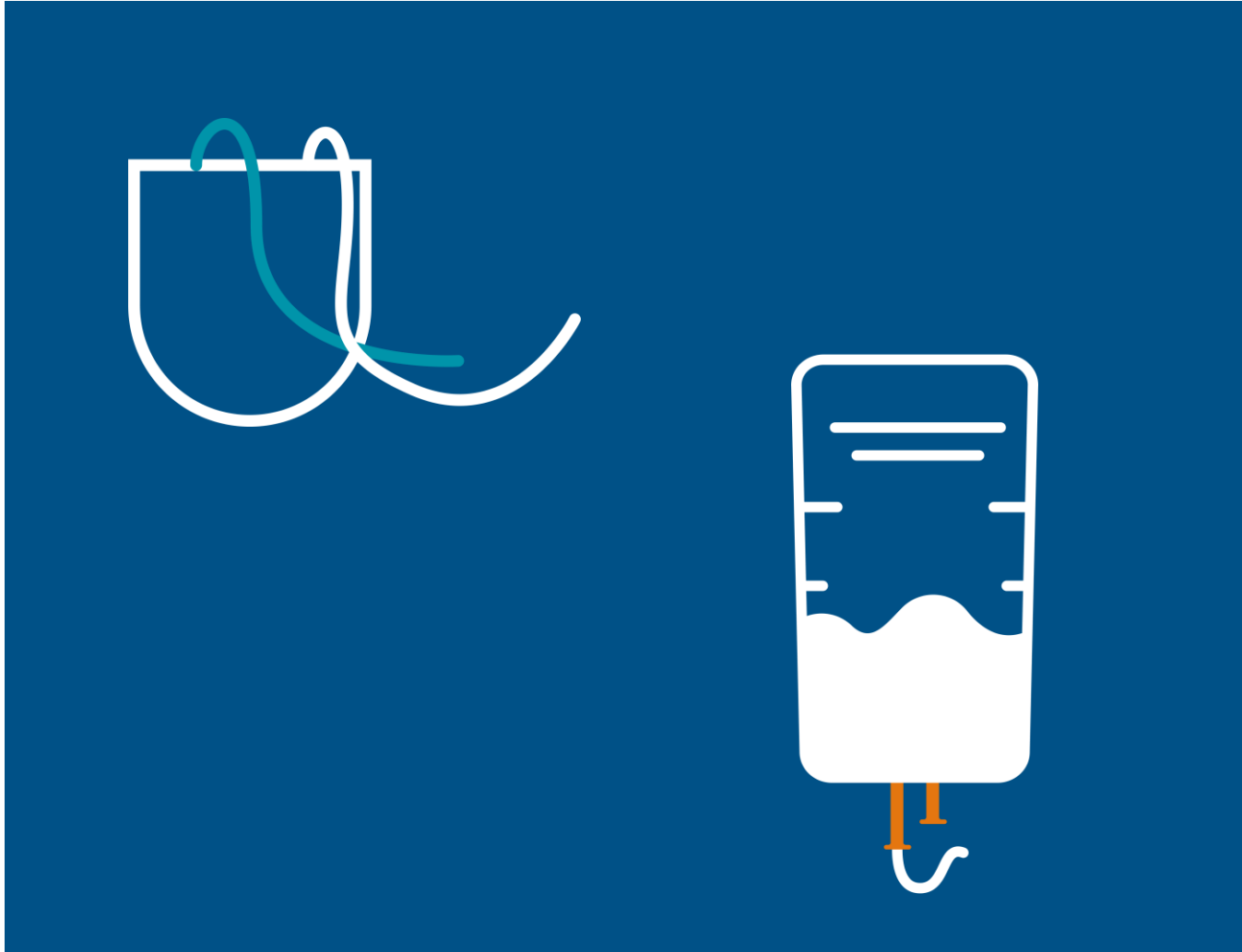


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Pioneers in the treatment of fluid overload

Transforming lives in
liver disease, heart failure & cancer

Investor presentation – May 2024

Euronext: SEQUA.BR

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- The **alfapump**[®] system has not yet received regulatory approval in the United States and Canada. Any statement in this presentation about safety and efficacy of the **alfapump**[®] system does not apply to the United States and Canada. In the United States and Canada, the **alfapump**[®] system is currently under clinical investigation (POSEIDON Study) and is being studied in adult patients with refractory or recurrent ascites due to liver cirrhosis.
- DSR[®] therapy is still under development and it should be noted that any statements regarding safety and efficacy arise from ongoing pre-clinical and clinical investigations which have yet to be completed. There is no link between DSR[®] therapy and ongoing investigations with the **alfapump**[®] system in Europe, the United States or Canada.

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- Sequana Medical is closely following the evolution of macroeconomic conditions, the geopolitical situation in Ukraine and the COVID-19 global health crisis and is in constant dialogue with its partners to assess the impact and adapt operations accordingly.
- Sequana Medical has put in place mitigation plans to minimise delays. The impact of increased demands on the healthcare systems, limitations on non-essential hospital visits and procedures, social-distancing and travel restrictions may result in further delays to execution of clinical studies and impact sales.
- Sequana Medical will continue to update the market as needed and whenever possible.

Note:

- **alfapump**[®] and DSR[®] are registered trademarks.

