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alfapump®
POSEIDON interim analysis 1

Webcast presentation – 19 November 2020

Today's presenters

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Disclaimers

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Disclaimers

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 liver cirrhosis. For more information regarding the POSEIDON clinical study see www.poseidonstudy.com.
- The DSR therapy is still in 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. The DSR therapy is not currently approved for clinical research in the United States or Canada. There is no link between the 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 its operations as necessary.
- Sequana Medical has put in place mitigation plans to minimise delays. The impact of increased demands on the healthcare systems, restrictions 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.

POSEIDON interim analysis 1
Positive outcomes against all primary endpoints

Results from first 13 patients in Roll-In Cohort of North American pivotal alfapump® **study**

- ✓ Over 90% reduction in mean frequency of therapeutic paracentesis (TP) post-implant vs. pre-implant
- ✓ All patients at least a 50% reduction in the mean frequency of TP per month
- ✓ Indication of rapid and persistent clinically relevant improvement in patients' quality of life
- ✓ Safety profile in line with expectations
- ✓ Results of the full Roll-In Cohort expected in H1 2021

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

Liver cirrhosis and recurrent or refractory ascites

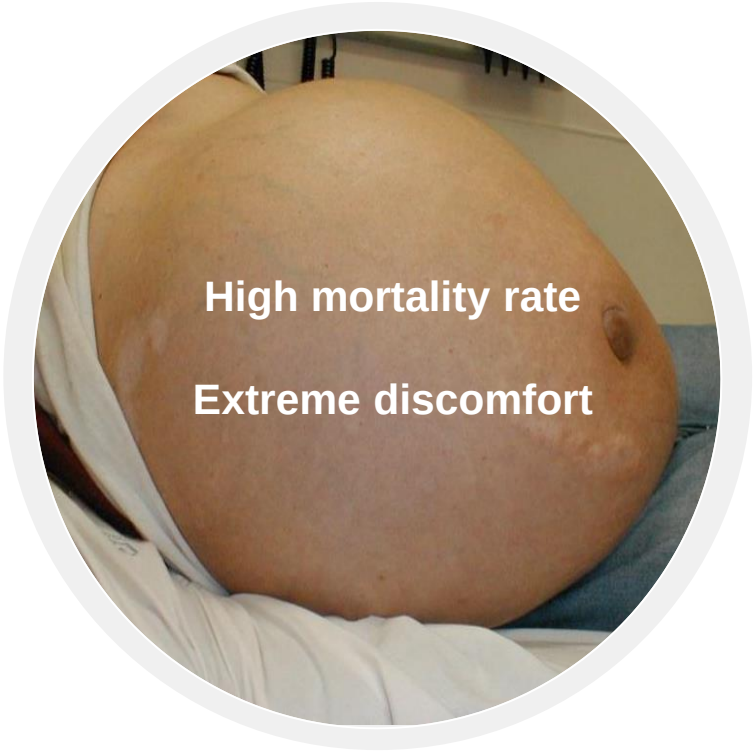
Recurrent or refractory ascites is a key complication of liver cirrhosis, with a dramatic impact on quality of life

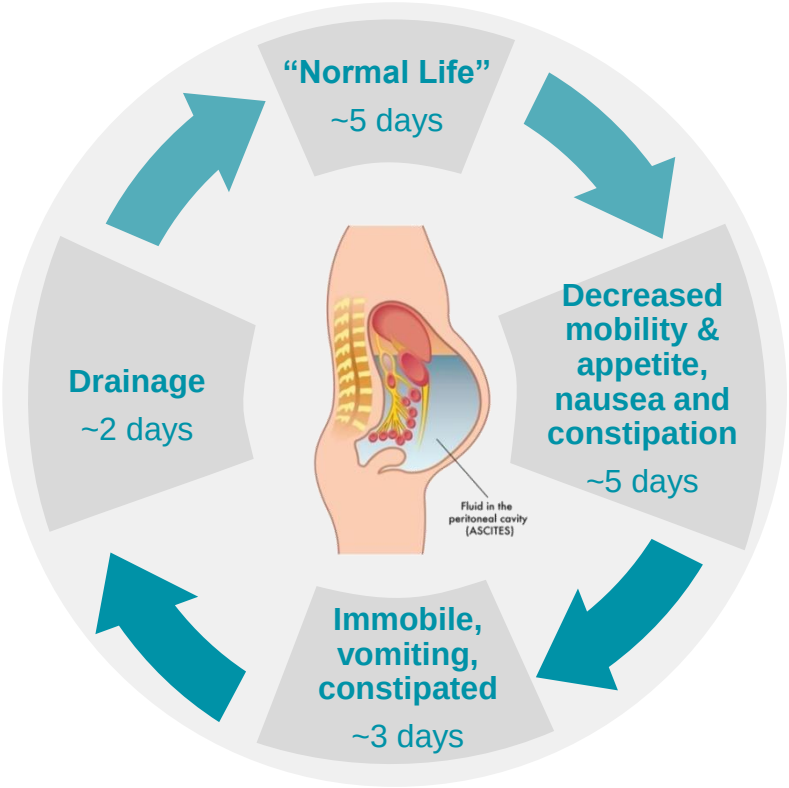
Viral infections (Hepatitis B & C)

