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Innovators in the treatment of diuretic-resistant fluid overload

liver disease – malignant ascites – heart failure

Needham Virtual Healthcare Conference

Ian Crosbie, CEO – 12 April 2021

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.

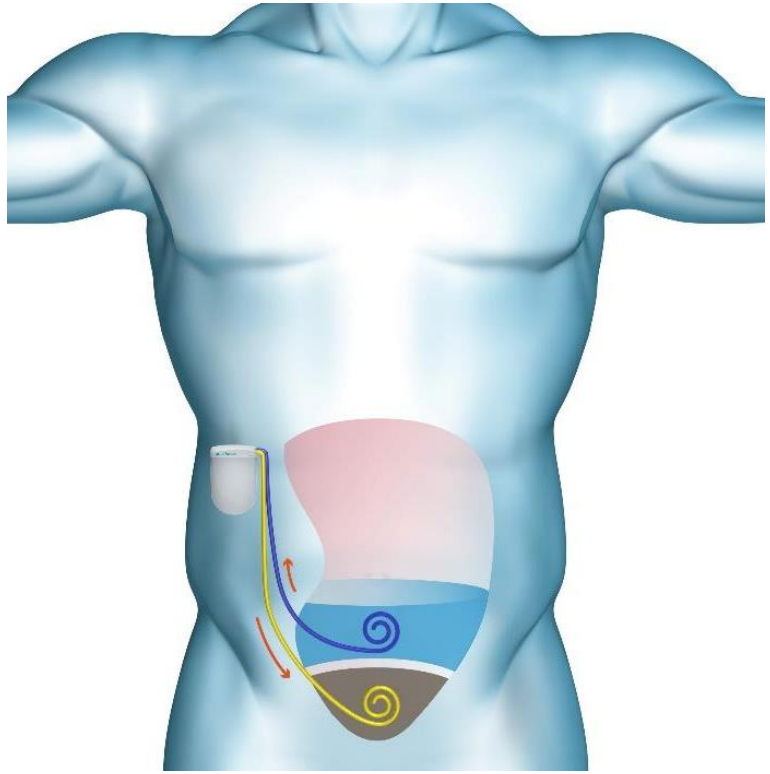
Sequana Medical NV

- Founded in 2006
- Gent, Belgium (HQ): corporate, clinical, commercial
- Zurich, Switzerland: manufacturing, engineering, QA/RA
- ~50 employees
- Euronext Brussels: SEQUA

alfapump® platform

Using the bladder to treat fluid overload

- Fully implanted
- Automatic operation
- Wireless battery charging
- Settings wirelessly adjusted
- Remote data monitoring



- Easy implantation
- Long-term implantation & catheter patency
- Moves up to 4 litres / day
- Virtually non-clogging
- No significant heating during charging and operation

Strong IP barriers through extensive patent portfolio & know-how

One platform – two products – € billion opportunities

alfapump®

Liver Disease (NASH)

Proven step change in liver refractory ascites and malignant ascites

Over 850 devices implanted

> €3 Bn / year market opportunity(1)

POSEIDON pivotal study ongoing

Self-commercialisation

alfapump DSR®

Heart Failure

Breakthrough approach to fluid overload in heart failure

Clinical proof-of-concept of Direct Sodium Removal (DSR®)

> €5 Bn / year market opportunity(2)

RED DESERT repeated dose study ongoing

Partnering after US efficacy study

Built upon proven European clinical & commercial experience

Source 1: Management estimate in US within 10-20 years, that is inclusive of estimated growth in prevalence of NASH for the US based on GlobalData Epidemiology Forecast to 2026
Source 2: Management estimate in US & EU by 2026 based on GlobalData Heart Failure Epidemiology Forecast to 2026; Costanzo et al. (2007). Kiglore et al (2017)

NASH drives US market attractiveness

Stronger competitive position in a much larger and dynamic market

alfapump® market potential	~€0.4 Bn / year	>€3 Bn / year
Underlying disease	Alcoholic Liver Disease, Hepatitis	**NASH**
Patient characteristic	“Outside mainstream”	**“Mainstream”**
Average age	40-50 yr	**70 yr+**
alfapump competitive positioning	✓	✓✓

Notes: current estimated EU Liver market: Data from 1980-2010, death rates between 9-12.4 per 100,000; Mokdad et al., 2014, Management estimates of 7.5% cirrhosis patients that die per year based on experts feedback.
forecast US Liver market: Management estimate that is inclusive of estimated growth in prevalence of NASH for the US based on GlobalData Epidemiology Forecast to 2026.

alfapump®

Proven step change in the management of liver refractory ascites and malignant ascites

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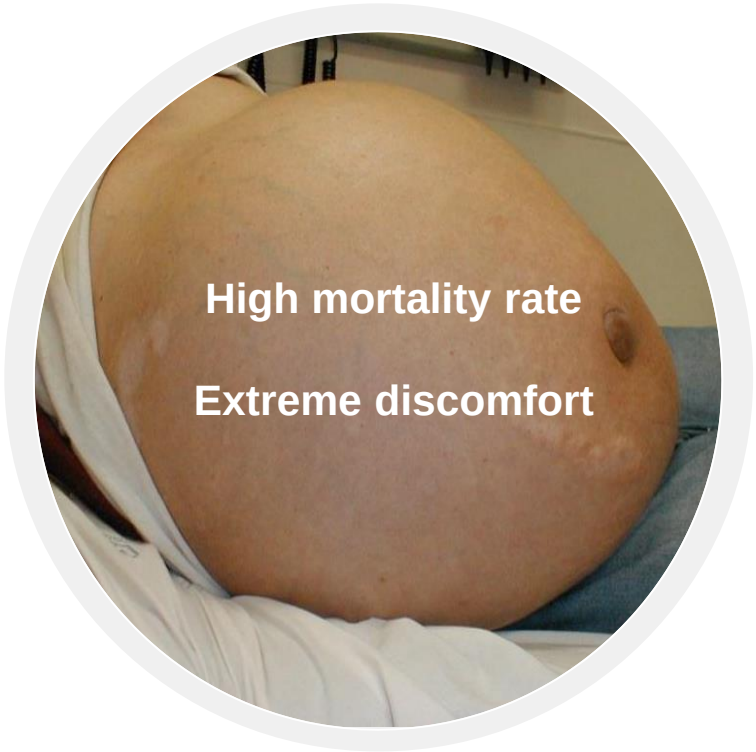
Liver cirrhosis and refractory ascites

