

# SEDANA MEDICAL

Pioneering volatile anaesthetic delivery

---

Interim Report Q3 2020 Presentation

CEO Christer Ahlberg  
CMO Peter Sackey  
CFO Maria Engström

5th November 2020



# Disclaimer

## Forward-looking statements

This presentation may contain certain forward-looking statements and forecasts based on uncertainty, since they relate to events and depend on circumstances that will occur in the future and which, by their nature, will have an impact on Sedana Medical's business, financial condition and results of operations. The terms "anticipates", "assumes", "believes", "can", "could", "estimates", "expects", "forecasts", "intends", "may", "might", "plans", "should", "projects", "will", "would" or, in each case, their negative, or other variations or comparable terminology are used to identify forward-looking statement. There are a number of factors that could cause actual results and developments to differ materially from those expressed or implied in a forward-looking statement or affect the extent to which a particular projection is realized. Factors that could cause these differences include, but are not limited to, implementation of Sedana Medical's strategy and its ability to further grow, risks associated with the development and/or approval of Sedana Medical's products candidates, ongoing clinical trials and expected trial results, the ability to further commercialize AnaConDa and IsoConDa, technology changes and new products in Sedana Medical's potential market and industry, the ability to develop new products and enhance existing products, the impact of competition, changes in general economy and industry conditions and legislative, regulatory and political factors.

No assurance can be given that such expectations will prove to have been correct. Sedana Medical disclaims any obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.



## **Our Purpose**

*To improve life during and beyond sedation*

## **Vision**

*To make inhaled sedation a global standard therapy for critical care patients*

**SEDANA**MEDICAL

# IsoConDa®/AnaConDa provides clear benefits over current standard of care

## Benefits

### ON-OFF EFFECTS AND RELIABLE WAKE UP

- ✓ Significantly reduced wake-up time<sup>2</sup>
- ✓ Reduction in ICU stay duration for deep sedation patients<sup>10</sup>
- ✓ Significantly reduced time to extubation (ventilator tube removal)<sup>2</sup>

### RELIABLE EFFECT AND SAFETY FOR THE DISTRESSED PATIENT

- ✓ Limits the occurrence of hallucination episodes/delirium<sup>6</sup>
- ✓ Reduction in use of opiates<sup>9</sup>

### POTENTIALLY ORGAN PROTECTIVE PROPERTIES

- ✓ Reduced *in-hospital* mortality in long-term ventilated patients (>96h)<sup>4</sup>
- ✓ Reduced 1 year mortality in long-term ventilated patients (>96h)<sup>4</sup>
- ✓ Improved gas exchange/oxygenation<sup>\*\*</sup>