Alcoholic Liver Disease

Non-Alcoholic Steatohepatitis (NASH)

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

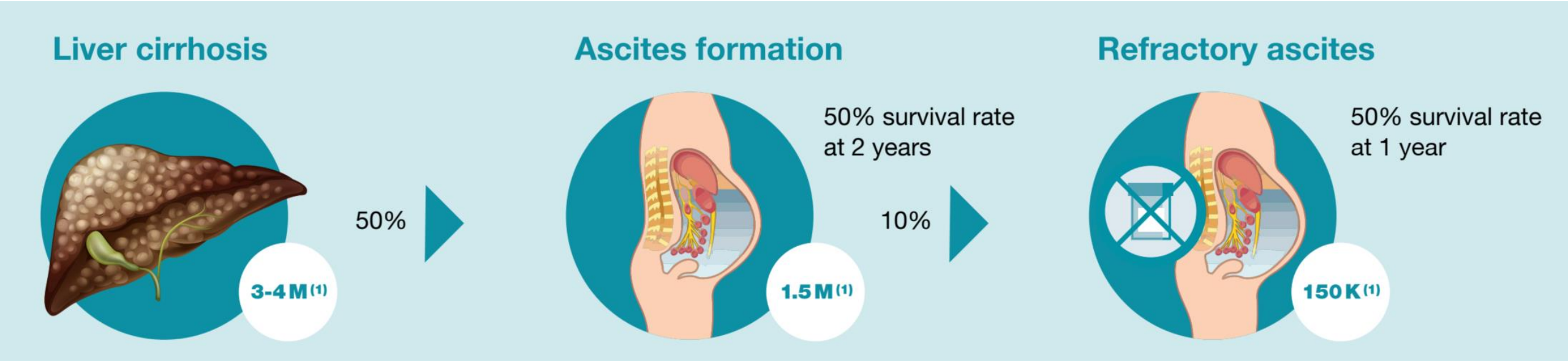




Typical patient life*

** Presentation of Dr. Rajiv Jalan at EASL in 2018, Paracentesis ("drainage") treatment cycle for refractory ascites*

US prevalence of NASH is large and growing

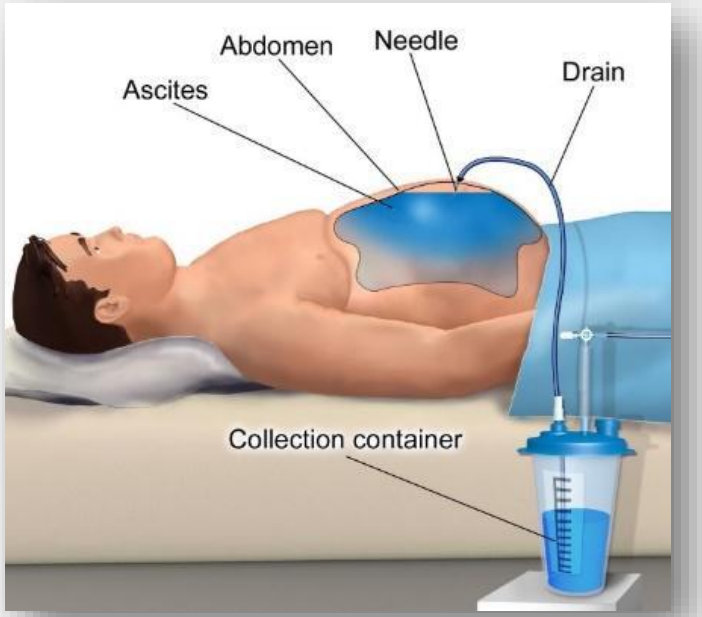


(1) US population forecast due to NASH

Sources: GlobalData Nash Epidemiology Forecast to 2026; Estes (2018); Runyon (2009); Ginès (2004); Fortune (2017); Perri (2013)

