

Sedana Medical

Jefferies conference
London, November 2021

President & CEO Johannes Doll



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Sedana Medical at a glance

- Swedish-based **Medical Device** and **Pharmaceutical company**, founded in 2005
- Aiming at establishing **inhaled sedation** as standard therapy in intensive care, offering the first and only on-label therapy
 - **Sedaconda ACD** device with existing sales in >30 countries
 - **Sedaconda (isoflurane)** approved in 11 European countries to date
- Addressing **EUR 2-3bn market potential**
- Listed on **Nasdaq Stockholm**
(main owners: Handelsbanken Funds, Swedbank Robur Funds, Linc AB)



Our Purpose

To improve life during
and beyond sedation

Our Vision

To make Inhaled Sedation a
global standard therapy for
critical care patients



~8 million ventilated patients in the ICU need sedation each year

>30
million

... patients world-wide receive care in an intensive care unit (ICU) every year

~12
million

... of these patients need help breathing by a ventilator, e.g. due to

- Trauma
- Sepsis
- Pneumonia
- Surgery
- Multiple organ failure
- Covid-19

~8
million

... patients need sedation to tolerate the ventilator and relieve anxiety, agitation, and pain.

Sedana Medical is addressing a global market potential of **EUR 2-3 billion**



Sedana Medical introduces a paradigm shift in the care of critically ill patients

Previous standard of care

Intravenous sedation



Drawbacks of i.v. sedation

- Risk of drug accumulation in the body
- Prolonged and unpredictable wake-up
- Delayed recovery from sedation, frequent occurrence of delirium
- Propofol infusion syndrome

Future standard of care

Inhaled sedation with Sedaconda



Advantages of inhaled sedation

- Minimal risk of drug accumulation
- Faster and more predictable wake-up
- Rapid recovery from sedation
- Lower opioid requirement
- More frequent spontaneous breathing

With the approval of Sedaconda (isoflurane)¹, we can now offer the full on-label therapy for inhaled sedation

So far



- Sedaconda ACD device available in >30 countries
- Volatile anaesthetics (e.g., isoflurane) have been used off-label

Going forward

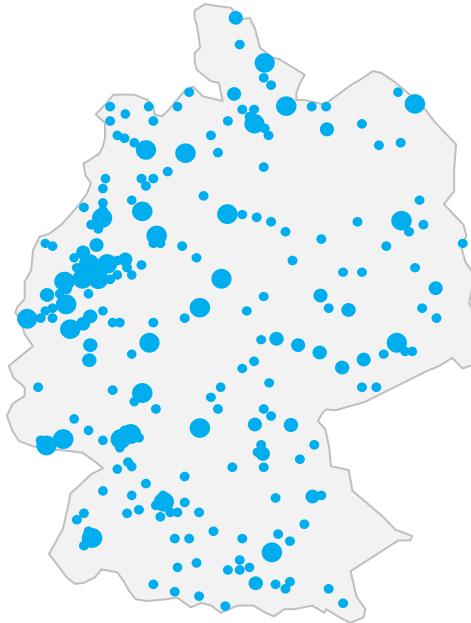


- Where approved, Sedana Medical can offer the full on-label inhaled sedation therapy: Sedaconda (isoflurane) delivered via the Sedaconda ACD device

¹ To date in 11 EU countries

Sedaconda ACD has broad existing use despite off-label status of the drug

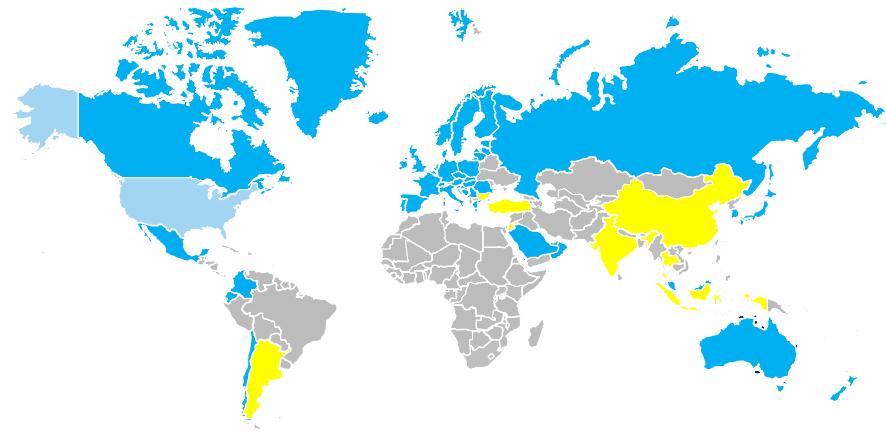
Use in majority of German ICUs



>900
ICUs use Sedaconda ACD

Increasing use globally

- Current use of Sedaconda ACD
- In registration process.