## IsoConDa®/AnaConDa

## IV sedation

10-20 min

90 min – 130 h

4-16 days

6-27 days

10-35 min

150-600 min

2 of 10 patients

5 of 7 patients

2.7 mg/hour

4.2 mg/hour

40%

63%

50%

70%

Yes<sup>\*\*</sup>

No<sup>\*\*</sup>

Price per day

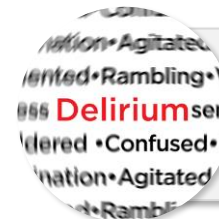
EUR 100\*

EUR 20-300<sup>\*\*\*</sup>



EUR 1-3k

Daily cost of an ICU bed in Europe<sup>14</sup>



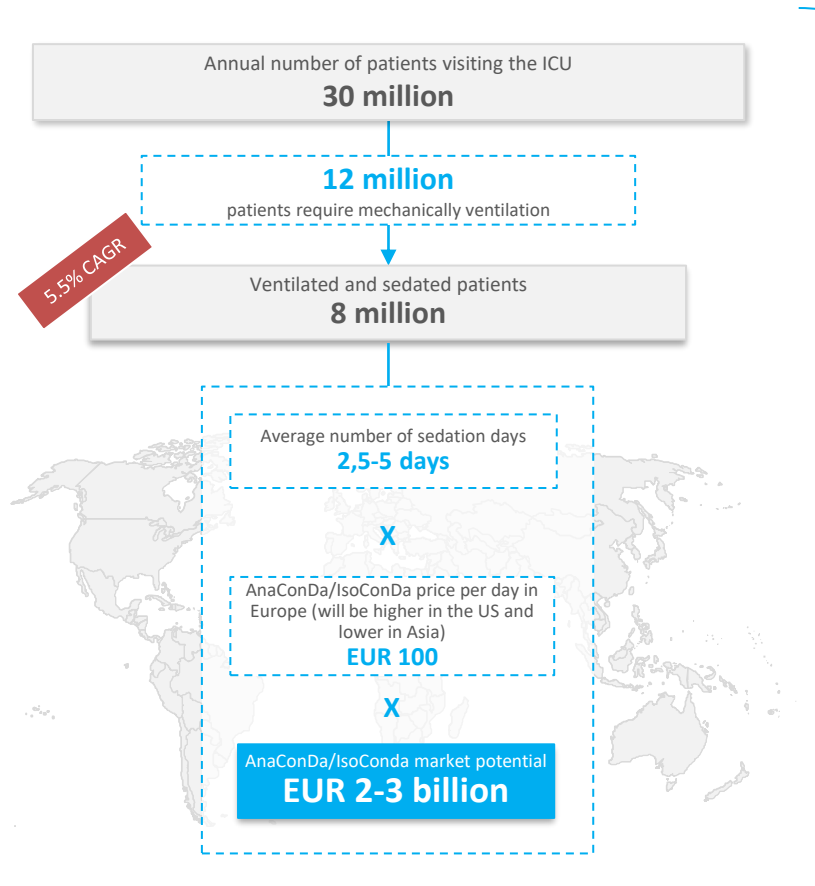
\$4-16bn

Annual cost of delirium from ventilated patients in the US<sup>15</sup>

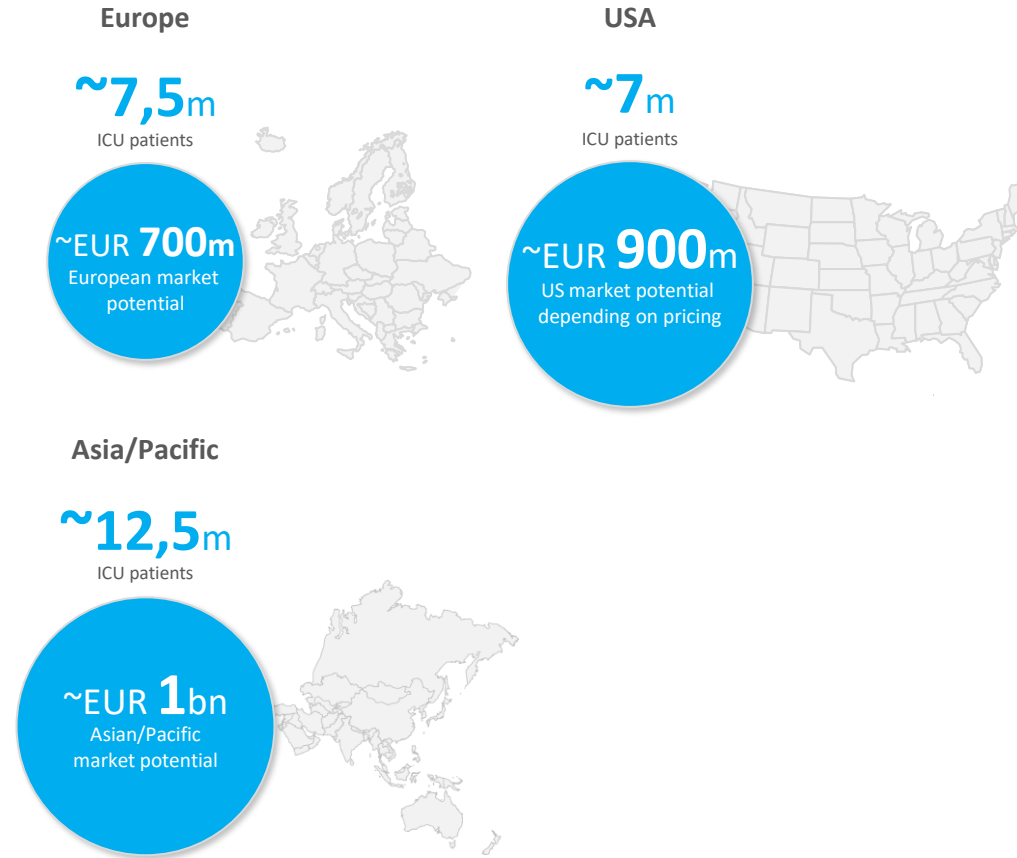
3. Large & clearly defined market opportunity for replacement of standard of care

