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RED DESERT top-line results & expansion of DSR® development programme

Webcast presentation – 11 May 2021

Today's presenters

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Disclaimers

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Regulatory disclaimer:

- The **alfa**pump® system has not yet received regulatory approval in the United States and Canada. Any statement in this presentation about safety and efficacy of the **alfa**pump® system does not apply to the United States and Canada. In the United States and Canada, the **alfa**pump® system is currently under clinical investigation (POSEIDON Study) and is being studied in adult patients with refractory or recurrent ascites due to cirrhosis. For more information regarding the POSEIDON clinical study visit www.poseidonstudy.com.
- 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. DSR® therapy is currently not approved for clinical research in the United States or Canada. There is no link between DSR® therapy and ongoing investigations with the **alfa**pump® system in Europe, the United States or Canada.

COVID-19 disclaimer:

- Sequana Medical is closely following the evolution of 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:

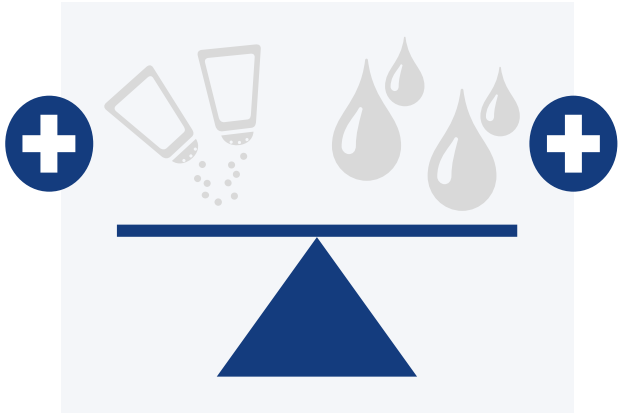
- **alfa**pump® is a registered trademark. DSR® and **alfa**pump DSR® are registered trademarks in Benelux.

Strong top-line results from RED DESERT

Confirming the potential clinical benefits of alfapump **DSR® therapy**

- RED DESERT data of all 8 patients confirm:
  - ✓ **alfa**pump DSR is highly effective at managing fluid and sodium balance in diuretic-resistant heart failure patients without need for loop diuretics
  - ✓ restoration of diuretic response and improvement in cardio-renal function
  - ✓ improvement in diuretic response maintained in long-term follow-up
- SAHARA DESERT study in heart failure patients with residual congestion to start in Q2 2021
- Expanding DSR® development programme with short-term DSR therapy
- Evaluating opportunity for DSR therapy for fluid and sodium removal in renal disease

Fluid overload in heart failure – major clinical problem and key driver of healthcare costs



Excess sodium drives fluid overload

- *40% of heart failure patients on IV loop diuretics have a poor response*
- *24% re-admission rate at 30 days*

Sources: Testani et al. (2014 & 2016); Ross et al. (2010); Costanzo et al. (2007); Kilgore et al. (2017)
***HF**: Heart Failure*

Proprietary Direct Sodium Removal (DSR®)

We remove the sodium and then the body “does the math” to maintain serum sodium balance

Key Principle

DSR therapy directly removes the sodium

Body eliminates excess fluid

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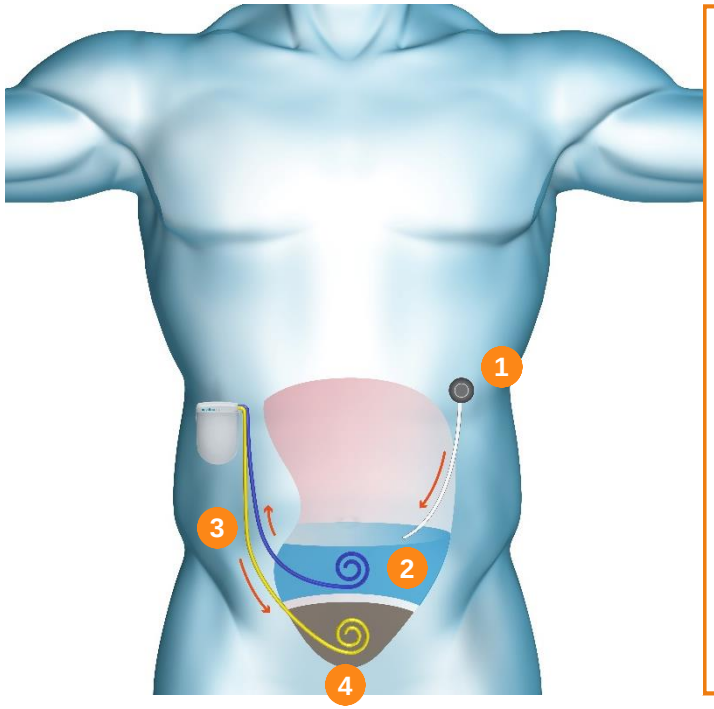
DSR therapy