>30
countries with Sedaconda ACD sales

Q3 2021 Highlights

Solid sales growth

- 34% growth¹ in Q3 sales (28 MSEK)
- 23% growth¹ in YTD sales (113 MSEK)
- All regions incl. Germany, other direct markets, and distributor markets contributed to the growth in Q3
- Continued use of Sedaconda ACD in non-Covid-19 patient groups in Europe

Launch preparation on track

- 11 out of 15 national approvals obtained for Sedaconda (isoflurane), following the European approval in July
- Product expected on shelf in first markets towards end of the year
- Sedaconda study results published in "The Lancet Respiratory Medicine"
- Country teams staffed up and trained

U.S. preparation intensifying

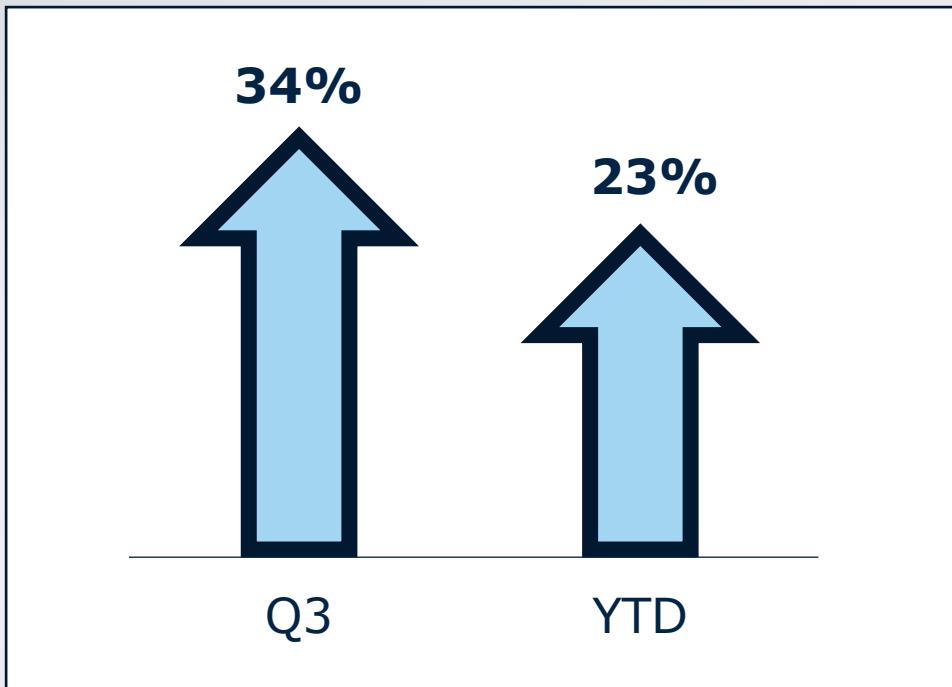
- Preparations for US clinical program well on track
- IND expected in Q4, 2021
- First employees hired into Sedana Medical US organization