# Blockbuster market potential for IsoConDa/AnaConDa

## Breakdown: total market potential for IsoConDa/AnaConDa\*



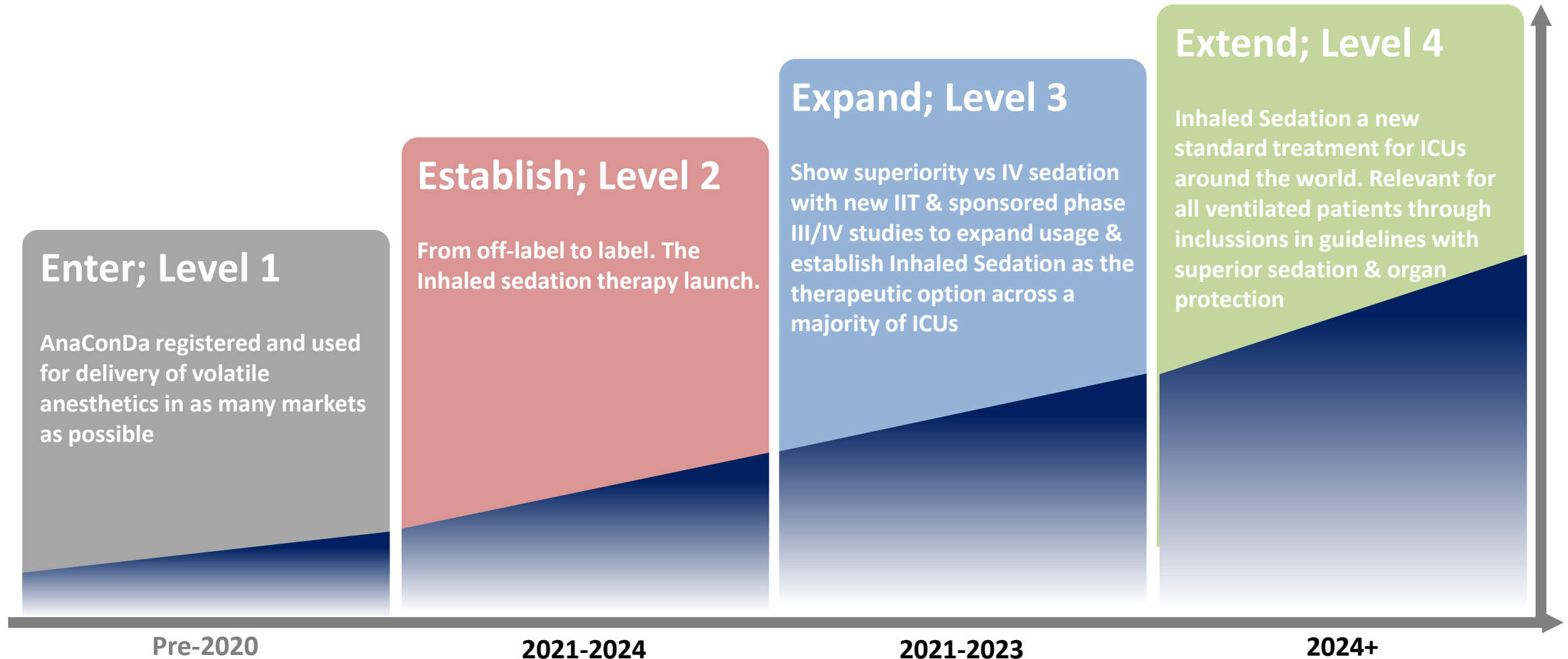
## Regional market potential



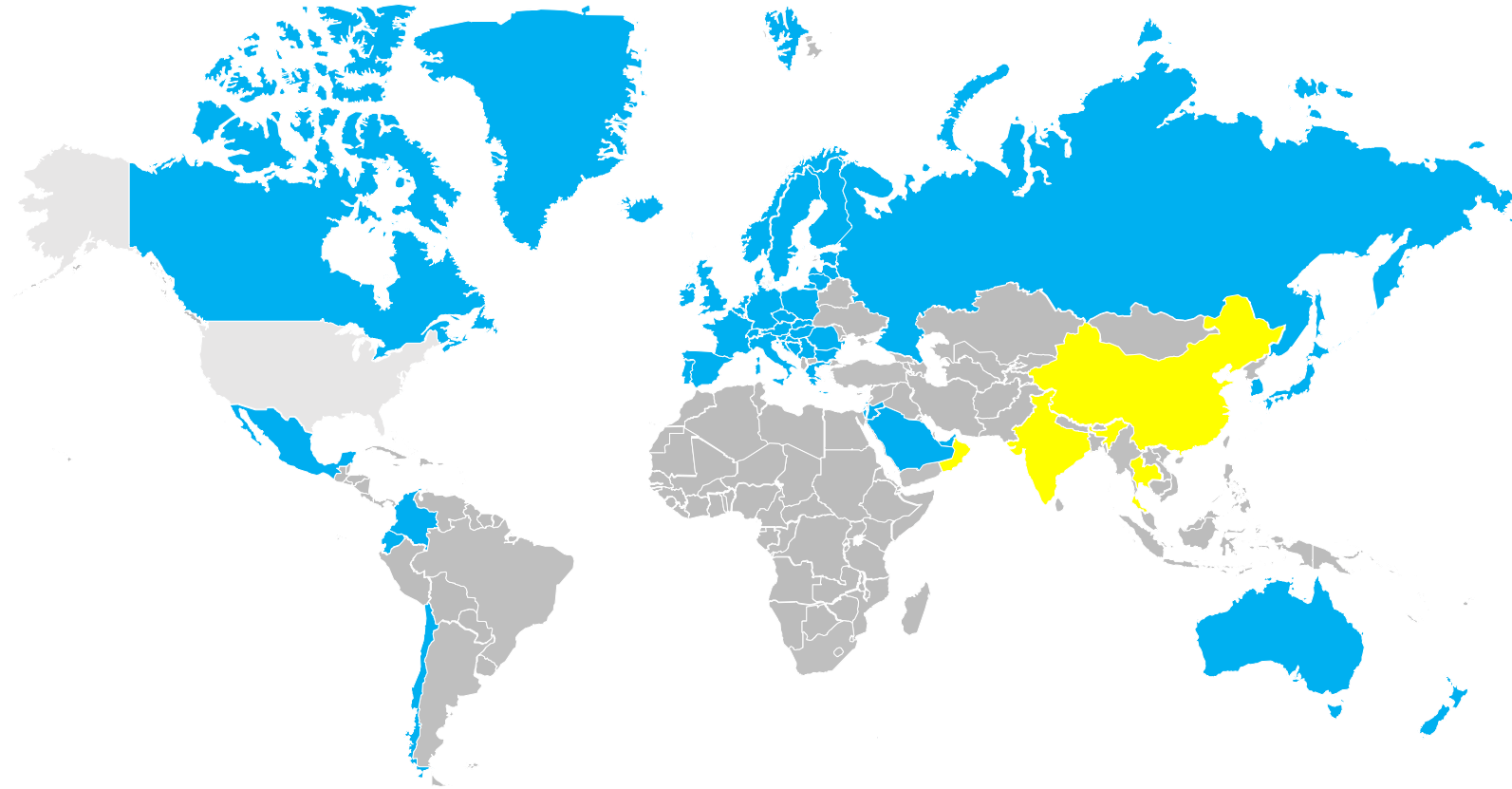