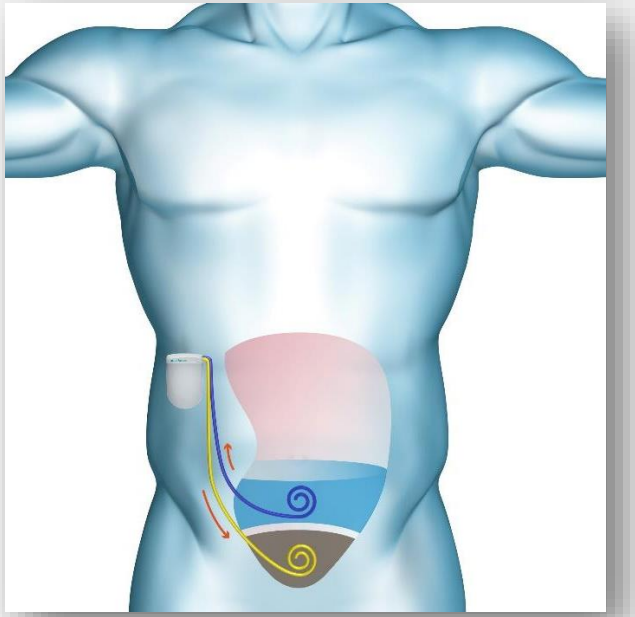
alfapump® – Reduce the need for Therapeutic Paracentesis (TP)

Therapeutic Paracentesis



- Painful
- Frequent hospitalisations
- Poor quality of life
- Short-term benefit

alfapump®



- ✓ Automatic and continuous removal of ascites
- ✓ Fully implanted and wirelessly battery charging
- ✓ CE mark / FDA breakthrough designation
- ✓ Over 800 implants to date

POSEIDON – study cohorts

Patients with recurrent or refractory ascites due to liver cirrhosis in up to 20 centres across US and Canada

Two study cohorts with the same inclusion / exclusion criteria

1 Pivotal Cohort

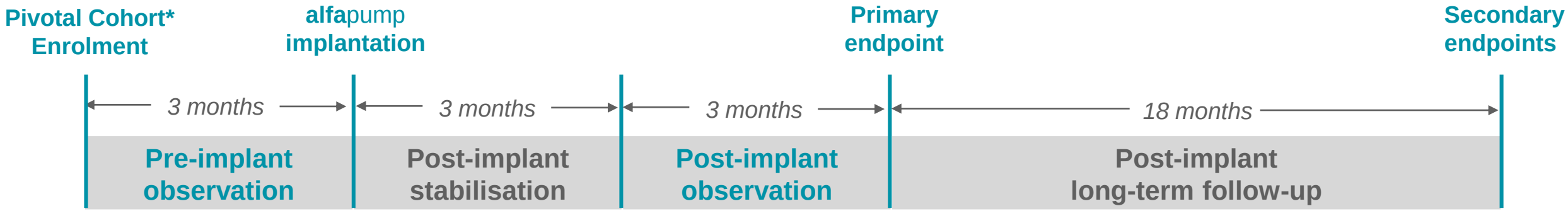
- Up to 50 patients implanted with the **alfa**pump®
- For primary and secondary endpoint analysis

2 Roll-In Cohort ➡ enables us to report interim data

- Up to 30 patients implanted with the **alfa**pump
- To teach clinicians and medical teams at new centres how to use the **alfa**pump

POSEIDON – study design

Pivotal study to support future marketing application of the alfapump® in the US and Canada



***Roll-In Cohort immediately implanted with the alfapump upon enrolment and followed up for safety, efficacy and QoL**

Primary efficacy:	1) 50% reduction in average monthly frequency of 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

***TP:** Therapeutic Paracentesis; **QoL**: Quality of Life; **AE:** Adverse Event*

Cirrhotic patients with recurrent or refractory ascites

First 13 patients in Roll-In Cohort of the POSEIDON study

Age (mean)	65 y
MELD score (mean ± SD)	10.5 ± 4.6
Cirrhosis etiology	
- Alcohol	- 61.5%
- NASH	- 23.1%
- Hepatitis C	- 7.7%
- Alcohol, Hepatitis C, and Hepatitis B	- 7.7%
TP per month prior to study (mean ± SD)	3.4 ± 1.8

MELD: *Model for End-stage Liver Disease;* ***SD:*** *Standard Deviation;* ***NASH:*** *Non-Alcoholic Steatohepatitis;* ***TP:*** *Therapeutic Paracentesis*

Willingness to treat earlier stage patients?