¹ Growth in local currencies

We have seen solid growth in Q3 sales,
continuing on the longer-term trend

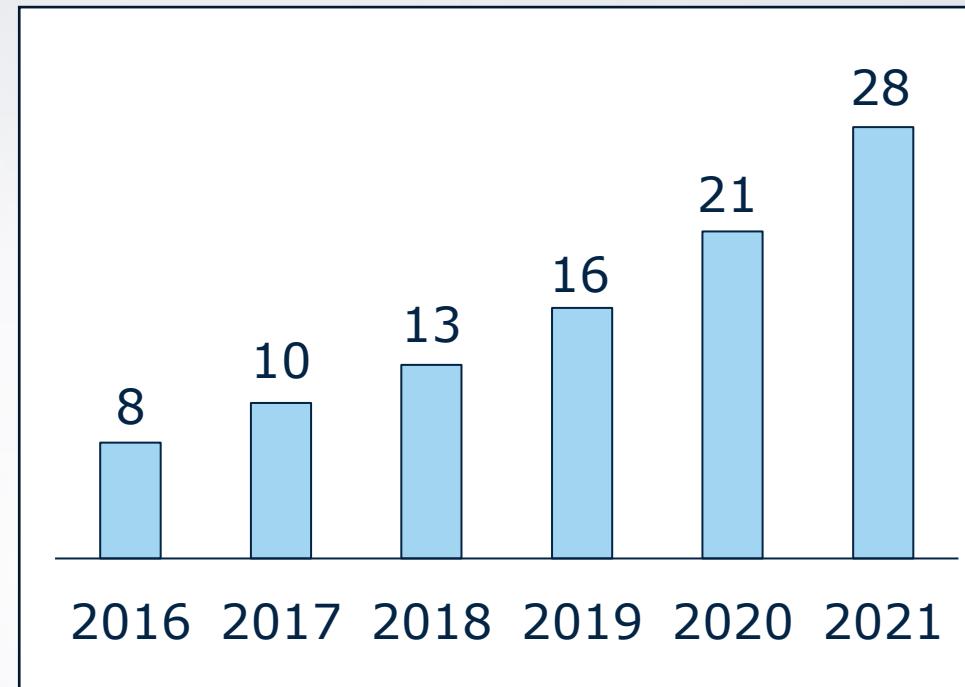
Sales growth

Percent¹



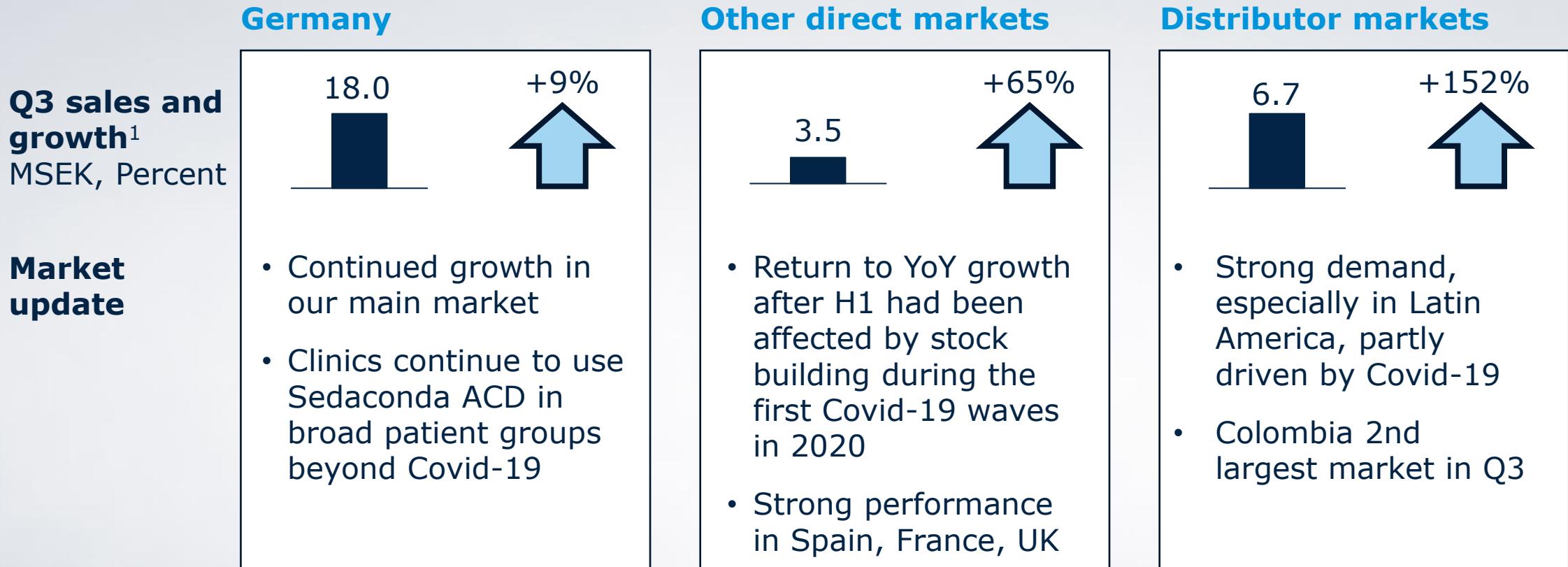
Q3 sales over time

SEK million



¹ Growth in local currencies

Every region has contributed to the Q3 growth vs. 2020



¹ Growth in local currencies

Use of Covid-19 as a predictor for Sedana Medical performance has limits

Actual market potential

- Patients who are
 - ... in the **ICU**,
 - ... **mechanically ventilated**, and
 - ... **sedated**

Limitations of Covid-19 as a proxy

(Germany example)

- Covid-19 patients never exceeded 30% of ICU patients
- Not all Covid-19 patients are ventilated (currently ~50%)
- Covid-19 patient demographics and treatment change over time

Our view on Covid-19

- **Some short-term impact, but long-term outlook unchanged**
 - Sales show less volatility than Covid-19, suggesting broad use outside Covid-19
 - We may see some regional fluctuation in our sales (positive or negative) due to Covid-19, but long-term potential is not affected
- **Stronger platform for launch**
Covid-19 has led to more clinics being equipped and trained to use Sedaconda ACD

Q3 sales showed resilience versus Covid-19 trend, suggesting broad use of our products outside Covid-19 patients

Covid-19 patients in ICU

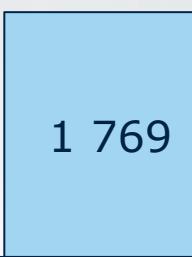
Drop from Q2 to Q3¹



Germany

Q3 Net sales

EUR thousands

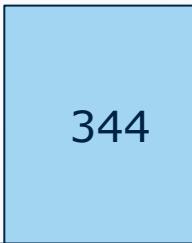


497

If we had followed
the Covid trend...

Actual

**Other
direct
markets²**



173

If we had followed
the Covid trend...

Actual

¹ Based on average number of Covid-19 ICU patients per day

² UK, France, Spain, Benelux, Sweden, Denmark

Source: own analysis based on European CDC and country data

Two growth horizons ahead: Europe and the United States