Targeting large markets with strong growth

Strong growth in NASH and unmet clinical needs in cardiorenal syndrome driving commercial opportunity



alfapump – device for recurrent & refractory ascites due to liver cirrhosis

- \$2.4 billion market by 2032⁽¹⁾ – 9% CAGR driven by NASH and alcohol
- Clear unmet clinical needs; minimal innovation
- PMA substantive review complete – FDA approval anticipated Q1 2025
- FDA breakthrough device status; approved in EU
- Successful pivotal study – primary endpoints met, strong clinical & commercial profile
- Direct sales in US & Canada; commercial team of 50
- Strong reimbursement profile; supporting \$30K price, 80% gross margin



DSR – novel drug treatment for cardiorenal syndrome in heart failure

- Over \$9 billion addressable market in US⁽²⁾
- Clear unmet clinical needs in cardiorenal syndrome
- Clinical proof-of-concept as disease-modifying drug
- Dramatic and long last impact on disease-status
- Low development risk, favourable safety profile & strong granted IP
- US Phase 1/2a randomized controlled study underway; positive data from first patients
- Partnering based on US Phase 1/2a readout planned for 2026



Source 1: Based on US and Canada market assessment conducted by leading international consulting group, estimating ~150,000 patients with recurrent or refractory ascites in North America by 2032, with estimated incidence of 60% and based on \$30K for price of **alfapump**



Source 2: Management estimate of ~200K chronically congested HF patients hospitalized per year in the US with a US annual HF hospitalization cost per patient of \$45K

PMA: Pre-Market Approval;

Key upcoming value drivers

Targeting US commercial launch for alfapump and Ph II data / partnering agreement for DSR

Medical Device	Indication	Development	Pivotal Trial	Approved
 alfapump Europe	Refractory liver & malignant ascites	CE Mark / MDR approval		
 alfapump US	Recurrent or refractory liver ascites	FDA breakthrough device designation / PMA Review Ongoing		

Therapeutic	Indication	Phase I	Phase II	Phase III
 DSR Europe	Heart failure / Cardiorenal Syndrome	RED DESERT & SAHARA: PoC		
 DSR US	Heart failure / Cardiorenal Syndrome	MOJAVE: Phase I/IIa		

Major Shareholders





alfapump[®]

Proven step change in the treatment of liver
refractory ascites



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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



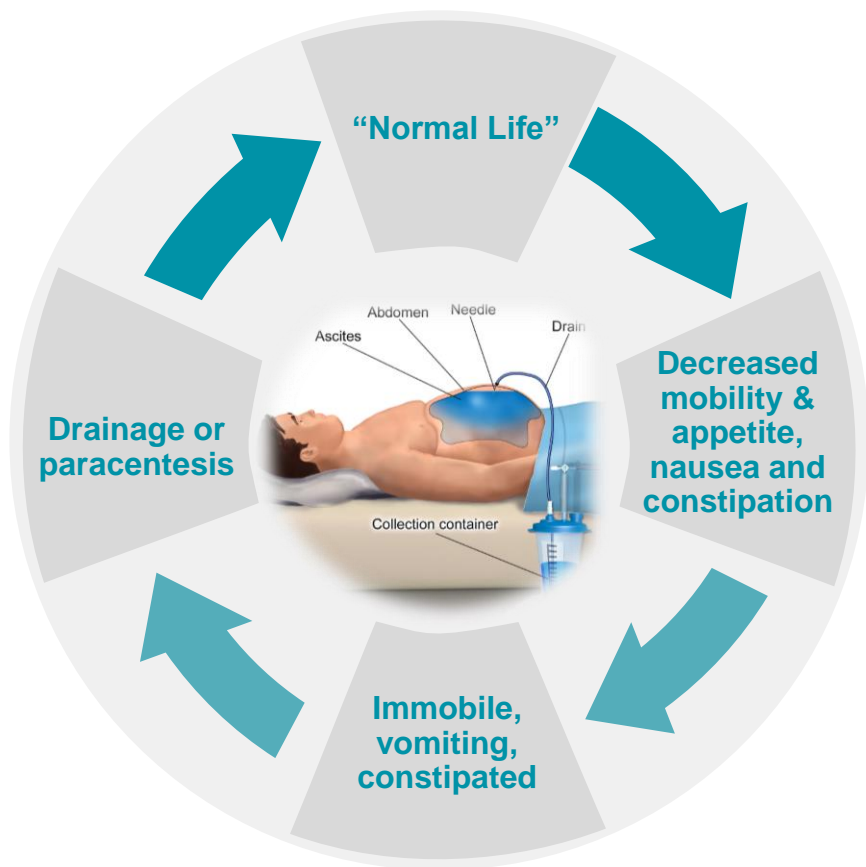


Clear limitations of treatment options

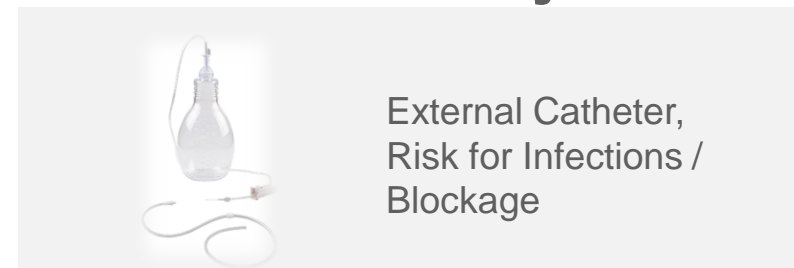
No new development apart from NASH drugs, which are not effective in late stage NASH / cirrhosis

SoC: Paracentesis (“drainage”)

Painful, burdensome, short term benefit, QoL impact

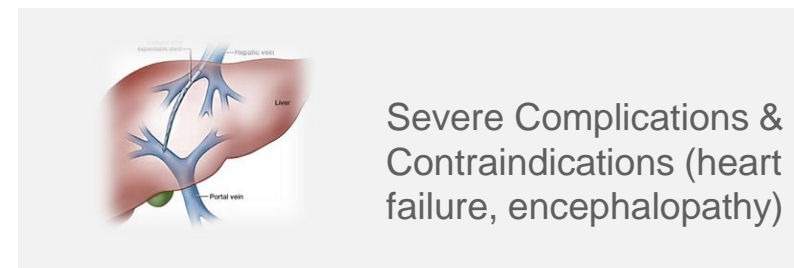


Permanent Catheter System



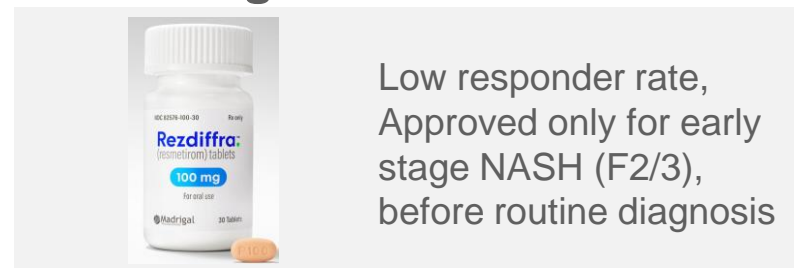
External Catheter,
Risk for Infections /
Blockage