1. Administer sodium-free DSR infusate to peritoneal cavity and allow to dwell
2. Sodium diffuses from the body down a steep diffusion gradient into DSR infusate
3. Remove DSR infusate + extracted sodium from the body
4. Body restores balance & eliminates associated fluid via osmotic ultrafiltration and/or urination

alfapump DSR® leveraging proven alfapump® platform

Fully implanted system for long-term DSR® therapy

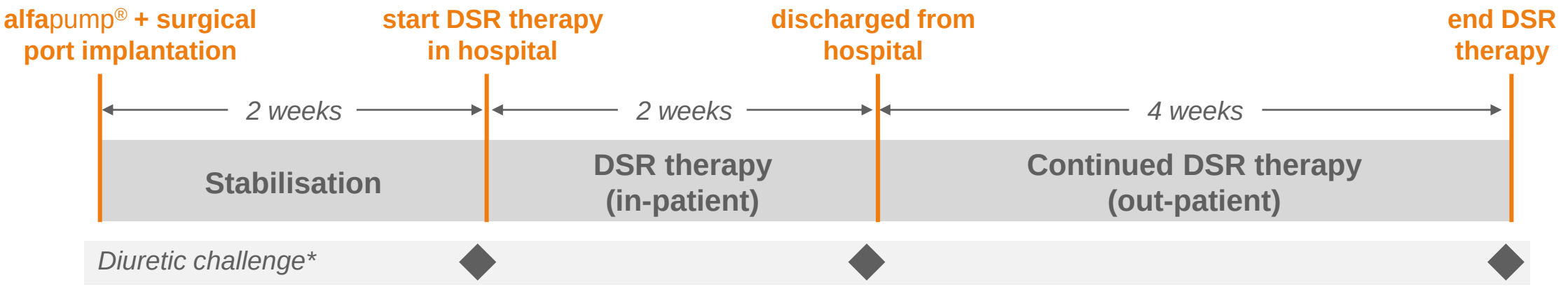


1. Sodium-free DSR infusate administered to peritoneal cavity via implanted port
2. Sodium diffuses into DSR infusate
3. **alfa**pump pumps sodium-rich DSR infusate into the bladder
4. Body eliminates excess fluid through osmotic ultrafiltration and urination

Fundamental patents to reduce fluid overload in heart failure patients granted in the US and Europe

RED DESERT – The first repeated DSR® therapy study

Repeated dose proof-of-concept study of alfapump DSR® in stable heart failure patients on high dose diuretics



Study Endpoints

- **Primary:** absence/rate of device, procedure and/or therapy related serious adverse events
- **Secondary:** ability of the **alfa**pump DSR to maintain a neutral sodium balance in the absence of diuretic therapy and the sustained effect of DSR to maintain euvolemia
- **Exploratory:** impact of DSR to restore response to diuretics following DSR treatment

** 40mg intravenous furosemide to evaluate diuretic response (6 hour sodium and fluid excretion)*

RED DESERT – Concluded at 8 patients implanted

Key lessons learned – so we can move ahead to our target patient population ASAP

	N=8
Ejection Fraction – % (Mean ± SD)	24.4 ± 3.1
NT-proBNP – pg/mL* (Mean ± SD)	4,589 ± 2,945
Furosemide equivalents – mg/day (Mean ± SD)	323 ± 263