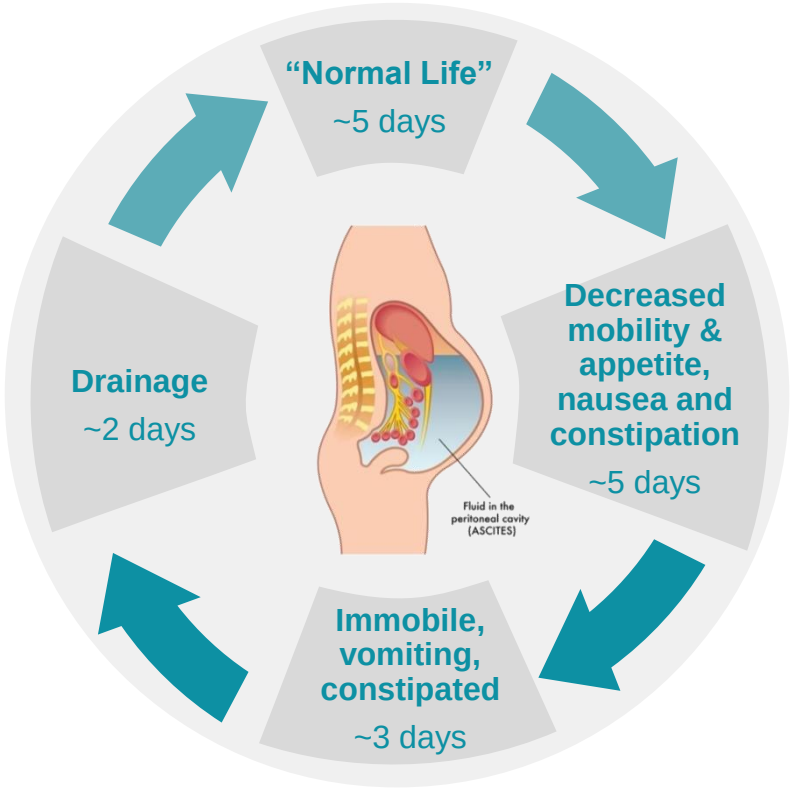
A key complication of liver cirrhosis, with a dramatic impact on quality of life

Viral infections (Hepatitis B & C)

Alcoholic Liver Disease

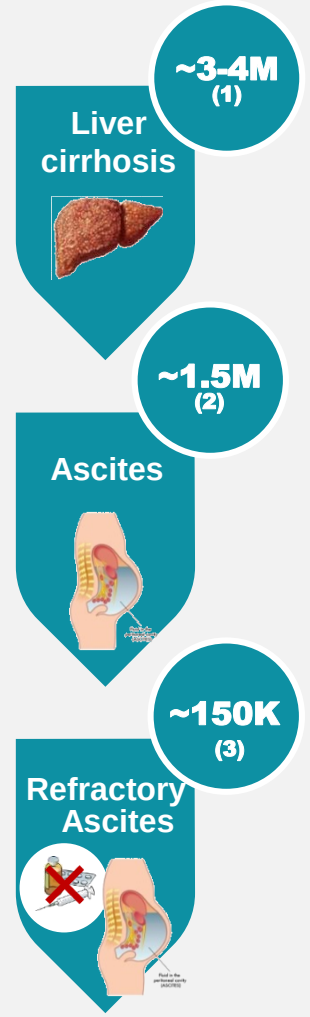
Non-Alcoholic Steatohepatitis (NASH)





Typical patient life(4)

US forecast



Note : Prevalence of NASH in US is expected to increase by 63% between 2015-2030; Estes et al., 2018

Source 1 Management estimate in US based on Estes et al; GlobalData Nash Epidemiology Forecast to 2026; Noureddin et al., 2013
Source 2: Runyon 2009: approximately 50% of cirrhotic patients develop ascites within 10 years of diagnosis of cirrhosis
Source 3: Ginès et al., NEJM 2004: refractory ascites occurs in 5-10% patients with ascites
Source 4: Presentation of Dr. Rajiv Jalan at EASL in 2018, Large Volume Paracentesis (LVP) treatment cycle for refractory ascites

Cancer and malignant ascites

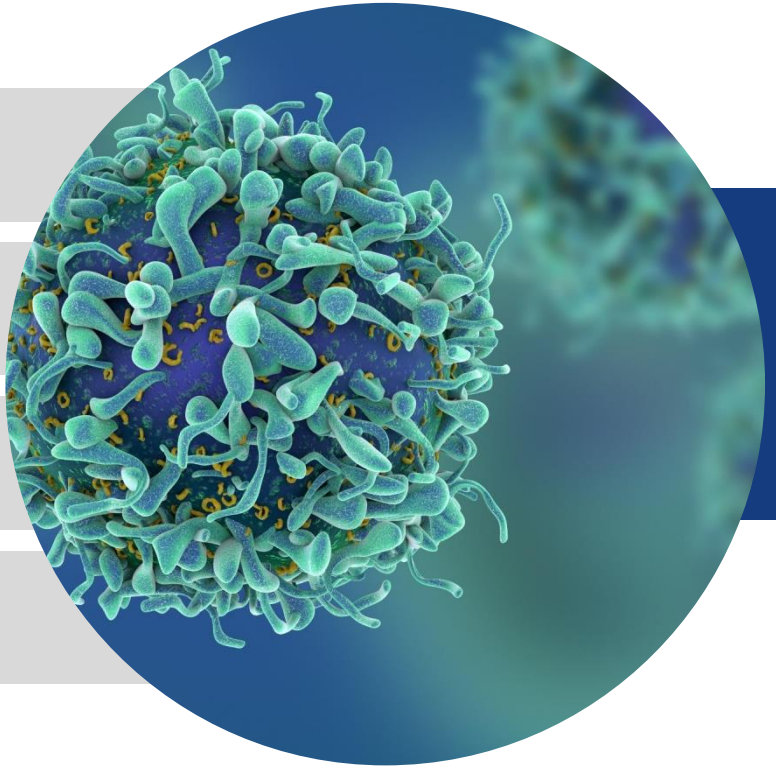
Severe complication of late-stage cancers