TIPS



Severe Complications &
Contraindications (heart
failure, encephalopathy)

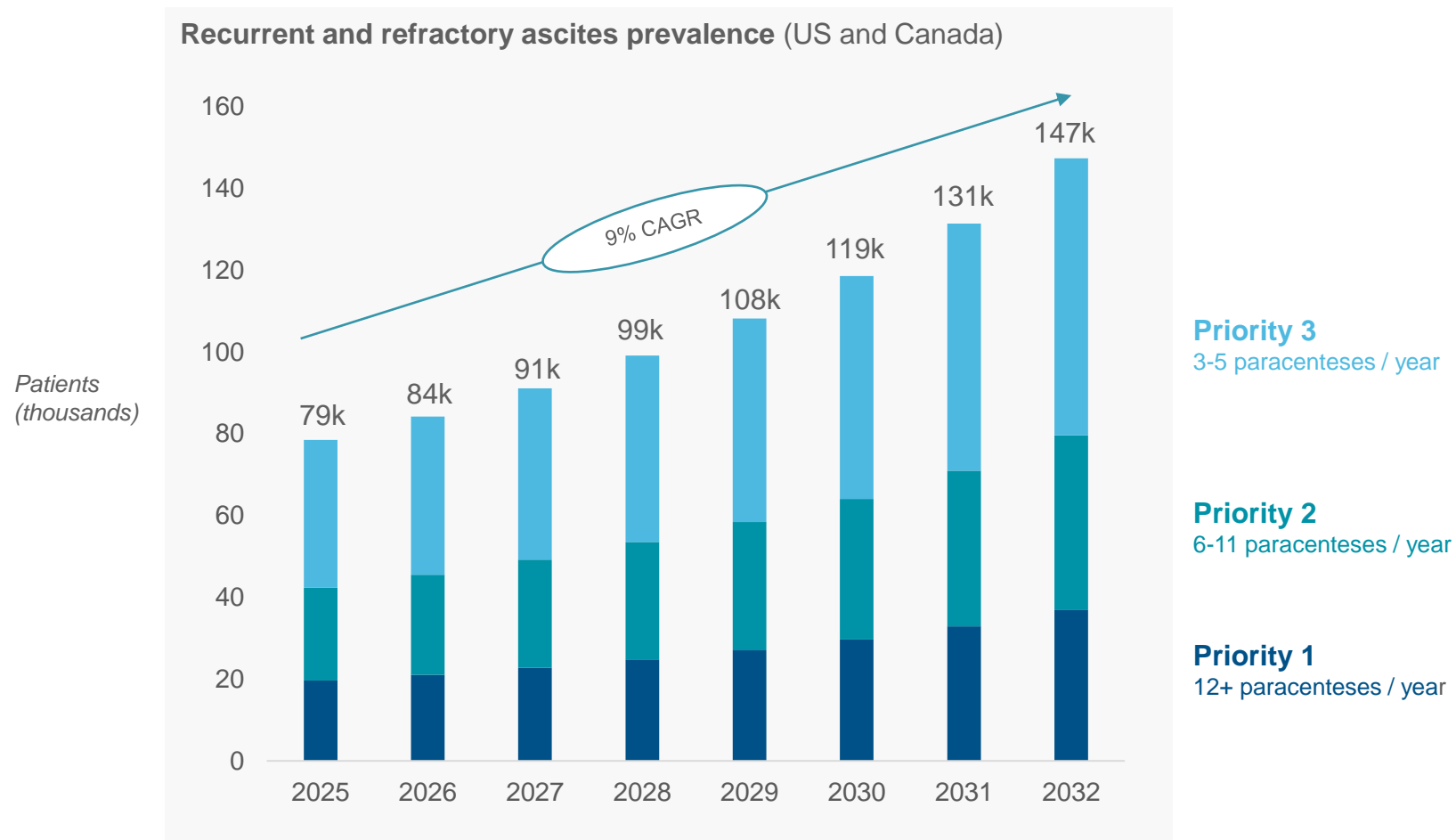
NASH Drugs



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

\$2.4bn market for alfapump - growing at 9% CAGR

\$600 million Priority One market – highest clinical burden, costs & QOL impact, and little competition



¹ Based on US and Canada market assessment conducted by highly experienced international consulting group, estimating 147,400 patients with recurrent or refractory ascites in North America by 2032 and based on an indicative 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