# Sedana Medical Vision & Strategic Evolution

To make inhaled sedation (IsoConDa and AnaConDa), a global standard therapy for critical care patients



# Approved AnaConDa Markets



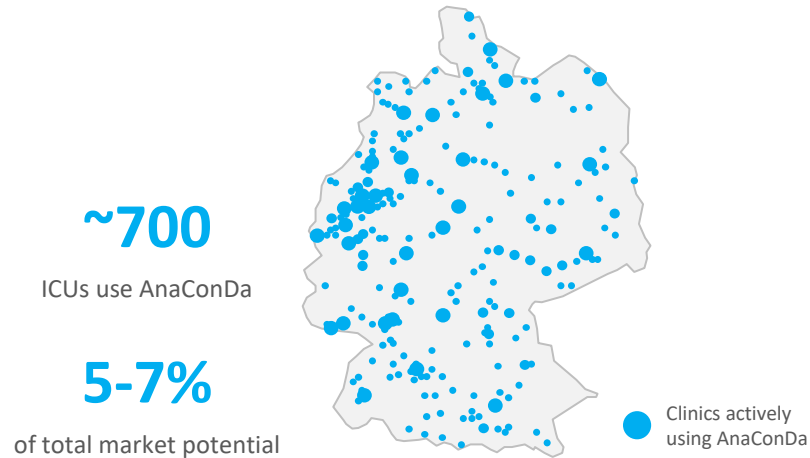
- Existing Registered AnaConDa markets
- In registration process.