NASH is already an important driver of this market

N. American patients appear to have more TP / month compared to Europe

Positive outcomes against all primary endpoints in first 13 Roll-In patients

Substantial reduction in therapeutic paracentesis (TP) and safety profile in line with expectations

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

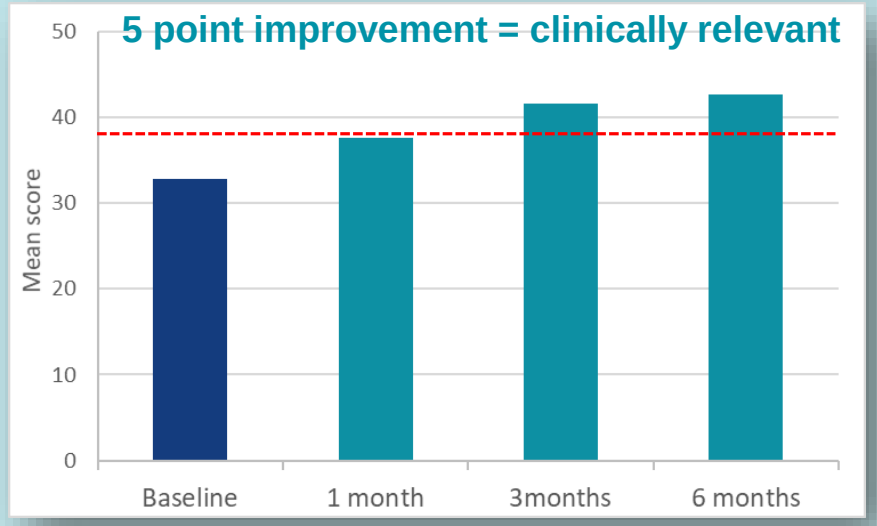
Note: Pre- and post-implant periods for this analysis of the Roll-In Cohort differ from those that will be used for the Pivotal Cohort analysis