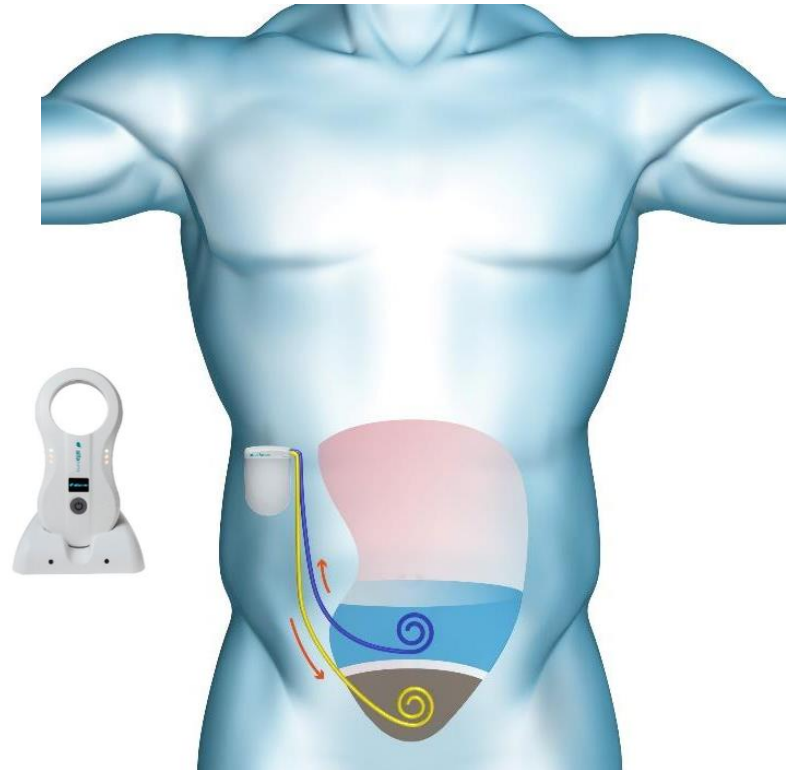
Settings wirelessly adjusted



Remote data monitoring



Moves up to 4 litres / day



Breakthrough Device Designation

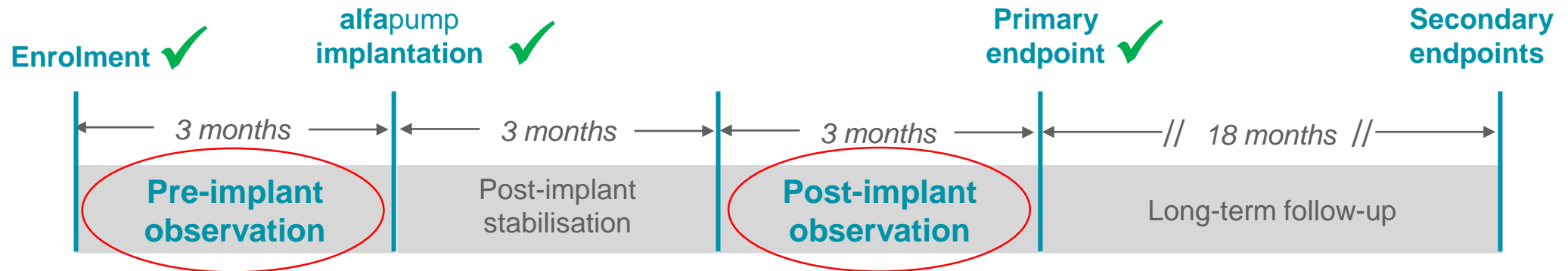


Strong IP barriers through extensive patent portfolio, know-how & PMA



Successful North American pivotal study

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



Primary effectiveness endpoints exceed predefined thresholds for study success

- **100%** median per-patient reduction in therapeutic paracentesis (N=40; $p < 0.001$)* vs at least 50%
- **77% of patients** with at least 50% reduction in therapeutic paracentesis (N=40; $p < 0.001$)* vs at least 50%

Primary safety endpoint data in line with expectations

- No unanticipated adverse device effects
- 6 primary safety events (3 explants due to skin erosion & 3 explants due to moderate bladder discomfort)

Clinically meaningful and statistically significant improvement in quality of life**

* Post vs Pre-implant observation period

** Quality of life assessed through the physical component score of SF36 and the Ascites Q score, at six months post-implant compared to baseline



Sustained efficacy and robust safety profile

12 month data demonstrates effectiveness and safety

✓ **Virtual elimination of needle paracentesis**

- Maintaining 100% median per-patient reduction in therapeutic paracentesis (N=19, p<0.001)*

✓ **Robust safety profile despite disease progression**

- 2 pumps explanted (1 patient with UTI and 1 patient with wound dehiscence)**
- Number of major adverse events and serious infections in line with expectations
- Maintaining stable kidney function

✓ **Maintaining clinically meaningful improvement in quality of life*****

✓ **Survival probability of 70% at 12 and 18 months post-implant**

- Comparing favorably to literature citing only ~17% predicted survival at 12 months and ~5% at 18 months⁽¹⁾

* 7-12 month post-implant period vs 3 month pre-implant observation period; ** during 7-12 month post-implant; *** at 12 months post-implant compared to baseline

Source 1: Salerno et al., *Gastroenterology* 2007; 133:825-834; predicted survival probability for refractory ascites patients with a MELD score of 15 and receiving paracentesis

UTI: Urinary Tract Infection





PMA regulatory review significantly derisked

On track for Q1 2025 US approval and H2 2025 US commercial launch

- **All audits completed**
- **Substantive review complete – no further new clinical or pre-clinical questions**
- **Day 90 (“major deficiencies”) letter received and Day 100 meeting held**
 - Response to preclinical questions to be submitted by end Q3 2024
- **No FDA Advisory Panel expected**
- **Targeting Marketing Approval in Q1 2025**
- **US commercial launch planned for H2 2025**
- **RPMS / DirectLink software to be submitted as PMA supplement post-approval**
 - Manual uploading of pump data for initial commercialisation



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 **alfapump** procedure of \$60-70K in target hospitals*
- Supports **alfapump** price of **\$30K** (80% gross margin)
- Breakthrough designation enables higher payments via NTAP
- CPT III codes granted