Fluid accumulation in the abdomen due to **drainage of lymph system**

Breast and ovarian cancer have longest survival with ascites(1)

Severe impact on **quality of life**

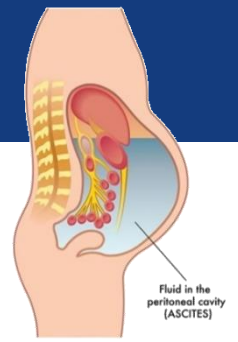
Reduces ability to undergo **anti-cancer treatment**



Malignant ascites due to breast and ovarian cancer(2):

EU5: ~18K

US: ~16K



Clear unmet need for improving Quality of Life and the ability to increase cancer treatment intensity

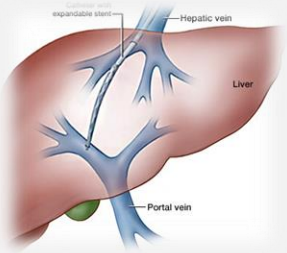
Source 1: Ayantunde & S. L. Parsons. Annals of Oncology 2007
Source 2: Management estimate based on WHO cancer incidence rates (2018) and Ayantunde & S. L. Parsons. Annals of Oncology 2007.

Severe limitations of existing therapies

Diet / Diuretics

Resistance,
Complications

Transjugular Intrahepatic Portosystemic Shunt (TIPS)

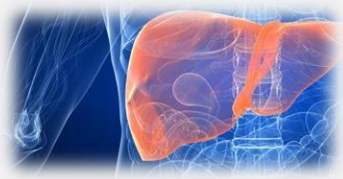


Complications,
Contraindications

Drainage (“Large Volume Paracentesis / LVP”)

Painful, Poor Quality of Life, Short Term Benefit

Liver transplantation



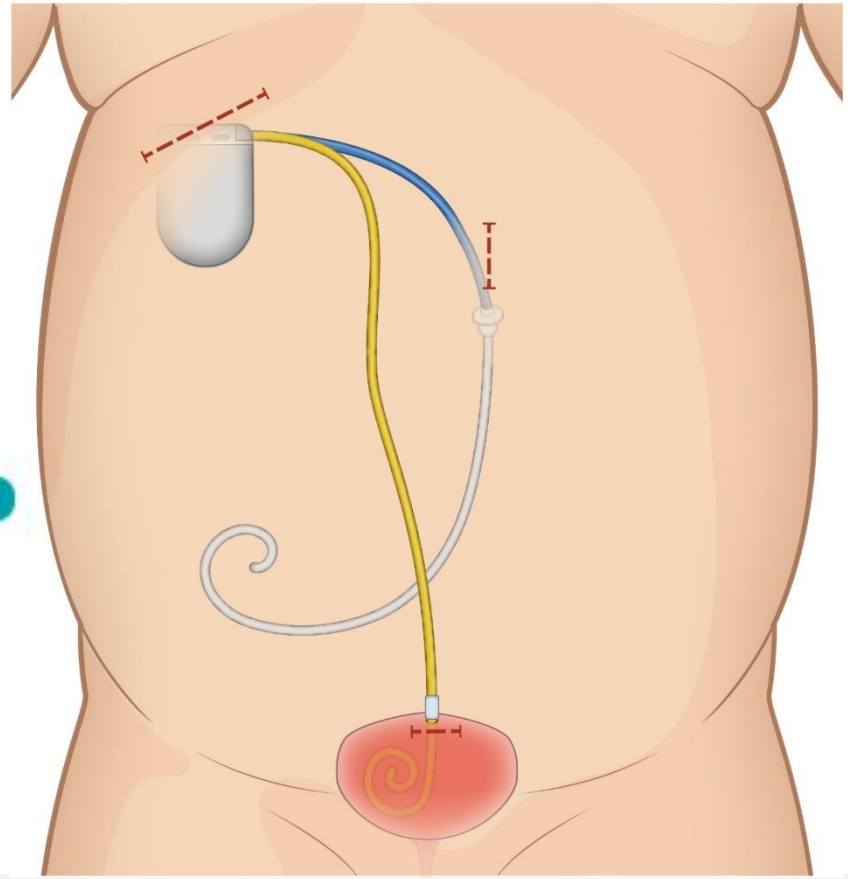
High Cost,
Limited Availability

alfapump®

alfapump® for long-term treatment

Over 850 implants and hundreds of years of patient experience

DirectLink Technology



CE

EASL The Home of Hepatology

NICE National Institute for Health and Care Excellence

1913 DGVS Deutsche Gesellschaft für Gastroenterologie, Verdauungs- und Stoffwechselkrankheiten

FDA **Breakthrough Device** Designation

Strong clinical and economic rationale

- Reduced burden of disease
- Improved patient QoL
- Cost savings for hospitals and payers

Estimated treatment cost / patient*:

LVP: ~$54K	**alfa**pump®**: ~$35K**
~$1,8K / LVP(1)	~$25K / **alfa**pump
2 LVP / month	~$10K / implantation
15 months	