Sedana Medical growth horizons

Europe

- Approval in 2021 (11 national approvals to date)
- Direct presence in Germany, UK, France, Spain, Benelux, Nordics
- Stated objective: 500 MSEK sales in 3rd year after approval



- Approval anticipated before year end 2024
- Highest-potential market
 - 107.000 ICU beds¹
 - Attractive price level
- Decision on go-to-market model in 2022

United States

¹ Source: American Hospital Association <https://www.aha.org/statistics/fast-facts-us-hospitals>

Our Sedaconda Study with >300 patients (SED-001) showed clear benefits versus sedation with propofol¹



Published in
Lancet Respiratory Medicine
Aug 26, 2021

THE LANCET Respiratory Medicine

Inhaled isoflurane via the anaesthetic conserving device versus propofol for sedation of invasively ventilated patients in intensive care units in Germany and Slovenia: an open-label, phase 3, randomised controlled, non-inferiority trial

Andreas Meiser, Thomas Volk, Jan Wallenborn, Ulf Guenther, Tobias Becher, Hendrik Bracht, Konrad Schwarzkopf, Rihard Knafelj, Andreas Falthauser, Serge C Thal, Jens Soukup, Patrick Kellner, Matthias Drüner, Heike Vogelsang, Martin Bellgardt*, Peter Sackey*, on behalf of the Sedaconda study group

1. Isoflurane was non-inferior to propofol in the primary endpoint – time within target RASS range without rescue sedation
2. Opioid requirements during treatment were 29% lower with isoflurane
3. Spontaneous breathing was more commonly observed in the isoflurane group
4. Wake-up times were shorter and more predictable with isoflurane
5. Isoflurane via Sedaconda ACD was well tolerated for sedation in the ICU



The study results have resulted in a strong SmPC, describing clinical key benefits



No time limitation for use of Sedaconda



Sedaconda ACD the only approved device for delivery of
Sedaconda (isoflurane)