** **NT-proBNP**: N-terminal-pro hormone B-type Natriuretic Peptide – analysed in local lab*

Study recruited severely ill heart failure patients on very high doses of oral loop diuretics

Highly effective management of fluid & sodium

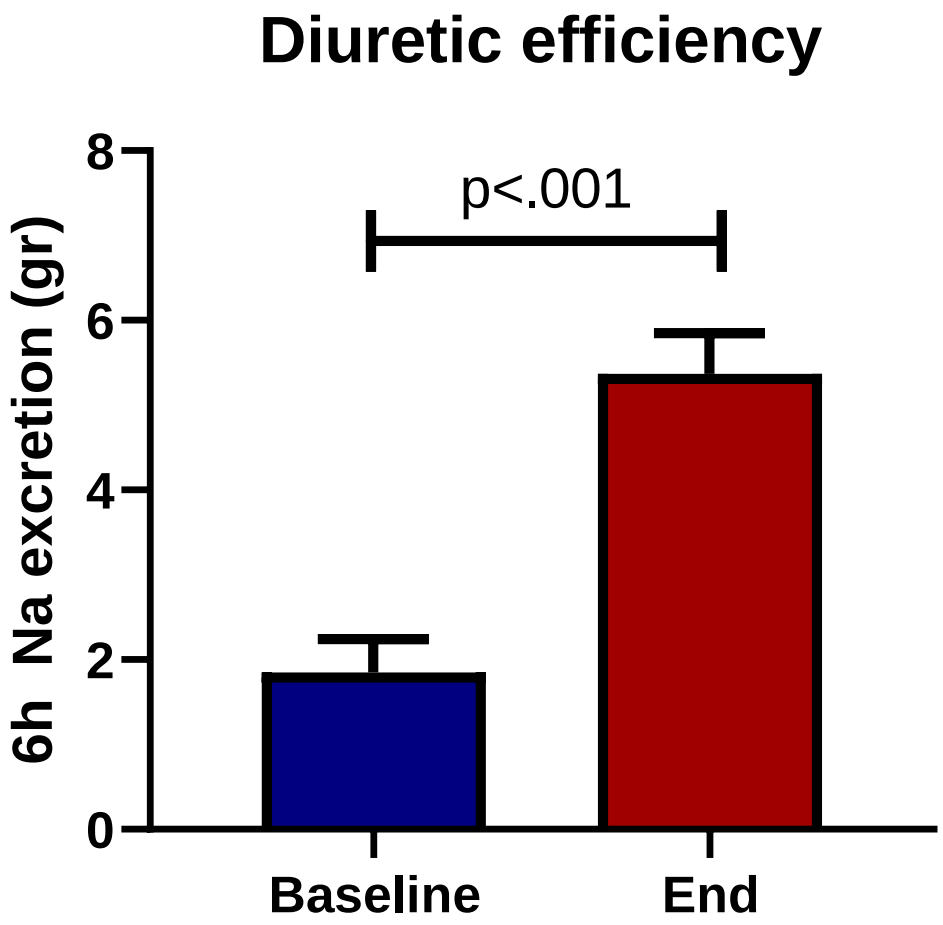
No loop diuretics required during study despite mean baseline dose of >300 mg/day furosemide equivalents

Subject	Daily Dose of loop diuretics (mg)**	
	At screening	During DSR Treatment (D0 - 42)
101-001	80	0
101-002	200	0
101-003	400	0
101-005	120	0
101-006*	80	0
101-007*	300	0
101-008*	600	0
101-009†	800	0

** in follow-up extension with DSR; † subject 101-009 died at D3*
*** loop diuretics in furosemide equivalents (mg)*

Dramatic improvement in diuretic efficiency

Over 250% increase in mean diuretic response*



** 6 hour Na excretion following administration of 40mg intravenous furosemide; paired statistical analysis of patients with baseline and D42 value (N=7)*