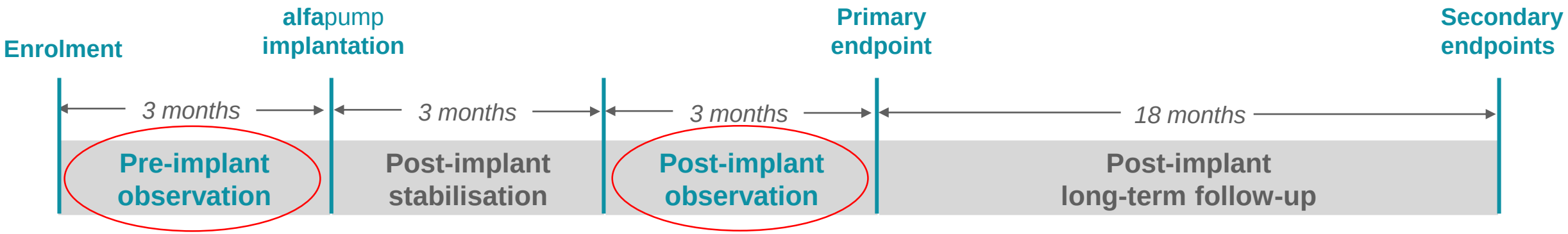
** Management estimate of US treatment costs, assuming no complications*

QoL: Quality of Life; LVP: Large Volume Paracentesis

Source 1: Kwan et al., J Vasc Interv Radiol 2018

North American Pivotal Study (POSEIDON) underway

Pivotal Cohort of up to 50 patients implanted; Roll-In ("training") cohort of up to 30 patients



POSEIDON Study Endpoints	
Primary efficacy:	1) 50% reduction in average monthly frequency of Therapeutic Paracentesis ("TP") post-implant vs. pre-implant
	2) 50% of patients achieve a 50% reduction in the requirement for TP post-implant vs. pre-implant
Primary safety:	Rate of **alfa**pump related re-interventions adjudicated by the Clinical Events Committee (CEC)
Secondary:	QoL (SF36, Ascites-Q), nutritional status, health economics, safety (device and/or procedure-related AEs), survival

***QoL**: Quality of Life; **AE:** Adverse Event*

POSEIDON Interim Data: Positive for primary endpoints

Data from first 13 Roll-In patients

EFFICACY

Mean values post-implant vs. pre-implant	N = 13
Reduction in frequency of TP	> 90%
Patients with >50% reduction in TP	100%

SAFETY

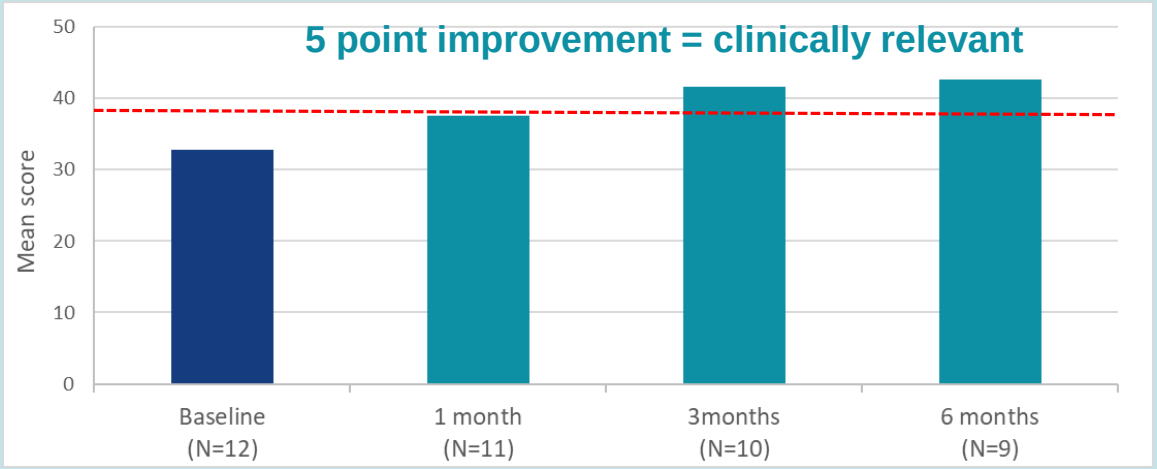
- Safety profile of the **alfa**pump consistent with previously reported data
- Adjudication process by the Clinical Events Committee for two **alfa**pump® explants ongoing

Note: Pre- and post-implant periods for this analysis of the Roll-In Cohort differ from those that will be used for the Pivotal Cohort analysis