Coverage – TCET potential from Breakthrough Device designation

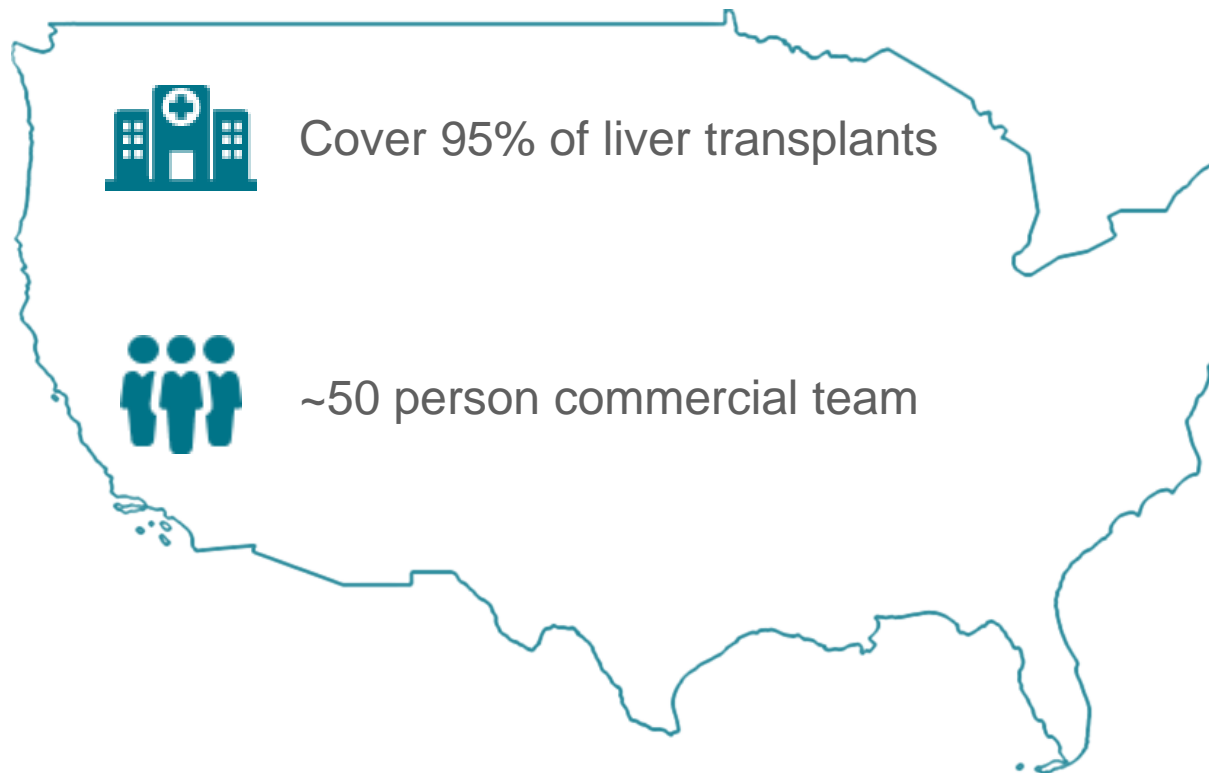
- Automatic coverage for 4 years with pathway to permanent coverage
- High pre-approval potential from targeted hospitals

*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”, payments adjusted with Medicare inflation rates to 2025



US – Go direct to 90 liver transplant centers

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



Targeting annualized revenues of over €35MM within 3 years of full commercial launch

- Estimated cash required of ~€80MM*

Cashflow breakeven forecast at ~€50MM

- 1, 750 alfapumps, representing less than 7% of market prevalence in our Priority One Market alone
- Estimated cash required of ~€90MM*

DSR[®]

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

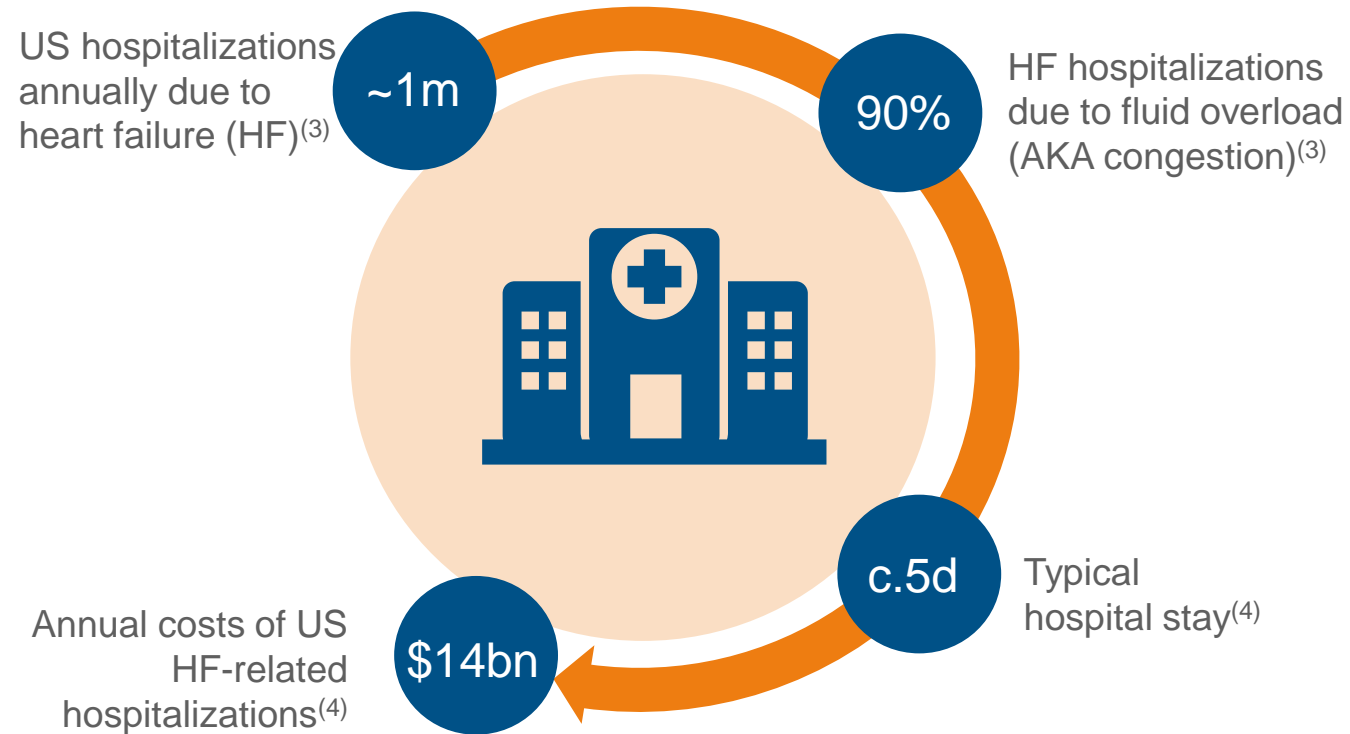


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Congestion is key driver of morbidity & hospitalization

Diuretic-resistance in heart failure is common and there are few effective clinical alternatives