"No effect on the exposure of isoflurane in patients with impaired
hepatic and/or renal function anticipated"

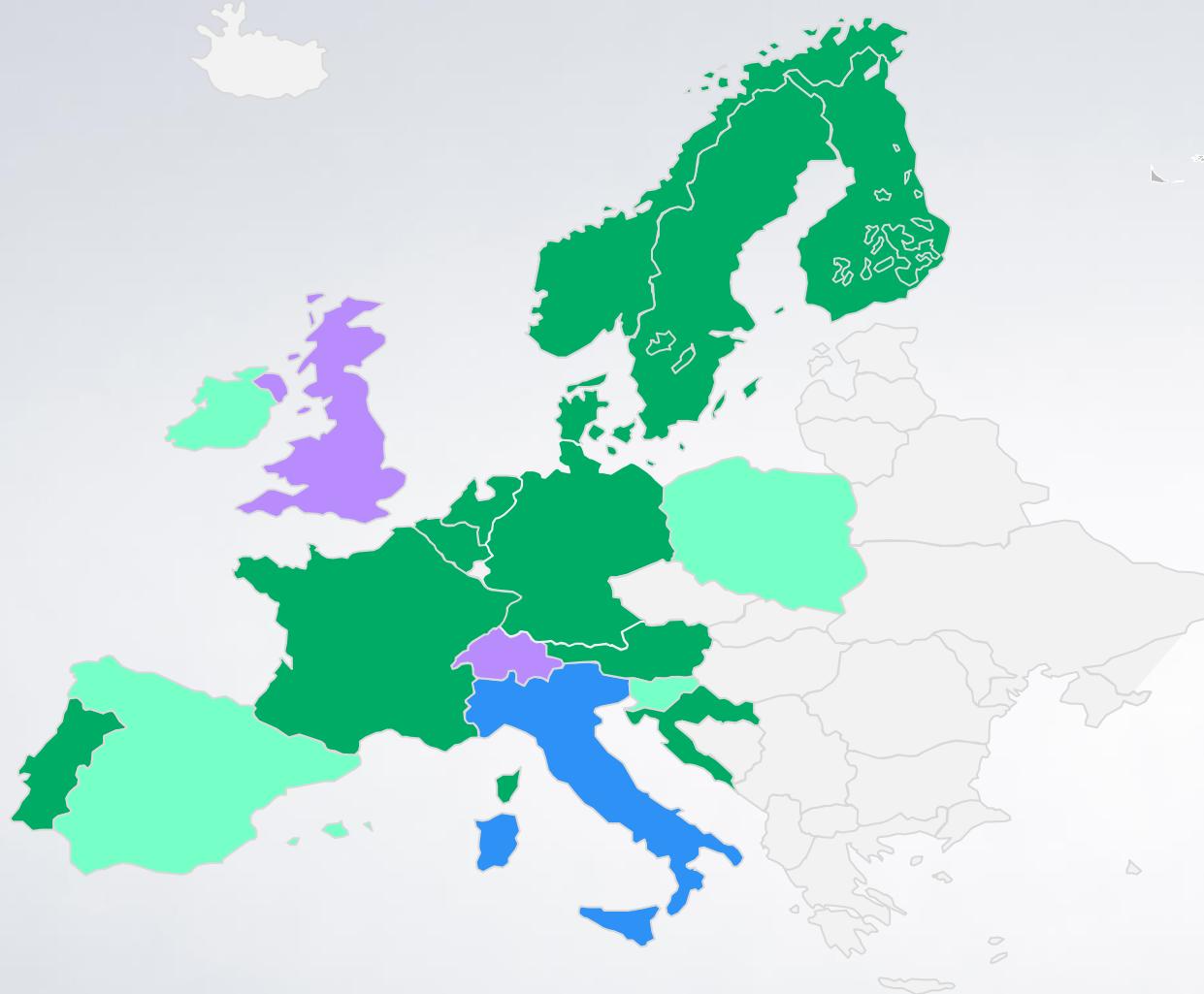


"Rapid and predictable onset of and recovery from sedation"



"Return of wakefulness and cognitive recovery, 10 to 60 minutes after
end of isoflurane administration"