Quality of Life: Indication of fast and persistent improvement

SF-36

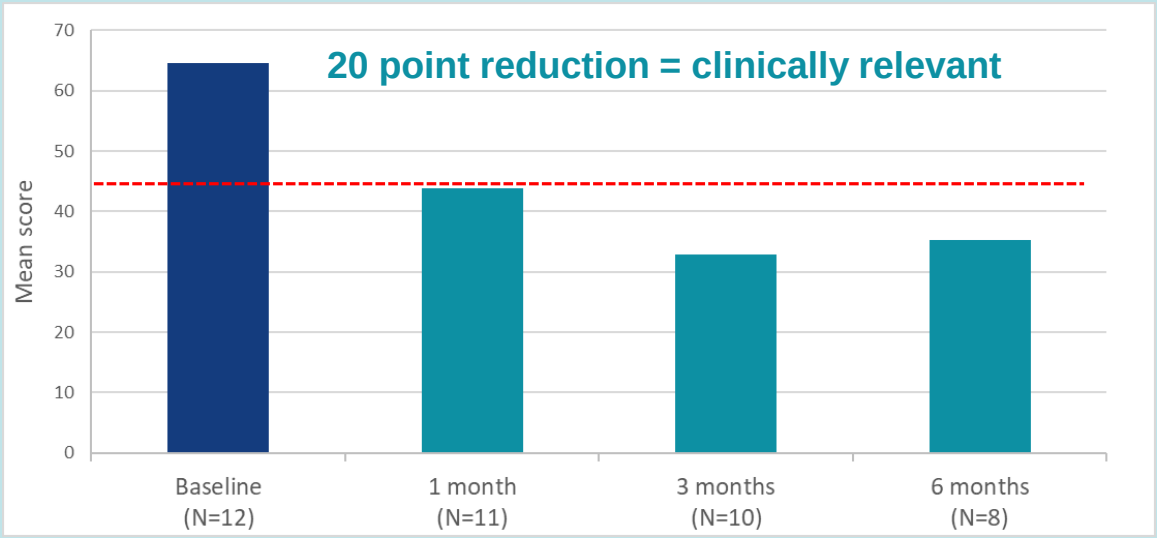
General health-survey questionnaire



Higher is better

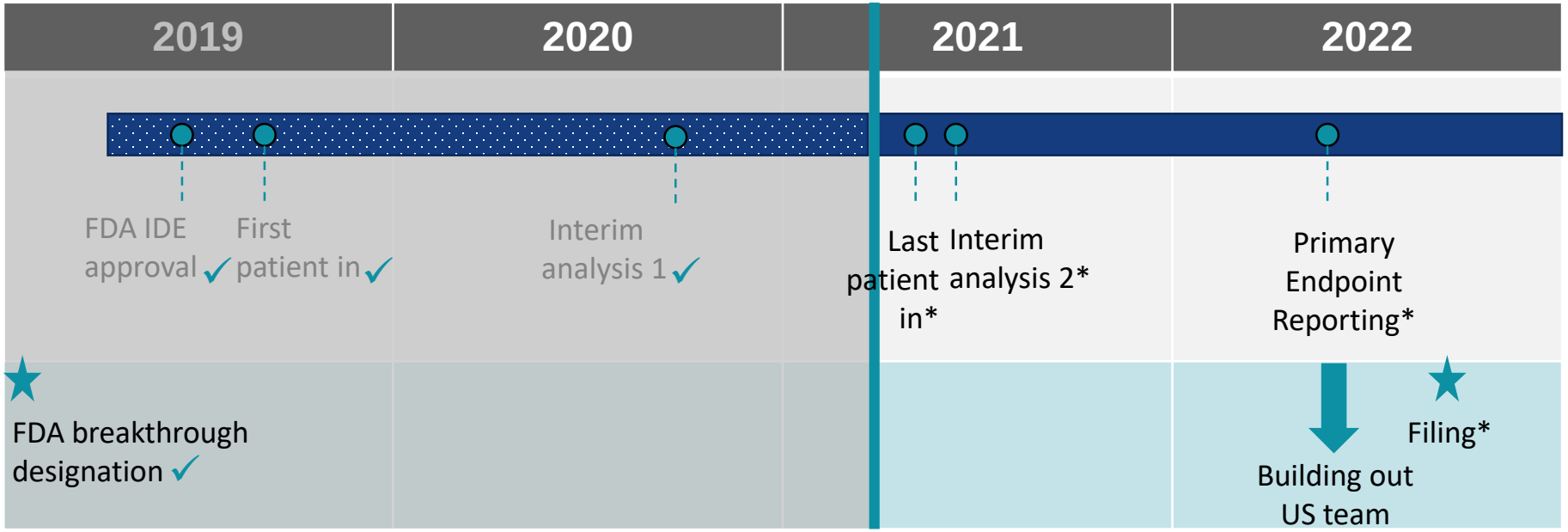
Ascites Q

Specific health-survey questionnaire for ascites



Lower is better

Targeting announcement of primary endpoint in Q2 2022

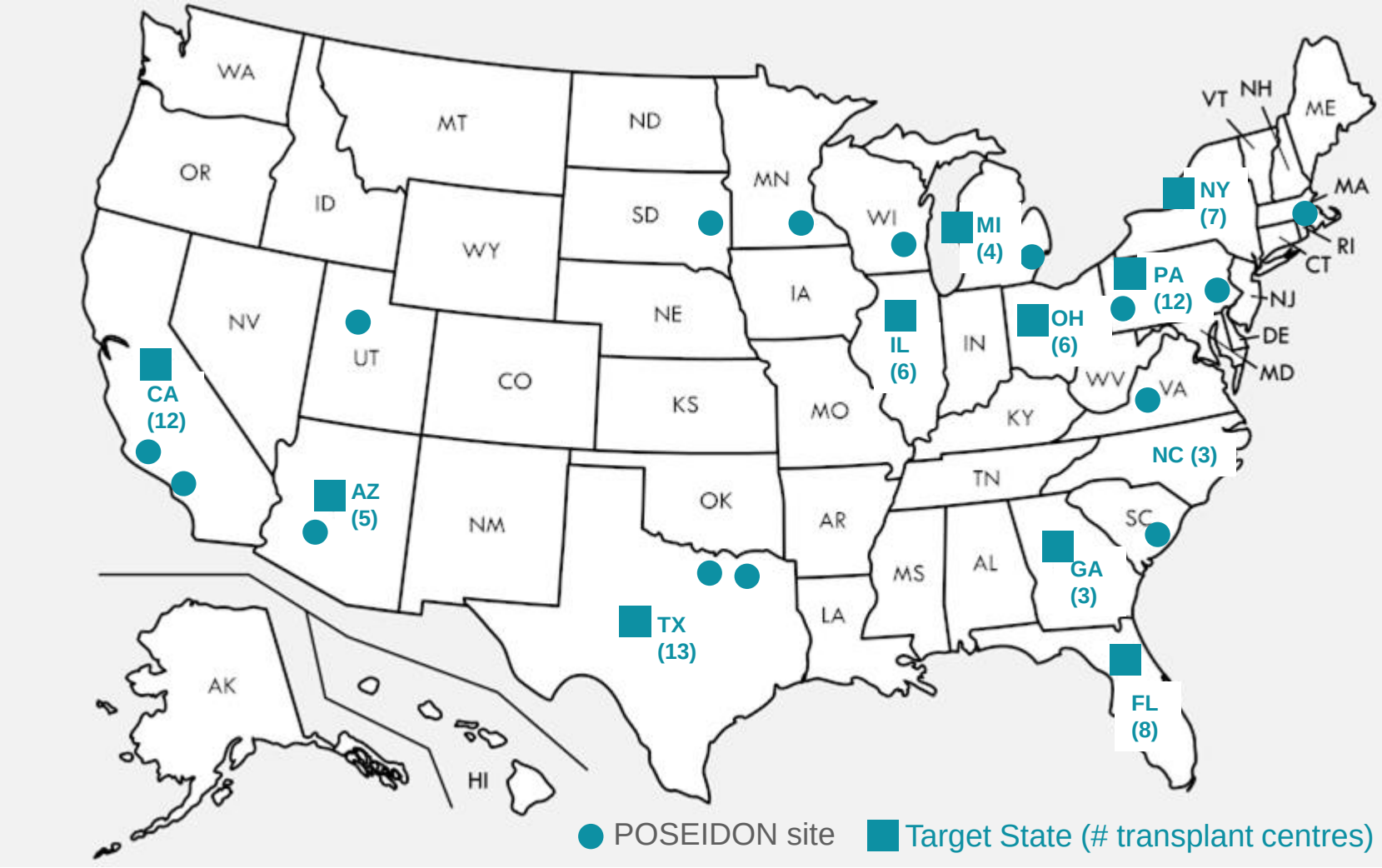


*MCIT & NTAP – final CMS rules for breakthrough devices to further support coverage & reimbursement for the **alfa**pump*

* *Subject to further developments related to the ongoing COVID-19 pandemic*

FDA: Food and Drug Administration (US); IDE: Investigational Device Exemption

US commercialisation through our specialty salesforce



Initial focus on key transplant centres

~50-person team:

35 sales reps, 10 clinical, 5 corporate

alfapump DSR®

Breakthrough approach to **fluid overload in heart failure** built on proven **alfa**pump® platform