Indication of fast and persistent improvement in Quality of Life

SF-36

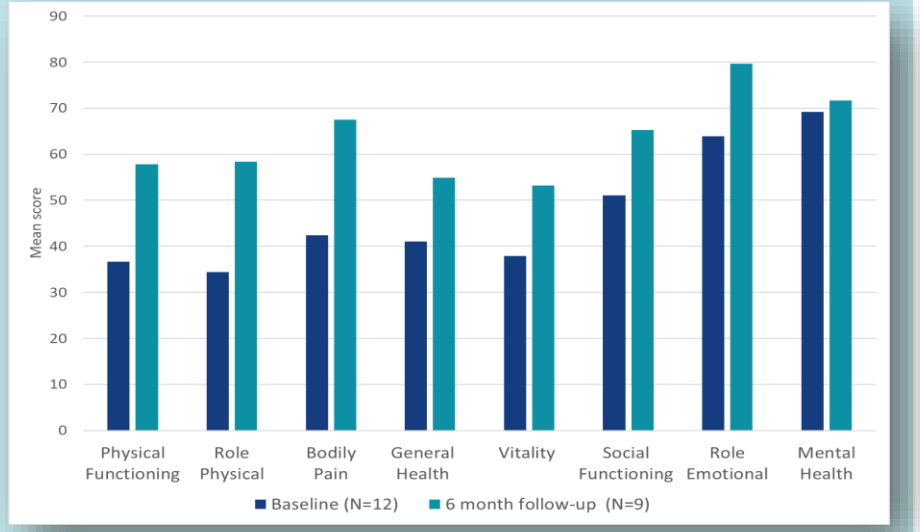
General health-survey questionnaire

Physical Component Score



Higher is better

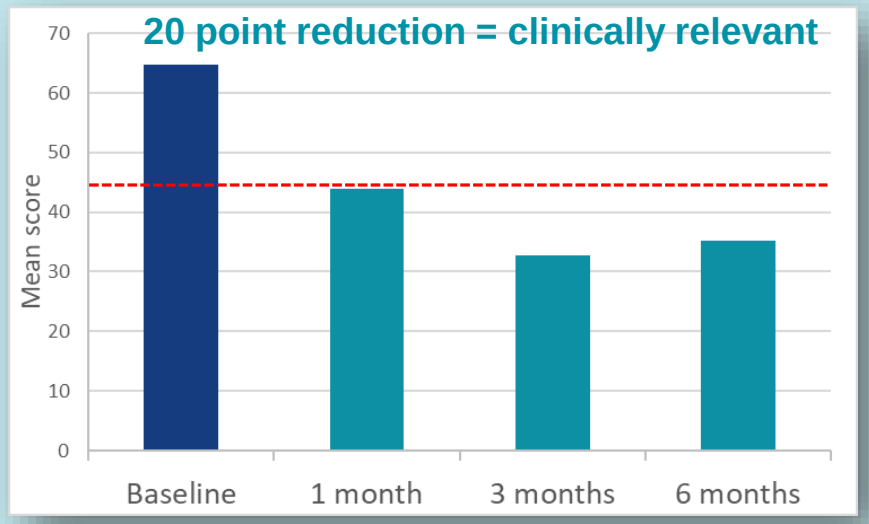
Subscales



Ascites Q

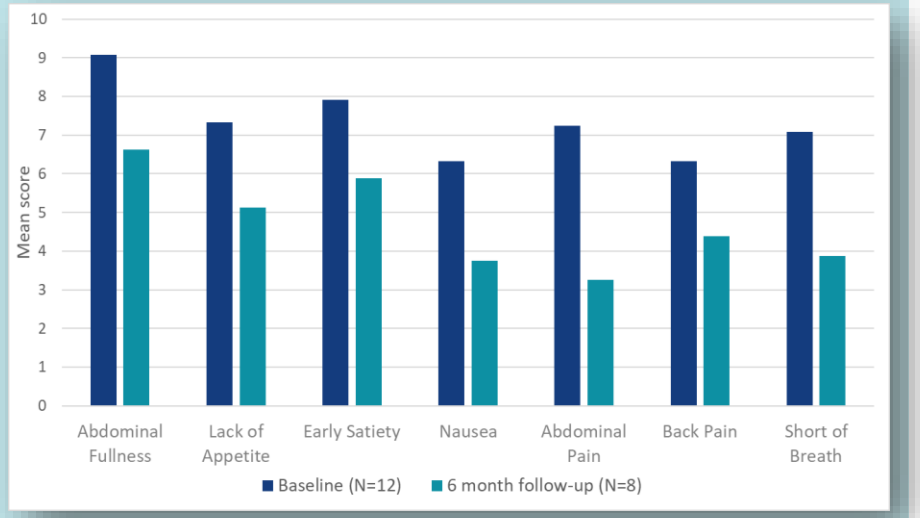
Specific health-survey questionnaire for ascites

Total Score



Lower is better

Subdomains



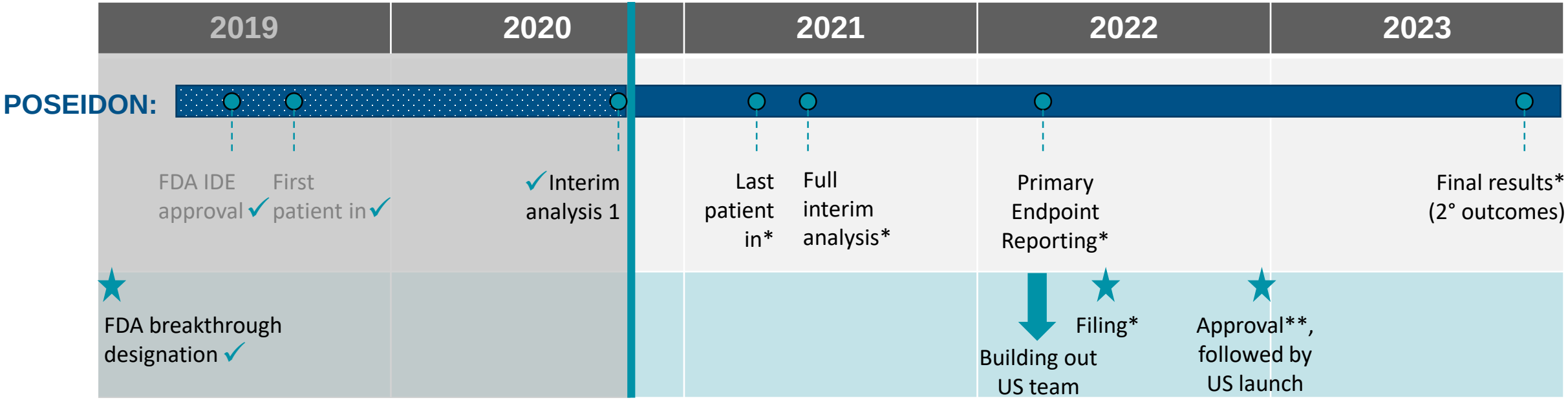
Encouraging results from first 13 patients in Roll-In Cohort