We have received national approval for Sedaconda (isoflurane) in 11 countries



- Approvals received in 11 out of 15 countries
- Approvals pending in 4 countries: Spain, Ireland, Poland & Slovenia
- Approvals anticipated in 2022: UK & Switzerland
- Submission planned for beginning of 2022: Italy

First Sedaconda on shelf anticipated towards the end of the year

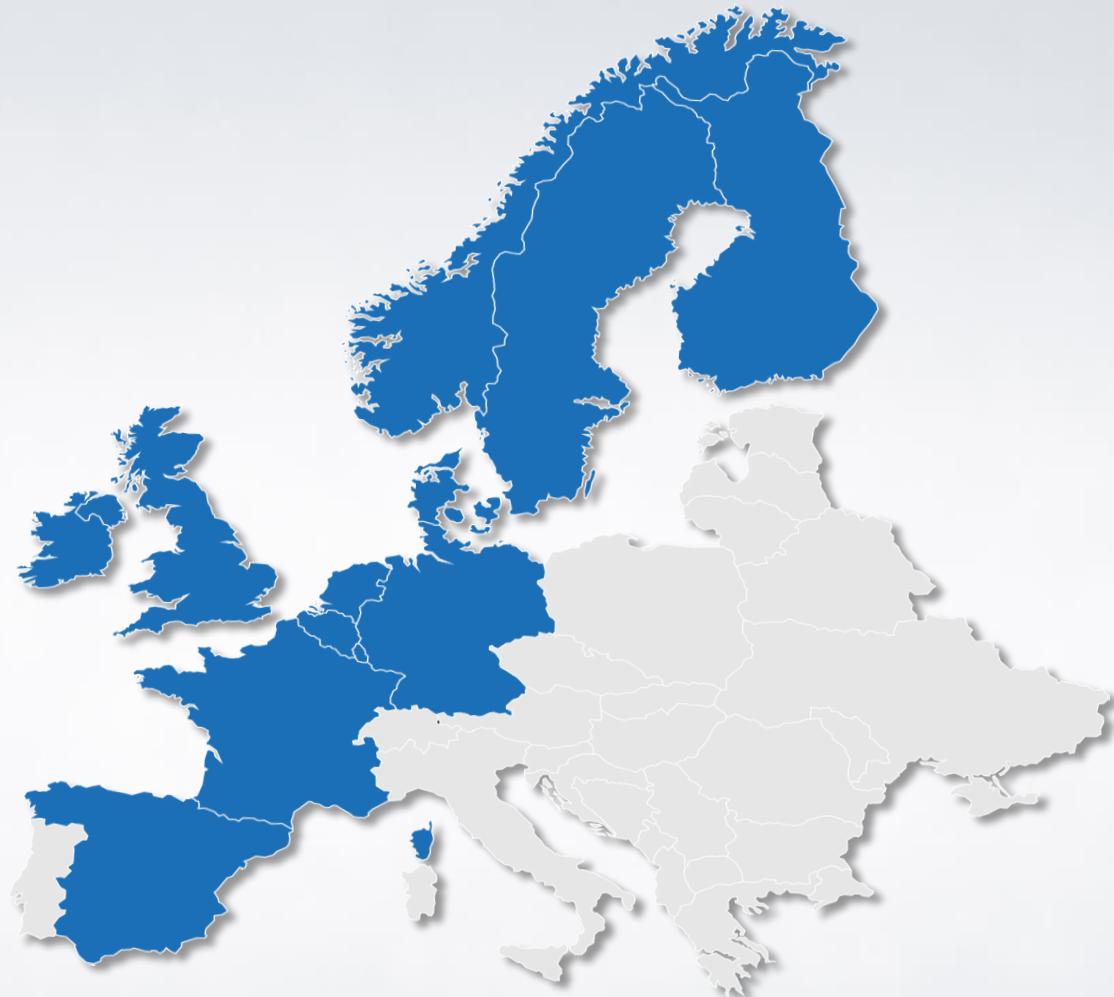


We are commercializing our products through our own commercial teams in key European markets