Long term improvement in diuretic response

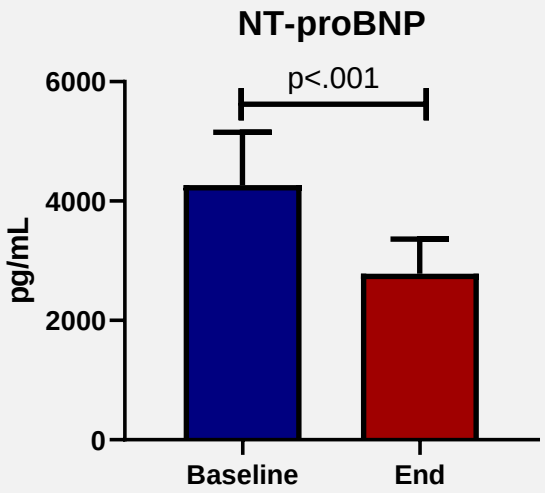
79% reduction in mean diuretic dose at median follow-up of 10 months

Subject	Daily Dose of loop diuretics (mg)***		Time since last DSR study treatment**	Current Daily dose (mg)***	Reduction in diuretic dosage
	At screening	During DSR Treatment (D0 - 42)			
101-001	80	0	12.5 months	40	**-50 %**
101-002	200	0	12.5 months	80	**-60 %**
101-003	400	0	10 months	80	**-80 %**
101-005	120	0	10.5 months	40 E3D	**-89 %**
101-006*	80	0	8.5 months	20 BIW	**-93 %**
101-007*	300	0	2 months	40 TIW	**-94 %**
101-008*	600	0	2 months	80	**-87 %**
101-009†	800	0	NA	NA	NA

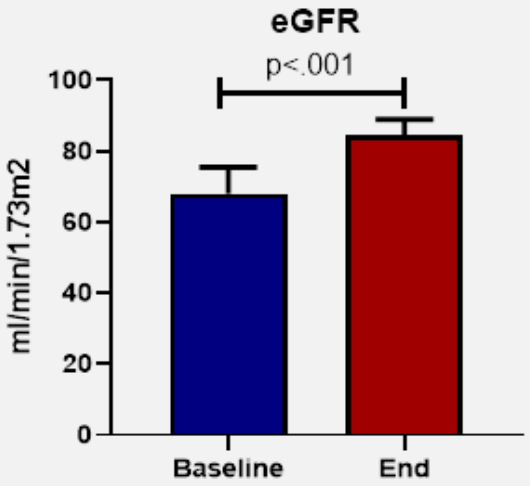
** in follow-up extension with DSR; † subject 101-009 died at D3*
*** excluding DSR treatment in follow-up extension*
**** loop diuretics in furosemide equivalents (mg)*

***E3D:** every third day; **BIW**: two times per week; **TIW:** three times per week*

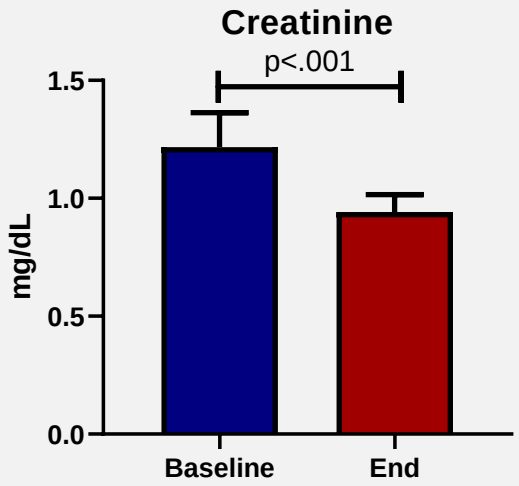
Significant improvement in cardio-renal function*



30% decrease in mean natriuretic peptides



22% increase in mean eGFR



22% decrease in mean creatinine

"The simultaneous normalisation of diuretic response and improvement in cardio-renal status of the RED DESERT patients is a never before seen treatment effect and could translate into important long-term clinical benefits in heart failure patients" – Dr. Testani