- Substantial reduction in the need for Therapeutic Paracentesis – primary efficacy endpoint* ✓
- Reported safety events generally those seen in decompensated cirrhotic patients and in line with expectations – primary safety endpoint* ✓
- Fast and persistent improvement in general and ascites-specific health-survey questionnaires indicating clinically relevant improvement in patient's quality of life

"These data are an important milestone towards achieving a future marketing application in the US and Canada"

** 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*

Pursuing approval of the alfapump® in North America for recurrent or refractory liver ascites



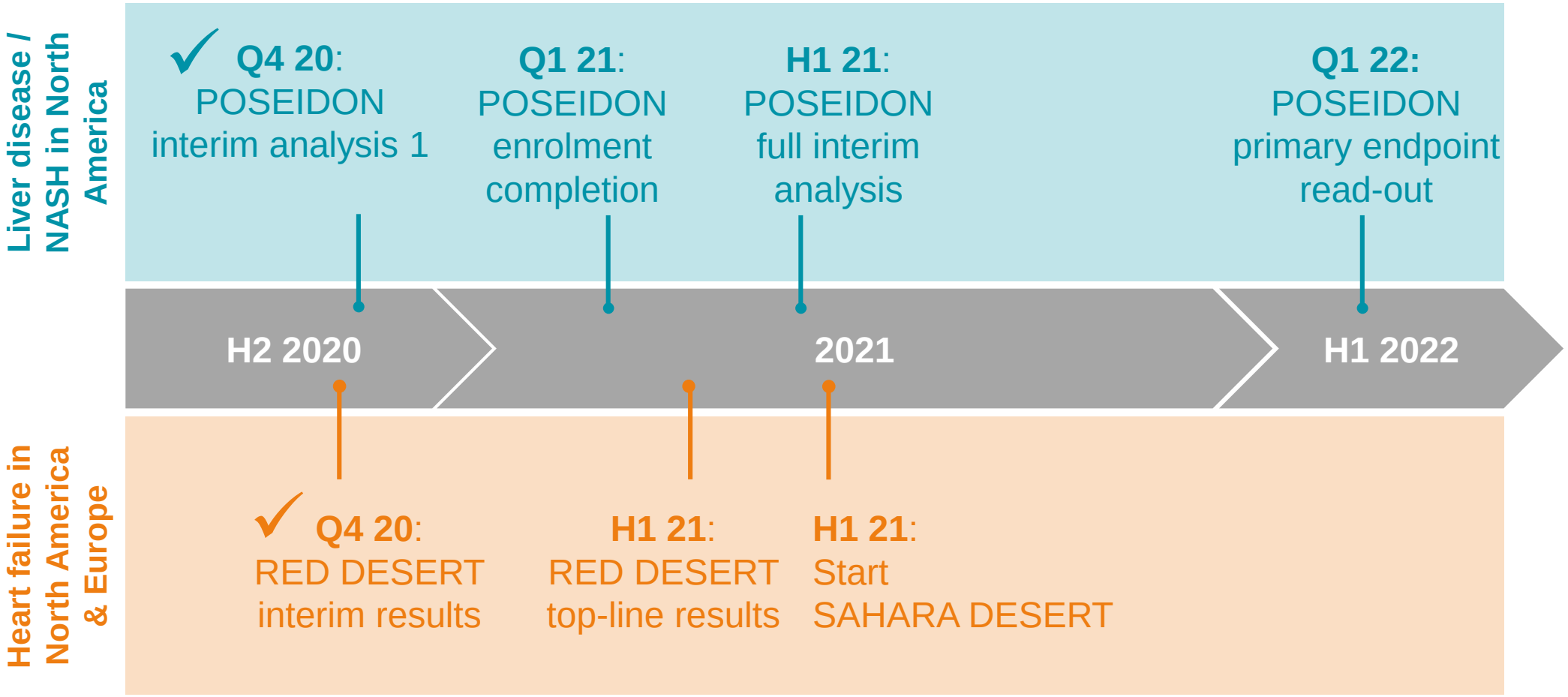
CMS CENTERS FOR MEDICARE & MEDICAID SERVICES

Proposed CMS rule for automatic Medicare coverage of breakthrough devices for four years post-approval

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

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

Expected core value drivers & outlook



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

Q&A