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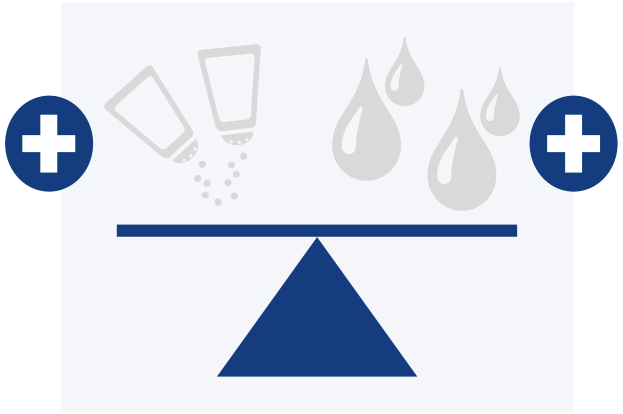
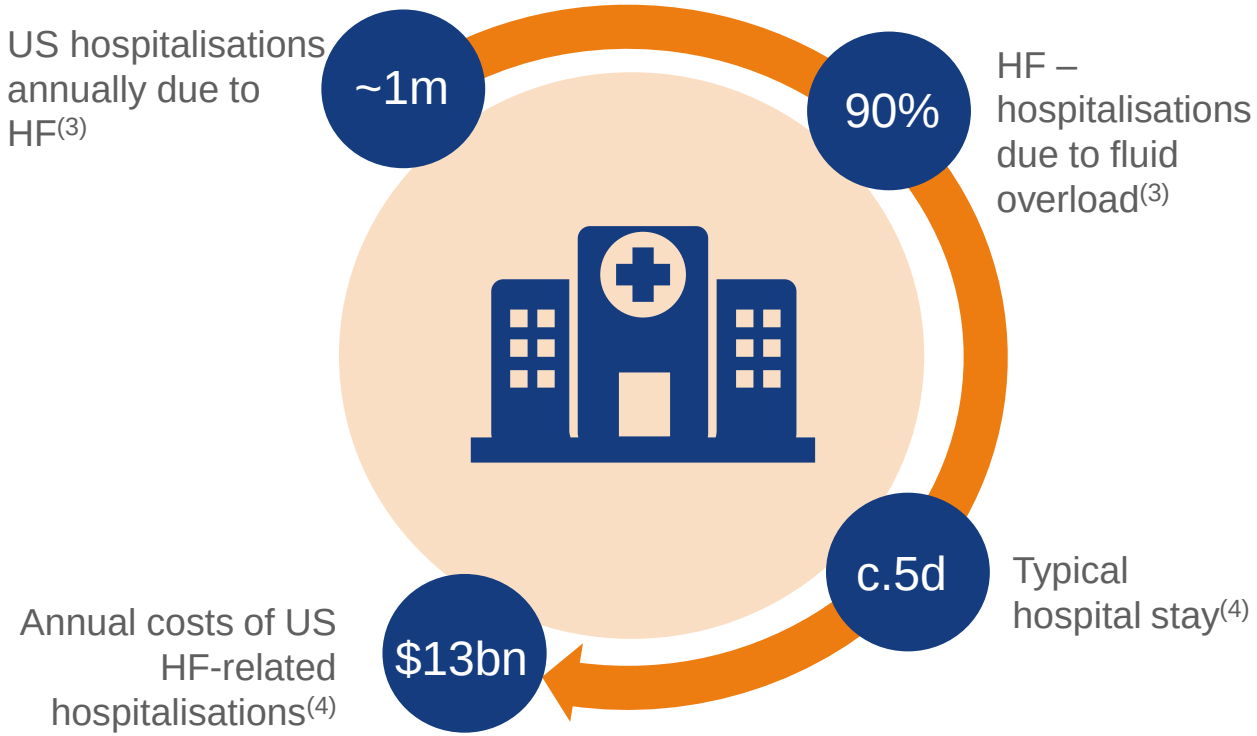
Diuretic-resistant fluid overload in heart failure

Key clinical challenge and driver of costs



Excess sodium drives fluid overload



- *40% of heart failure patients on IV loop diuretics have a poor response(1)*
- *24% re-admission rate at 30 days(2)*

Source 1: Testani, Circ Heart Failure, 2014 & 2016; Source 2: Ross et al. (2010); Source 3: Costanzo et al., J. Am. Coll., 2007; Source 4: Kilgore et al. (2017)

Direct Sodium Removal (DSR®)

Proprietary approach to fluid overload – supported by interim RED DESERT clinical data

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

DSR therapy directly removes the sodium

Body eliminates excess fluid

"DSR represents a new potential therapy for non-renal sodium and fluid removal in edematous disorders such as heart failure"