Countries with direct presence

- Germany
- France
- Spain
- Great Britain
- Nordics
- Benelux



Launch readiness in Europe is on track



Product

- First and only on-label option for inhaled sedation of mechanically ventilated adult patients in the ICU
- Strong clinical trial results and meaningful patient benefits
- Lancet publication



Market

- Existing use of inhaled sedation and Sedaconda ACD in all launch markets
- Increasing awareness through symposia and congresses, e.g., ESICM Lives and ISICEM



Company

- All country teams staffed up for launch
- KAMs trained and upskilled as pharmaceutical sales representatives

The United States represent the largest potential market for Sedana Medical



	Germany	United States
	ICU beds ~22.000	~107.000
	Propofol list price Based on average propofol dose/kg from SED-001 study EUR 47 - 57 per day	EUR 360 - 438 per day
	Current penetration 10.6 MEUR sales LTM ² (8-10% market penetration)	Approval expected in 2024

Note that discounts from list price are higher in the US¹

¹ Discounts for propofol in the range of 40-50% based on payor research conducted in 2020

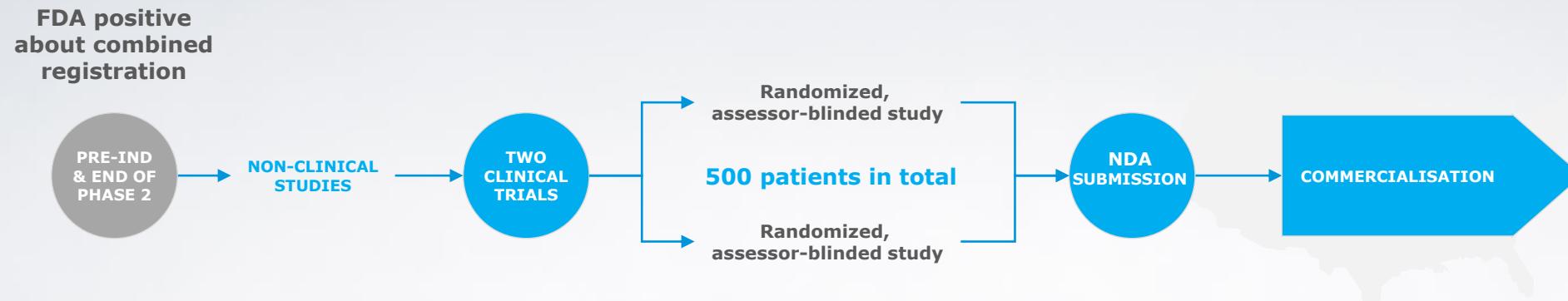
² Last twelve months

The regulatory pathway in the US is agreed with the FDA



505 (b) (2) approval pathway

The FDA has accepted that Sedana Medical is taking the 505 (b) (2) path to registration, which somewhat simplifies the use of previously collected data. FDA input in 2019 and 2021 has informed the Clinical Development plan and the study designs



NON-CLINICAL STUDIES

- Non-clinical toxicity studies
- Human factors program

CLINICAL STUDIES

- Two clinical, randomized, assessor-blinded studies to confirm the efficacy and safety of Sedaconda.
- Besides randomized patients, 3-5 run-in patients per ICU.