** Paired statistical analysis of patients with baseline and D42 value (N=7)*

***NT-proBNP**: N-terminal-pro hormone B-type Natriuretic Peptide (analysed in local lab); **eGFR**: estimated glomerular filtration rate*

Adverse event overview

No clinically significant changes in serum sodium levels / no progressive hyponatremia

- Study system related adverse events: 3 in 2 patients
  - 2x SAE blockage of peritoneal catheter in 1 patient
  - 1x site AE hematoma in 1 patient
- Therapy related adverse events: 1 in 1 patient
  - 1x AE abdominal discomfort during pumping phase in 1 patient
- Implant procedure related adverse events: 2 in 2 patients
  - 1x AE site hematoma in 1 patient (see above “Study System related AE”)
  - 1x AE hematuria in 1 patient
- Other SAEs: 2 in 2 patients
  - 1x SAE TIA in 1 patient (D29 - D35)
  - 1x SAE Cardiac Arrest 1 patient (D3)

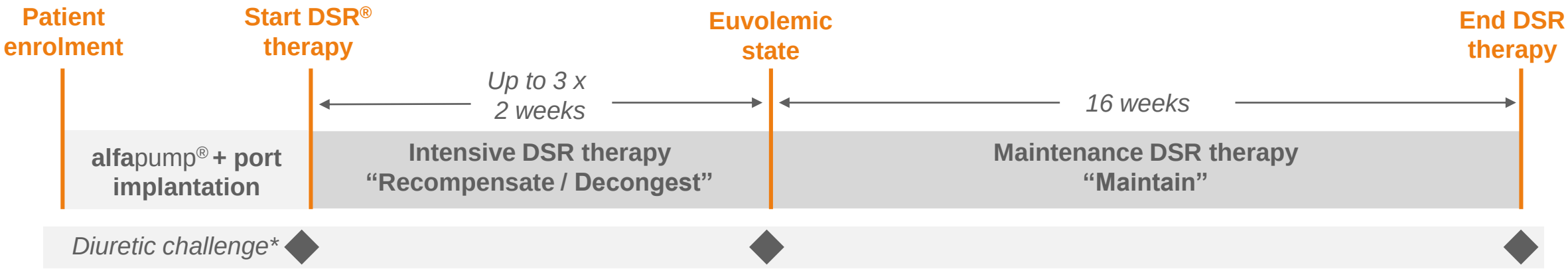
DMC: possibly related to study therapy/procedure but unlikely related to device

Site PI: not related to study therapy, procedure or device

SAE: *Serious Adverse Event;* ***AE:*** *Adverse Event;* ***TIA:*** *Transient Ischemic Attack;* ***DMC****: Data Monitoring Committee;* ***PI:*** *Principal Investigator at site in Georgia*

SAHARA DESERT – On track to start in Q2 2021

20 decompensated heart failure patients with residual congestion on high doses of loop diuretics



Study Endpoints

- **Primary:** safety and tolerability of **alfa**pump DSR® therapy
- **Secondary:** feasibility of DSR therapy to restore and maintain euvolemia without additional loop diuretics
- **Exploratory:** evaluate potential impact of SGLT-2 inhibitors on DSR therapy**

Interim results expected Q4 2021 / Top-line results expected H2 2022

** 40 mg intravenous furosemide to evaluate diuretic response (6 hour sodium and fluid excretion)*

*** patients will be randomised 1:1 to DSR therapy +/- SGLT-2 inhibitor therapy*

Development of proprietary DSR® Infusate 2.0 ongoing

- D10% was chosen as the initial DSR infusate for fastest proof-of-concept
- We are developing our proprietary next-generation DSR infusate:

- ✓ Improved therapeutic profile compared to D10%
- ✓ IP protected
- ✓ Recurring revenue from high gross margin consumable

Note: This image is intended for illustration purposes only

- Pre-clinical development work ongoing & preparing for CMC activities

***CMC**: Chemistry, Manufacturing and Controls*

Short-term DSR® – Expanding development programme

Building upon the success of RED DESERT to extend and strengthen the DSR franchise

Short-term DSR therapy:

- "one off" ~2 weeks intensive DSR treatment
- With peritoneal catheter (w/o **alfa**pump®)