# Rapidly increasing adoption and usage despite off-label status

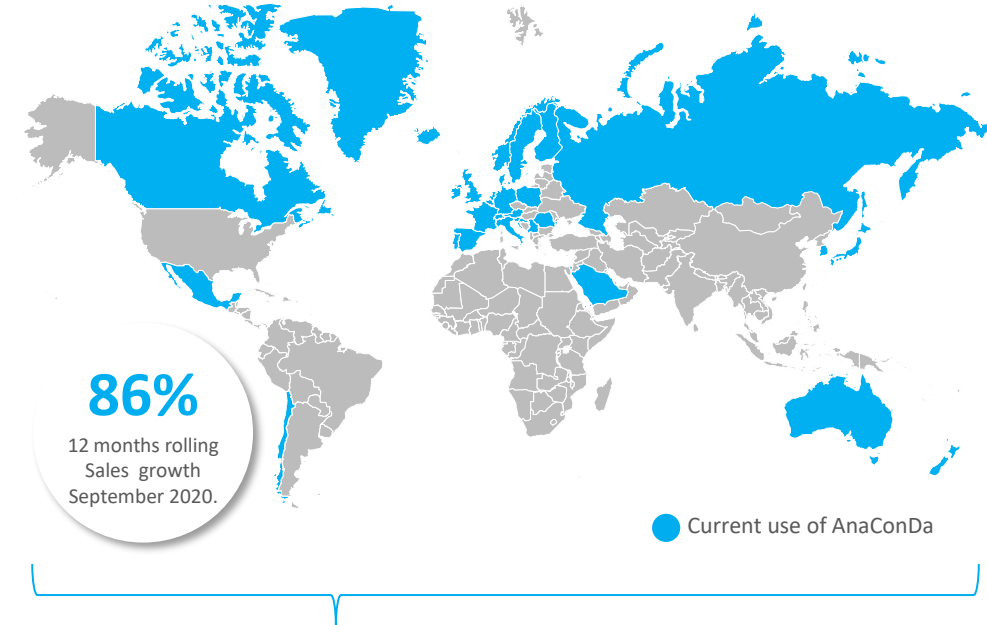
## Case study: AnaConDa in Germany

- In 2010, new guidelines for sedation were published in Germany.
- The guidelines put forward inhalation sedation and the use of isoflurane as an alternative to IV sedation in intensive care for certain patient groups.
- The new guidelines together with positive statements from a number of German KOLs have led to extensive use of AnaConDa in Germany.
- Sedana Medical's largest market is currently Germany, which together with other markets where it conducts direct selling, has functioned as a test market to study demand.