Circulation

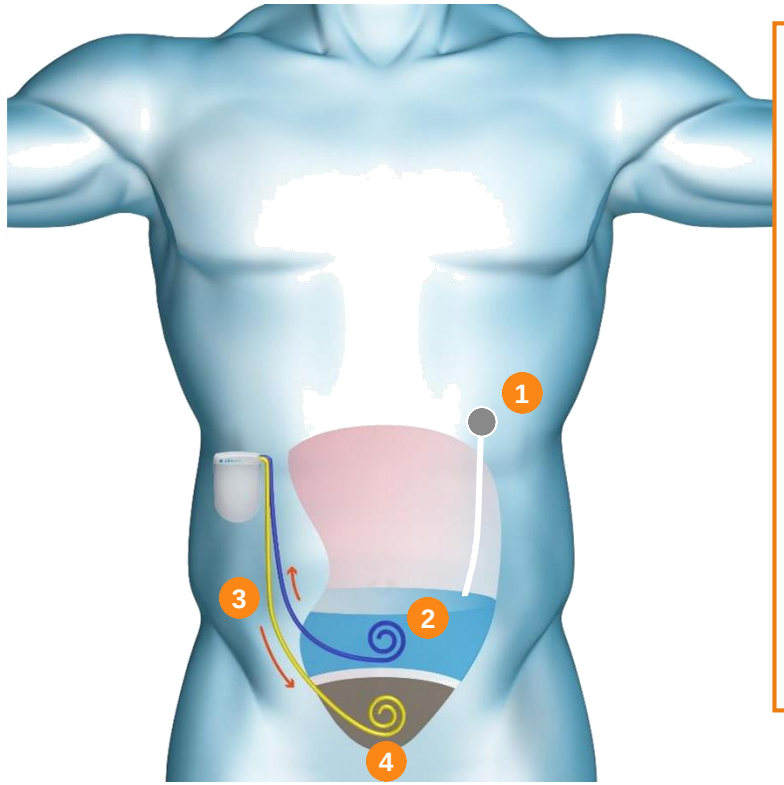
First in Human Experience with Peritoneal Direct Sodium Removal Using a Zero Sodium Solution: A New Candidate Therapy for Volume Overload

Veena S. Rao, Jeffrey M. Turner, Matthew Griffin, Devin Mahoney, Jennifer Asher, Sangchoon Jeon, Peter S. Yoo, Nabil Boutagy, Attila Feher, Albert Sinusas, F. Perry Wilson, ... **Show all Authors**

Originally published 8 Jan 2020 | https://doi.org/10.1161/CIRCULATIONAHA.119.043062 | Circulation. ;0:null

alfapump DSR®

Potential chronic therapy for diuretic-resistant heart failure patients with fluid overload

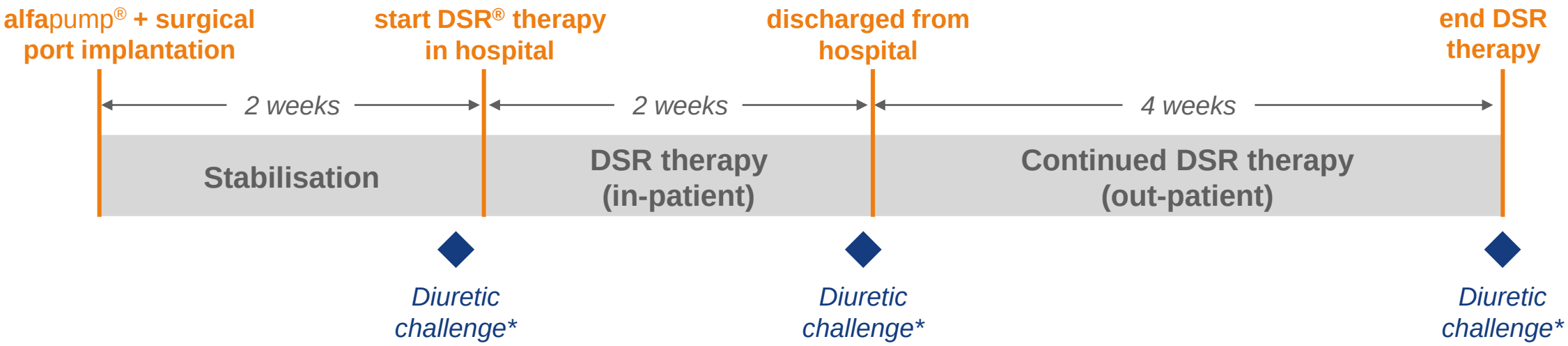


1. Sodium-free DSR® infusate administered to peritoneal cavity via implanted port
2. Sodium diffuses into DSR infusate
3. **alfa**pump pumps sodium-rich DSR infusate into the bladder
4. Body eliminates excess fluid through osmotic ultrafiltration and urination

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

RED DESERT: Study design

Repeated dose proof-of-concept study of alfapump DSR® in diuretic-resistant heart failure patients



✓ ***Positive interim results (5 patients) reported***

Top-line results (up to 10 patients) expected in Q2 2021

* intravenous dose of 40mg dose furosemide

Interim RED DESERT: Strong safety & efficacy results

Results from first five patients

SAFETY

- Implant procedure of **alfa**pump DSR® and repeated dosing of DSR® therapy were well-tolerated
- No clinically significant changes in serum sodium levels / no progressive hyponatremia
- Reported adverse events were manageable

EFFICACY

- No diuretics required in any of the patients during 6-week **alfa**pump DSR treatment
- Reduced doses of DSR therapy and / or less frequent DSR dosing in majority of patients
  ⇨ maintaining stable to lower weight and NT-proBNP compared to baseline

Interim RED DESERT: Restored normal kidney response

Results from first five patients

- **Diuretic response restored to near normal levels**
  - Sodium excretion more than doubled after DSR study period (to near normal levels)