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

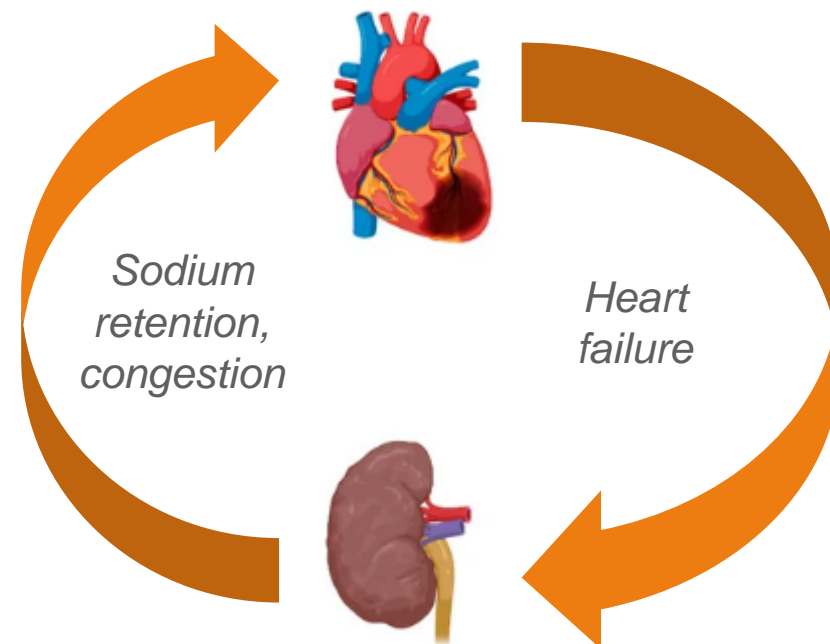
24% re-admission rate at 30 days⁽²⁾



Cardiorenal Syndrome – key clinical challenge in HF

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

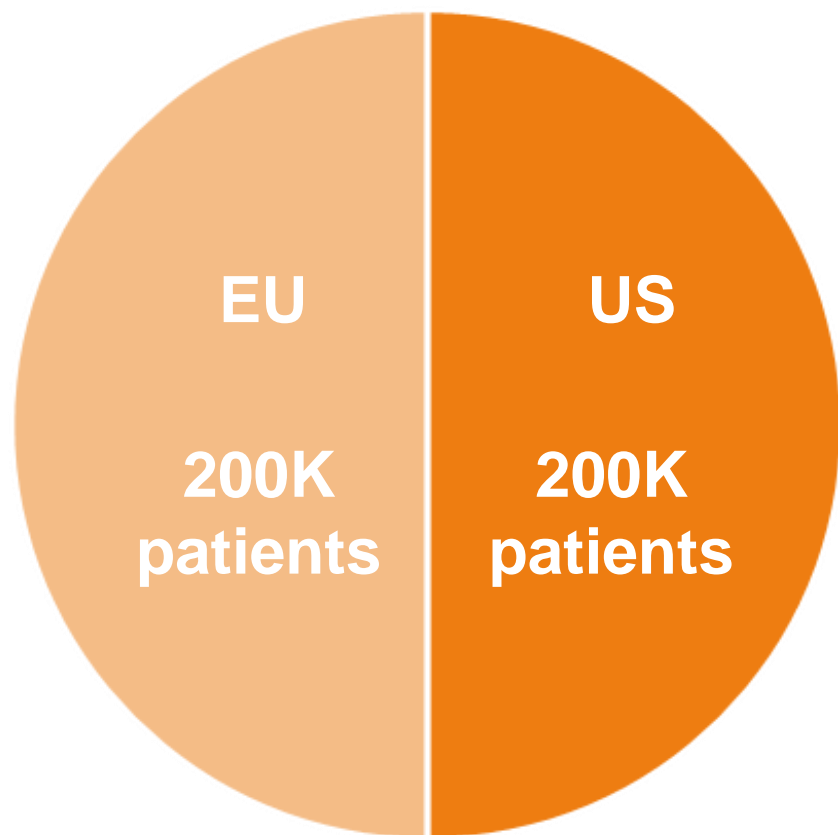
- Combined, and self-reinforcing **dysfunction of heart and kidneys** with hypothesised **complex and interconnected mechanisms**
- Clinical profile of **self-reinforcing negative feedback cycle** that is challenging to break
- **Loop diuretics** are mainstay of decongestion therapy **BUT exacerbate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





Multi-billion commercial opportunity

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

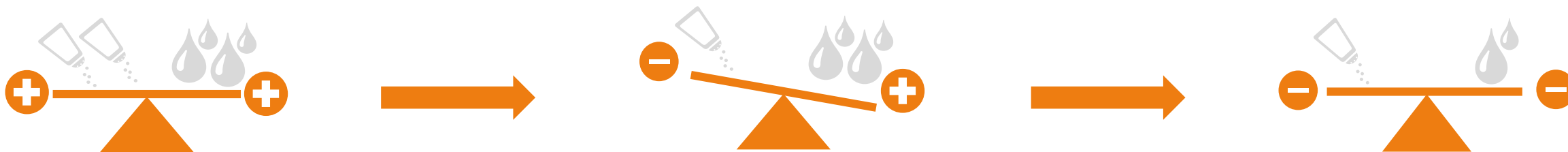


Potential for premium DSR pricing through reduced hospitalization and improved survival



DSR (Direct Sodium Removal) targets key driver

Eliminating fluid spread across the body – working in partnership with the kidneys