### AnaConDa in Germany



## Increasing use globally



### Proven in clinical practice

**>500,000**

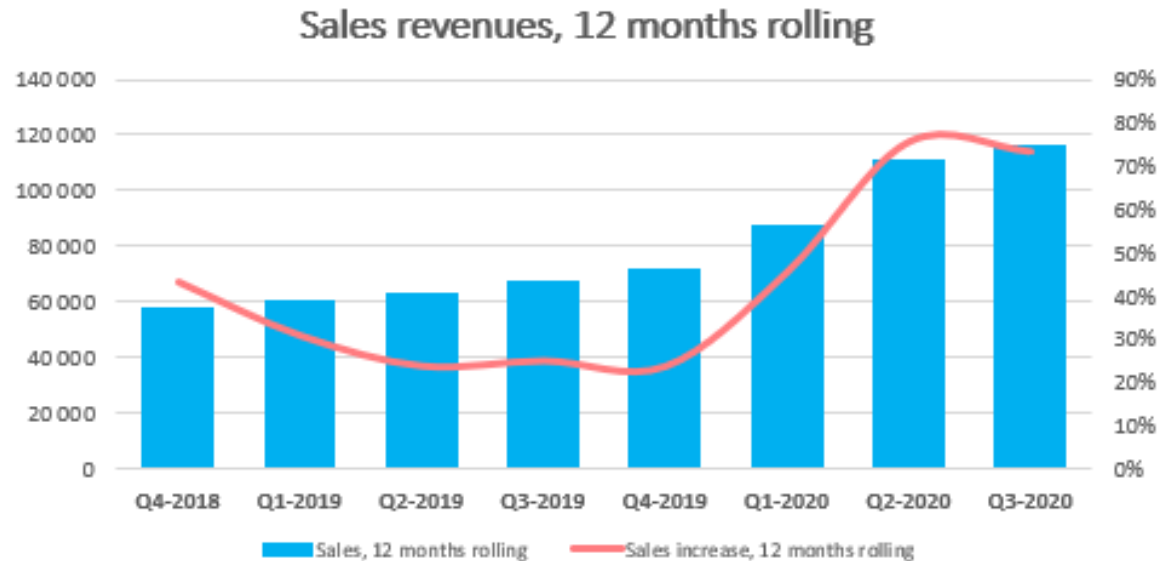
AnaConDa units sold

**>600,000**

treatment days



# Sales Development Q3 2020



## Sales increase:

- 31% sales growth in Q3 2020 vs Q3 2019 (39% in local currencies)
- 86% sales growth rolling 12 months (86% in local currencies) equal to 116 MSEK sales turnover annually (September 2020)

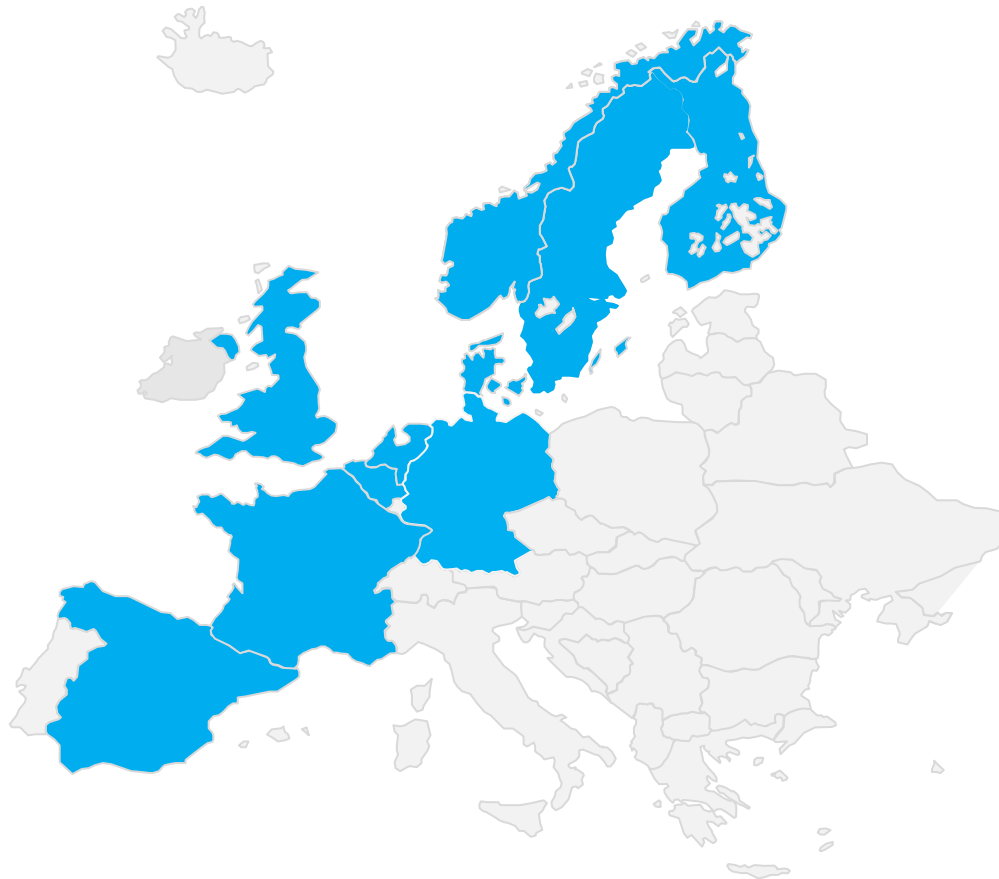
**31%**  
Sales  
increase  
vs. Q3 2019

**86%**  
Sales  
increase  
rolling 12  
months

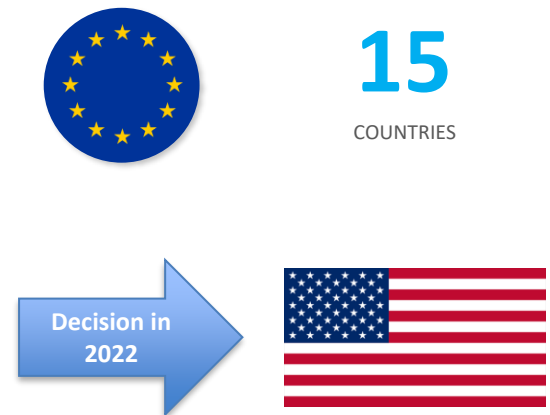
# Sales organisation buildup in preparation for regulatory approval