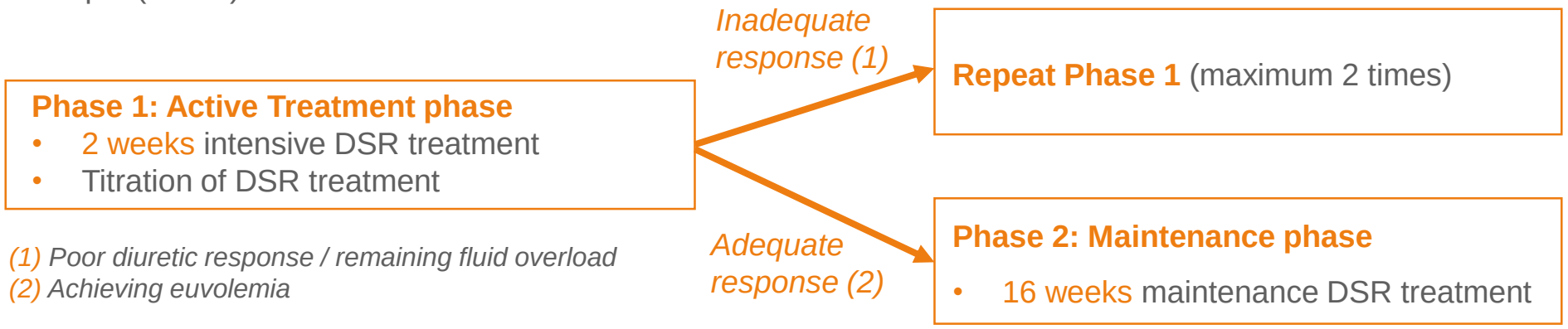
- **Long-lasting improvement in diuretic responsiveness**
  - Dramatic reduction in oral loop diuretic dosage in majority of patients at end of DSR study period
  - Major reduction in oral diuretic dosage vs baseline even months after end of DSR study period

- ***Indicates DSR therapy is more than just a means to remove sodium and water***
- ***Supports intermittent dosing to restore natural kidney response***
- ***Potential expansion into other fluid overload indications***

SAHARA DESERT: Study design

Dose-ranging study to investigate improvement in diuretic response and durability of effect

- 20 decompensated heart failure patients with residual congestion, implanted with **alfa**pump DSR®
  - Group 1 (N= 10): DSR treatment plus standard dose of SGLT2-inhibitor
  - Group 2 (N= 10): DSR treatment



(1) Poor diuretic response / remaining fluid overload
(2) Achieving euvolemia

- Study objectives:
  - 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 treatment

- ***First patient expected in Q2 2021***
- ***Interim results expected in Q4 2021 / Top-line results expected in H1 2022***

Developing high value proprietary DSR® Infusate

- 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

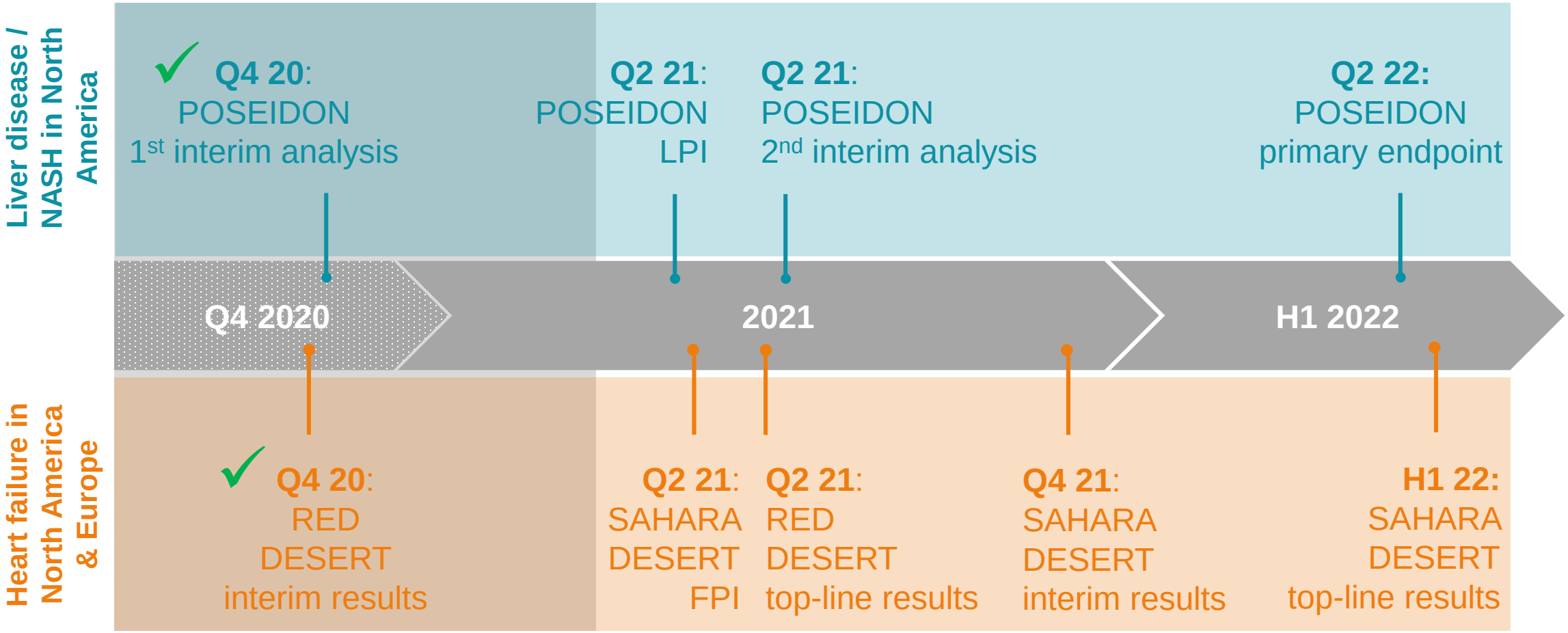
Note: This image is intended for illustration purposes only

Outlook

Strong **near term value drivers**

with clear **long term potential**

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

Thank You

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