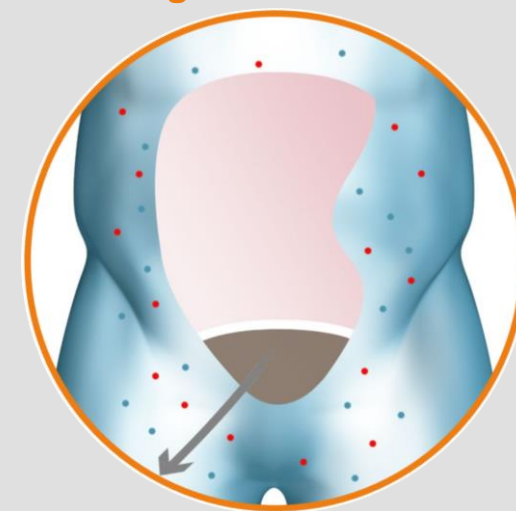
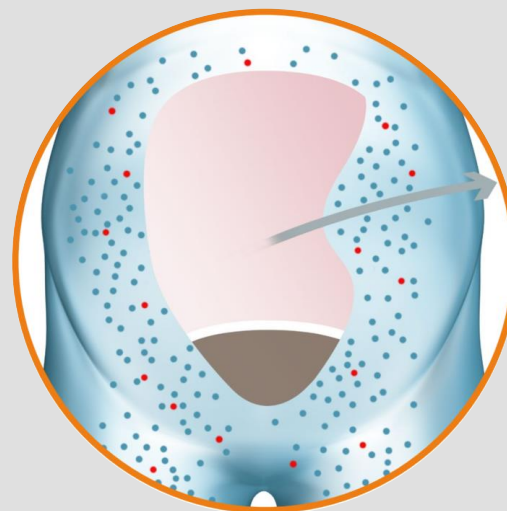
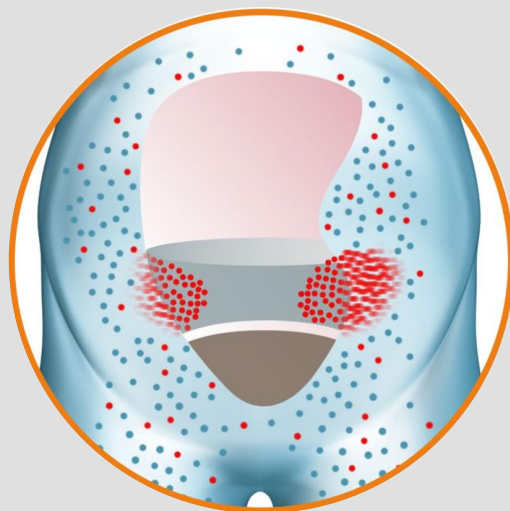
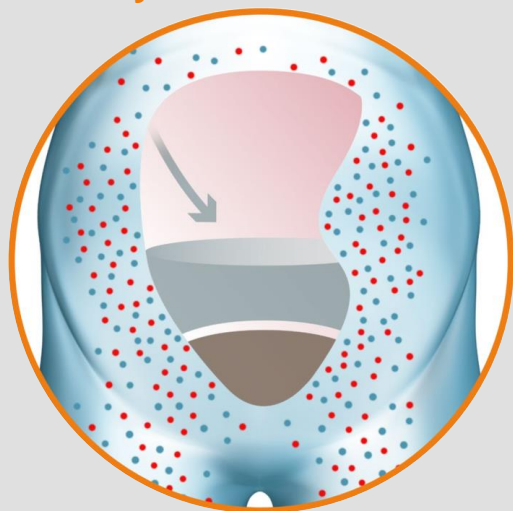


1 Sodium-free DSR product administered to peritoneal cavity

2 Sodium diffuses from body into DSR product

3 DSR product + extracted sodium 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 syndrome

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

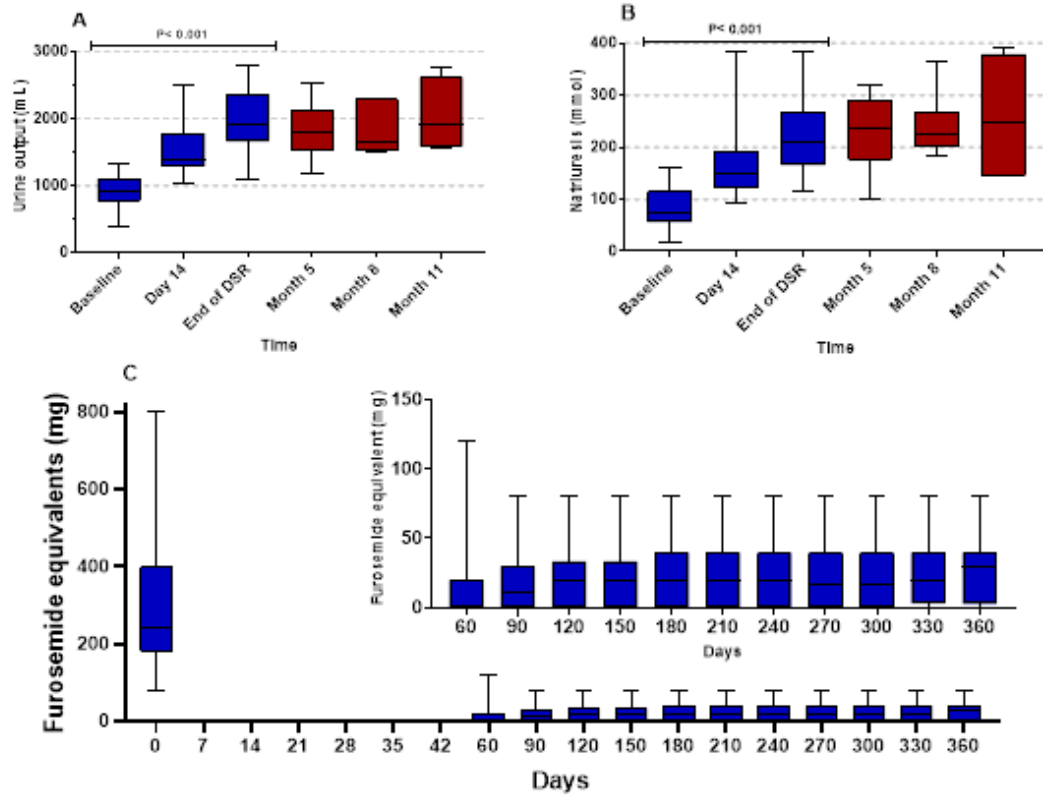
NYHA: New York Heart Association classification (data collected outside study protocols of RED DESERT and SAHARA)



Improvement in diuretic response and renal function

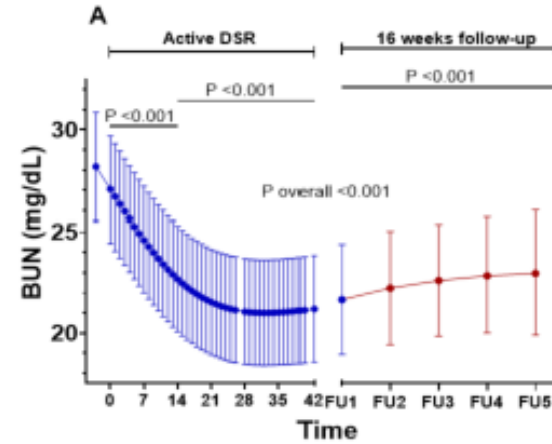
Normalization of diuretic-response with dramatic durable reduction in LD needs post-DSR therapy