Sedana Medical applies a direct sales model to key markets with plans to cover 15 EU countries in time for approval

## SEDANA MEDICAL CURRENT DIRECT SALES ORGANISATION



## SEDANA MEDICAL DIRECT SALES ORGANISATION 2021



# AnaConDa from Sedana Medical reviewed by NICE in UK (6 October 2020)

**NICE** National Institute for  
Health and Care Excellence



## AnaConDa-S for sedation with volatile anaesthetics in intensive care

Medtech innovation briefing

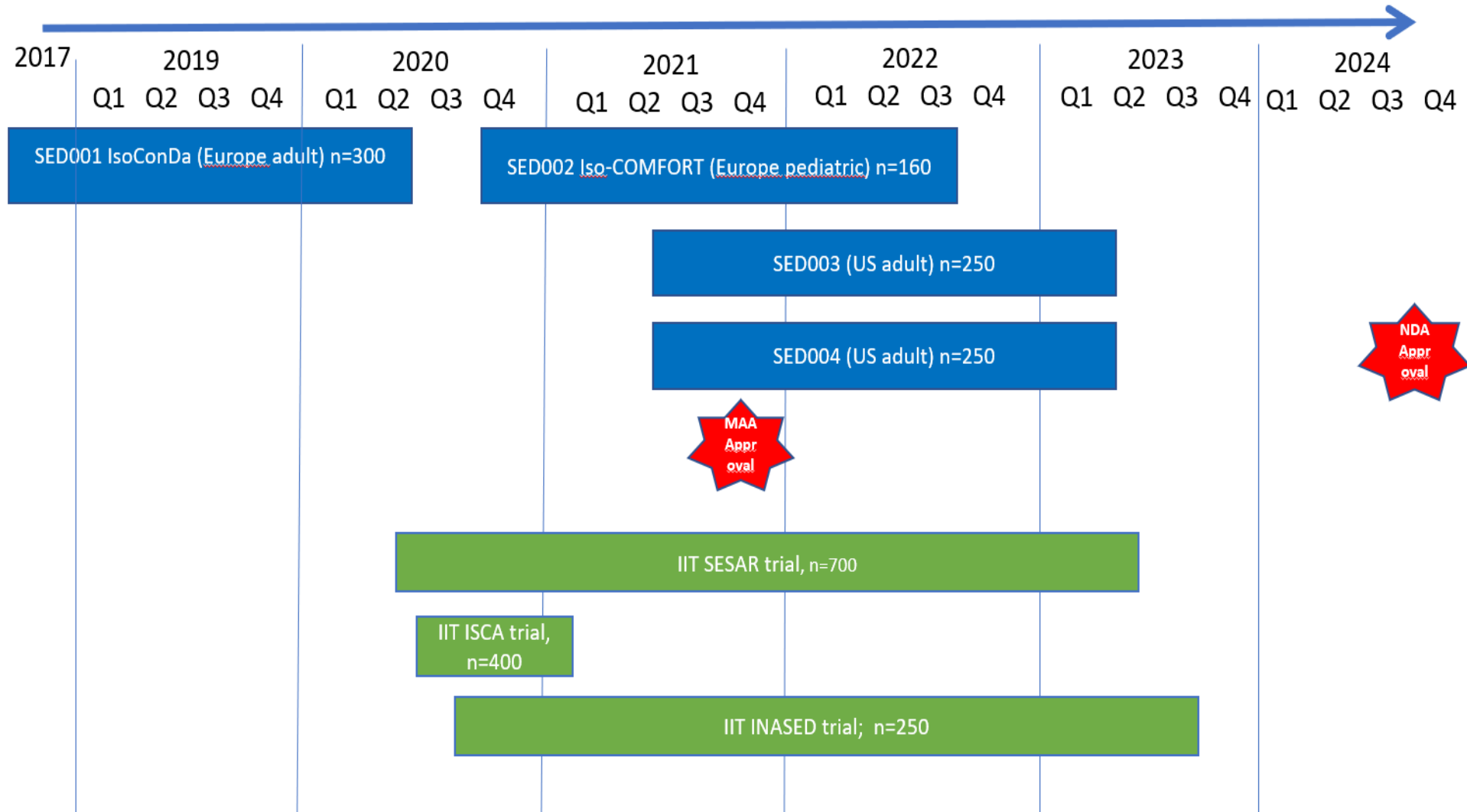
Published: 6 October 2020

[www.nice.org.uk/guidance/mib229](http://www.nice.org.uk/guidance/mib229)

### Summary

- The **technology** described in this briefing is AnaConDa-S. It is a volatile anaesthetic delivery system for use with ventilators to allow people to be sedated using inhaled anaesthetics (isoflurane or sevoflurane).