Long-term alfapump DSR® therapy:

- Intermittent, recurring, intensive DSR treatment
- With **alfa**pump

Faster adoption by clinical community

Support **alfa**pump DSR market entry

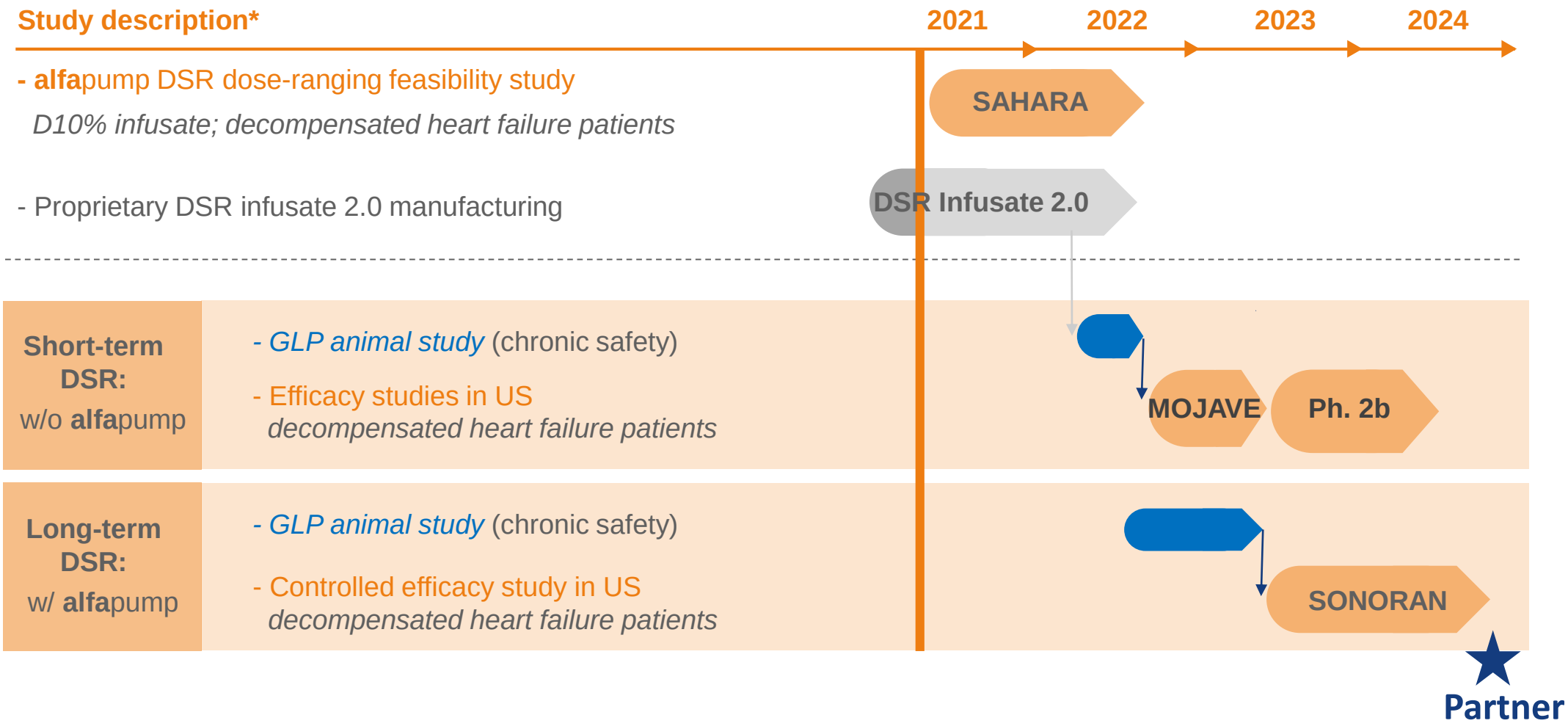
Expand potential market opportunity

Target earlier entry into the US

Both DSR therapies will target diuretic-resistant heart failure patients with residual congestion and aim to restore patients' diuretic response and cardio-renal status