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

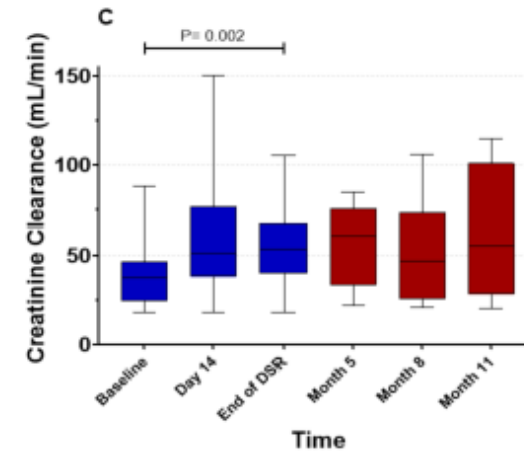


Oral loop diuretic dose over the first year of follow-up

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



Blood urea nitrogen (BUN) and creatinine clearance

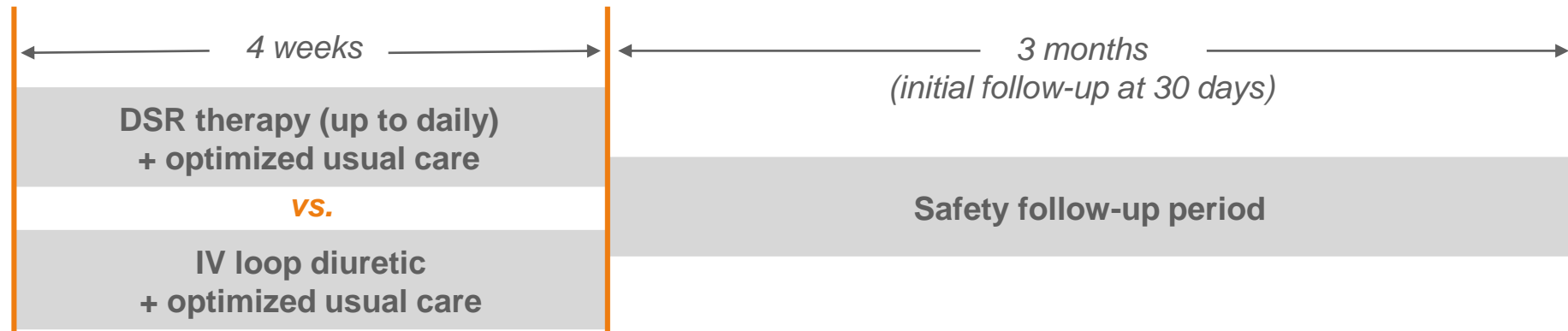


Blue bars indicate data from both RED DESERT and SAHARA, and red bars indicate data only from SAHARA.



MOJAVE – Phase 1/2a randomized controlled US study

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



Endpoints

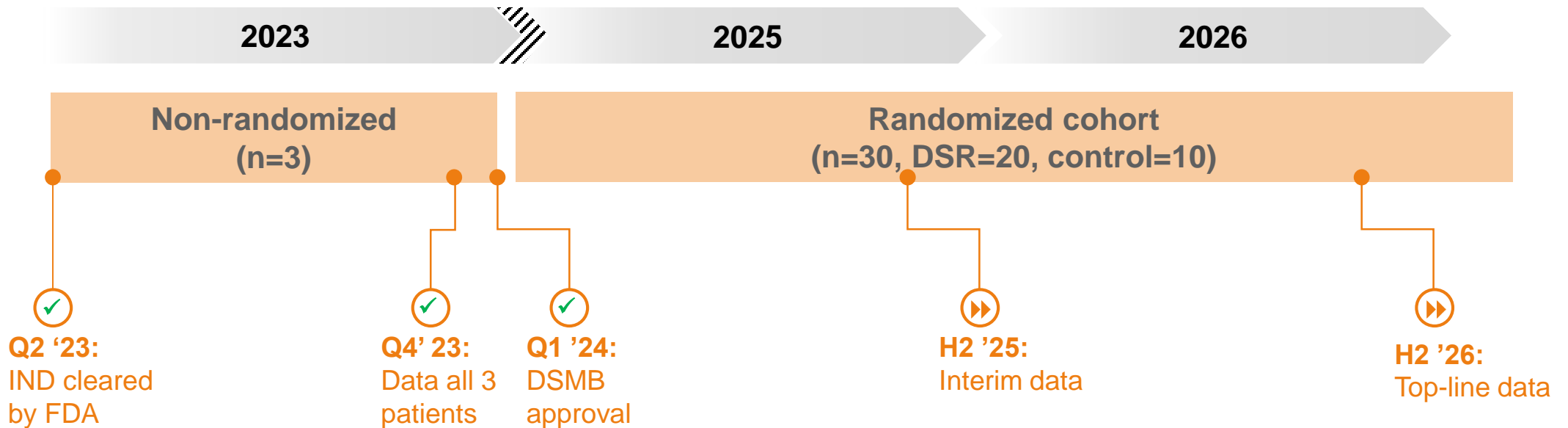
- **Safety:** rate of adverse and serious adverse events
- **Efficacy:** improvement in diuretic response (6-hour urine sodium output)
- **Exploratory:** change in weight (volume status), creatinine (renal function), natriuretic peptides (heart function), NYHA functional class, number of HF-related re-hospitalizations



MOJAVE: Strong data from 3 non-randomised patients

Data from first randomised cohort planned for H2 '25; top-line data expected H2 '26 for partnering

- 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*



* Mean increase of 326% in six-hour urinary sodium excretion three months after DSR therapy vs baseline



Outlook

Strong near term value drivers with clear
long term potential

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Strong near-term value inflection points



- US FDA approval expected Q1 '25
- US commercial launch H2 2025



- Interim results expected H2 '25 and top-line data in H2 '26
- Partnering following completion of MOJAVE study