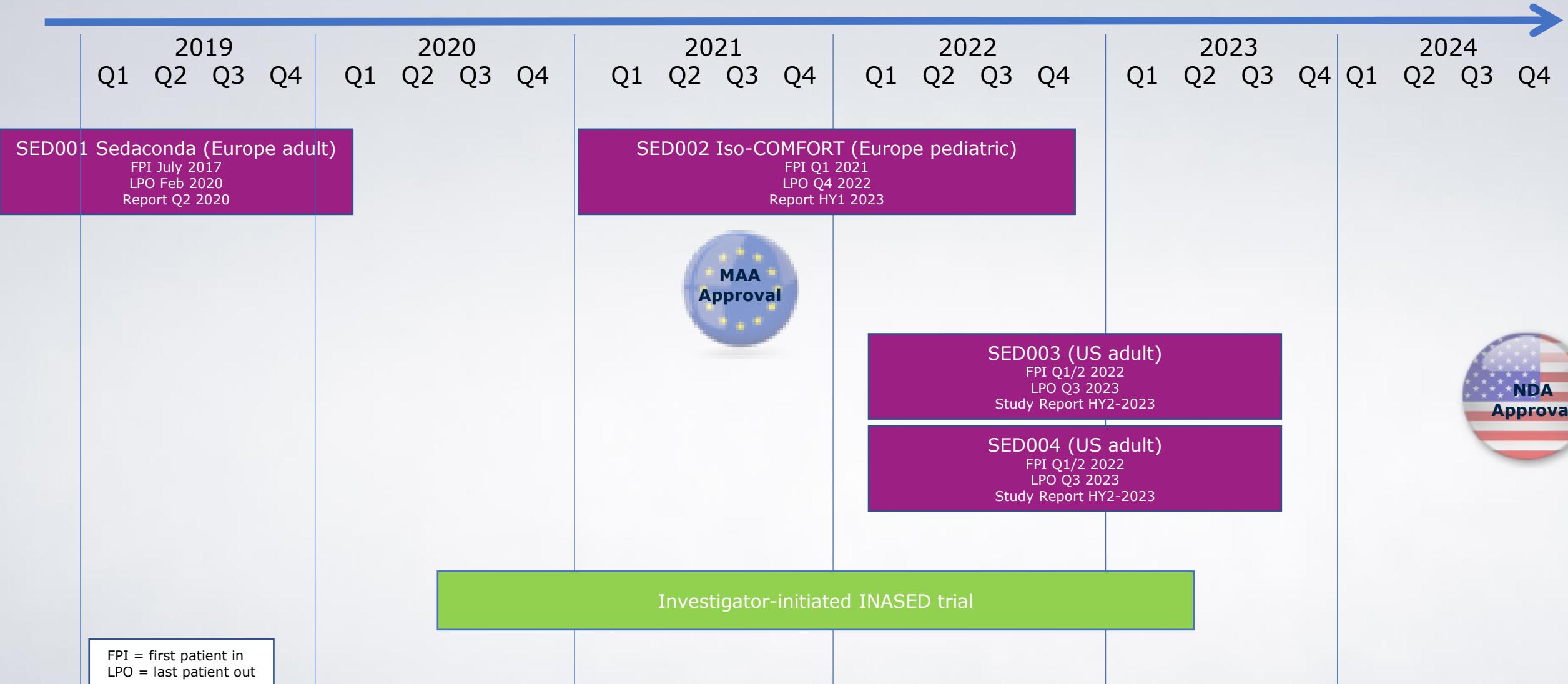
SAFETY DATABASE

- Patients from the US clinical studies, and the European study will be included in the safety database of 500 isoflurane patients.

COMMERCIALISATION

- Commercialisation strategy for USA – whether to launch alone or together with a local partner – to be decided during 2022.

US approval is anticipated in 2024



Clinical program will be performed by top US institutions



- Collaboration in study preparations with top US academic institutions, including
 - Columbia
 - Duke
 - Cleveland Clinic
 - Harvard
 - Johns Hopkins
 - Mayo
 - Vanderbilt
 - UCLA
 - University of Chicago
- Site contract negotiations and IRB applications underway
- Clinical education specialists employed for site training
- First patient in is anticipated at the turn of Q1/Q2 2022

Preparations for the US market are intensifying



Product

- Clinical and regulatory program aligned with FDA
- IND expected in Q4, 2021
- Preparations for the clinical program ongoing (start at the turn of Q1/Q2 2022)



Market

- Top centers recruited for clinical trials, e.g., Mayo Clinic, Cleveland Clinic, Stanford, John Hopkins, etc.
- Building a network of key opinion leaders



Company

- Sedana Medical US subsidiary set-up
- First employees recruited during Q3, 2021 (clinical educators for the upcoming trials)

Sedana Medical – strong foundation for further value creation

Highly differentiated products

- First and only on-label therapy for inhaled sedation in the ICU (approved in 11 EU countries to date)
- Clear benefits over previous standard of care (IV sedation), supported by strong clinical evidence

Broad adoption despite previous off-label status

- Sedaconda ACD used in >50% of ICUs in Germany
- Active sales in >30 countries

Addressing significant market potential

- Full on-label therapy ready for launch in Europe
- Approval in largest potential market US expected in 2024
- Global market potential of EUR 2-3 billion





THANK YOU!