DSR® and alfapump DSR® development strategy

Short-term DSR therapy extends portfolio



* *Timelines subject to further developments related to the ongoing COVID-19 pandemic*
Description and timing of these studies are subject to change and/or feedback from applicable regulatory authorities

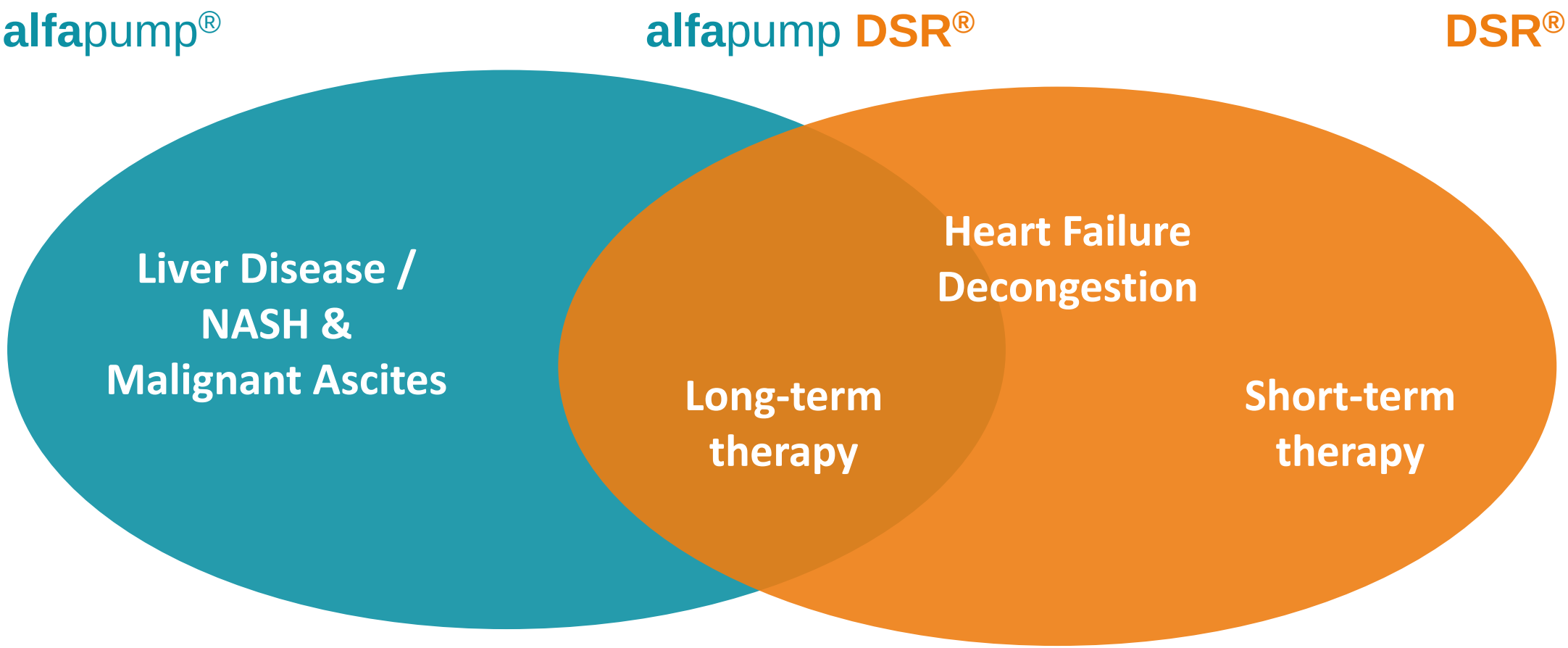
Evaluating potential for DSR® in renal failure

Complementary opportunity leveraging heart failure programme capabilities

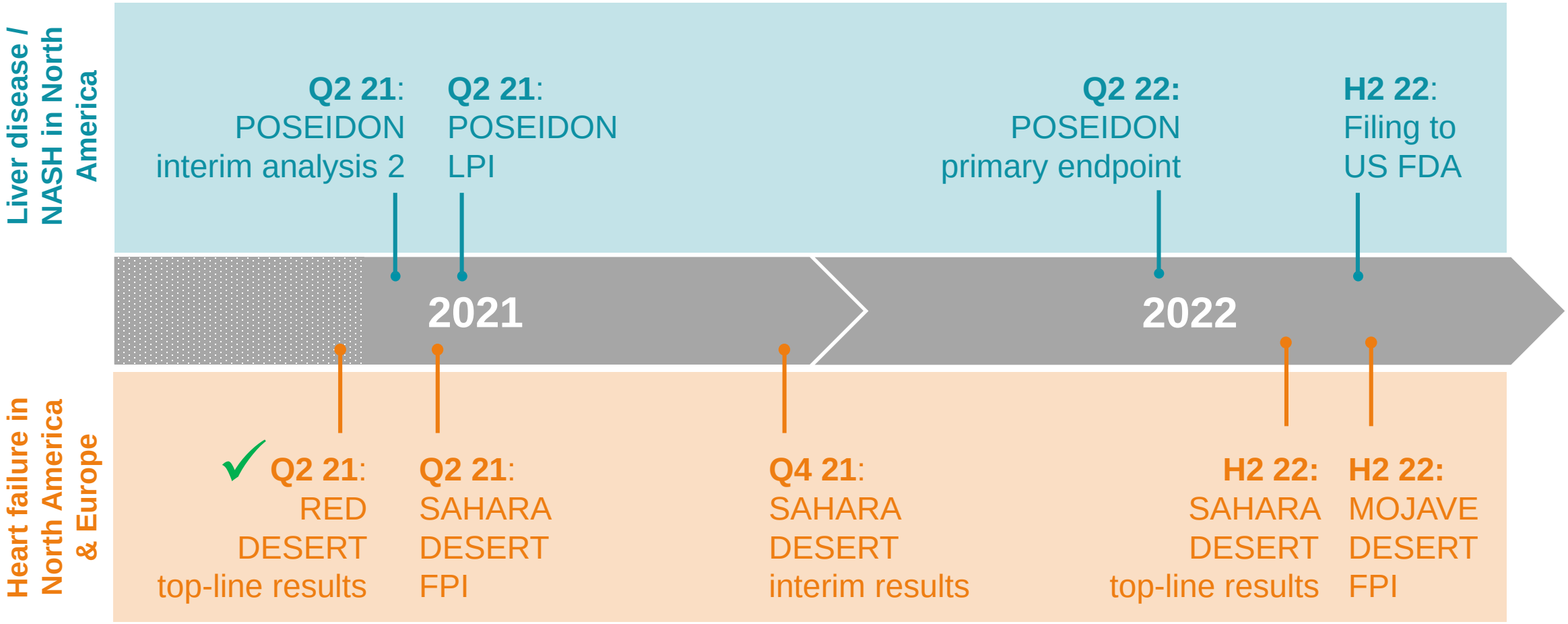
- Like heart failure, kidney failure / dialysis is one of the leading burdens for healthcare systems and carries a high mortality / morbidity burden
- Hemodialysis seeks to tackle two different challenges – removal of uremic toxins as well as managing the sodium and fluid balance – creating clinical and economic challenges
- DSR therapy has the potential to more effectively manage the fluid and sodium balance of this large patient group
  - ⇨ Leveraging all of our experience from congestion / fluid overload in heart failure
- We are exploring the potential of DSR in this large and important patient group, potentially reducing hospitalisations, the cost and burden of hemodialysis therapy as well as mortality
  - ⇨ Supporting work of Dr McIntyre (Lawson Health Research Institute, Ontario, Canada): evaluating the use of DSR therapy in effective volume management and sodium removal in prevalent hemodialysis patients (NCT04603014)

Building Sequana Medical on Two Platforms

Complementary approaches to diuretic-resistant fluid overload



Expected core value drivers & outlook



Note: Presented timelines are subject to further developments related to the COVID-19 pandemic

FPI: First Patient In; LPI: Last Patient In

Q&A