# From proven off-label treatment to approved therapy and a new standard of care in the ICU



# SEDANA MEDICAL

Pioneering volatile anaesthetic delivery

---

**The SED-001  
pivotal registration study  
First results**

.....

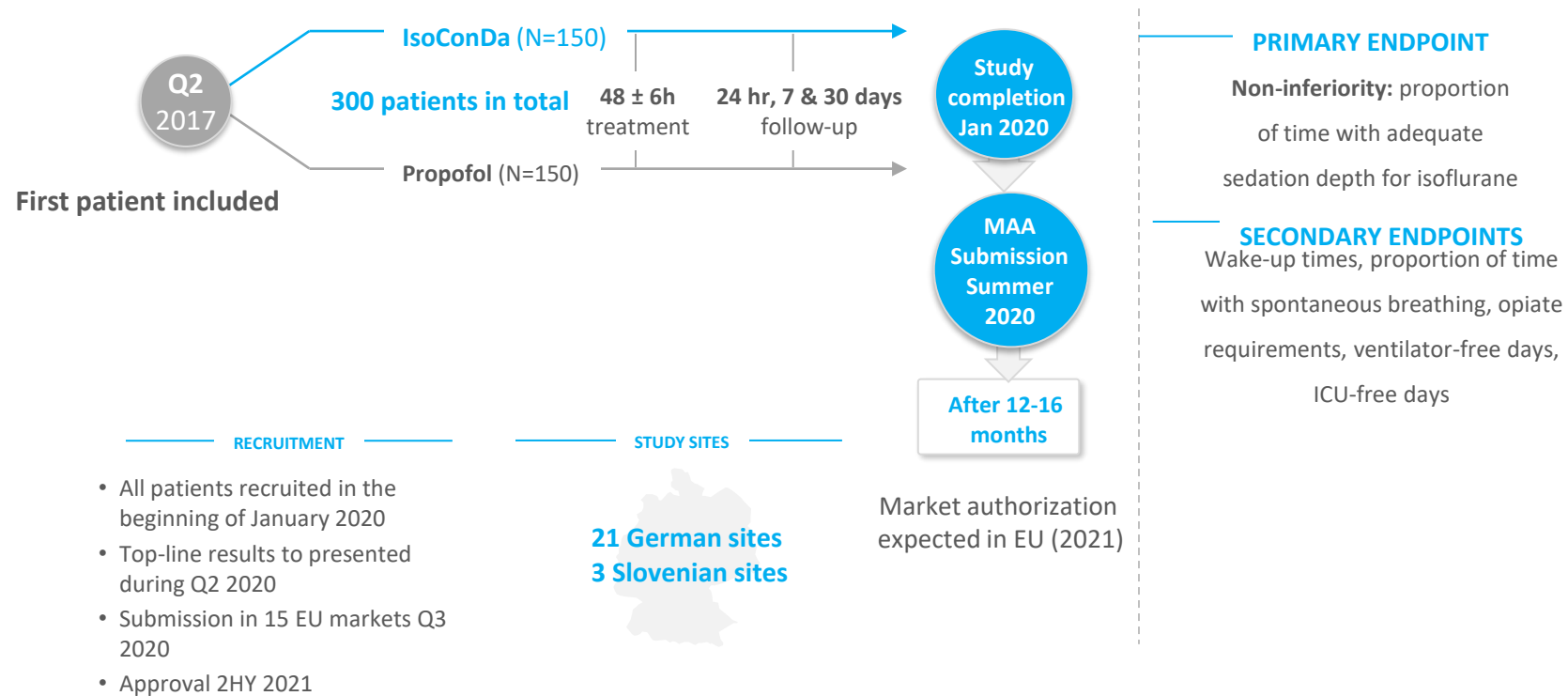


# European market registration study – the IsoConDa study



## Phase III trial: Non-inferiority study of IsoConDa compared to propofol

A randomized, controlled, open-label study to confirm efficacy and safety of sedation with isoflurane in invasively ventilated ICU patients using the AnaConDa administration system.



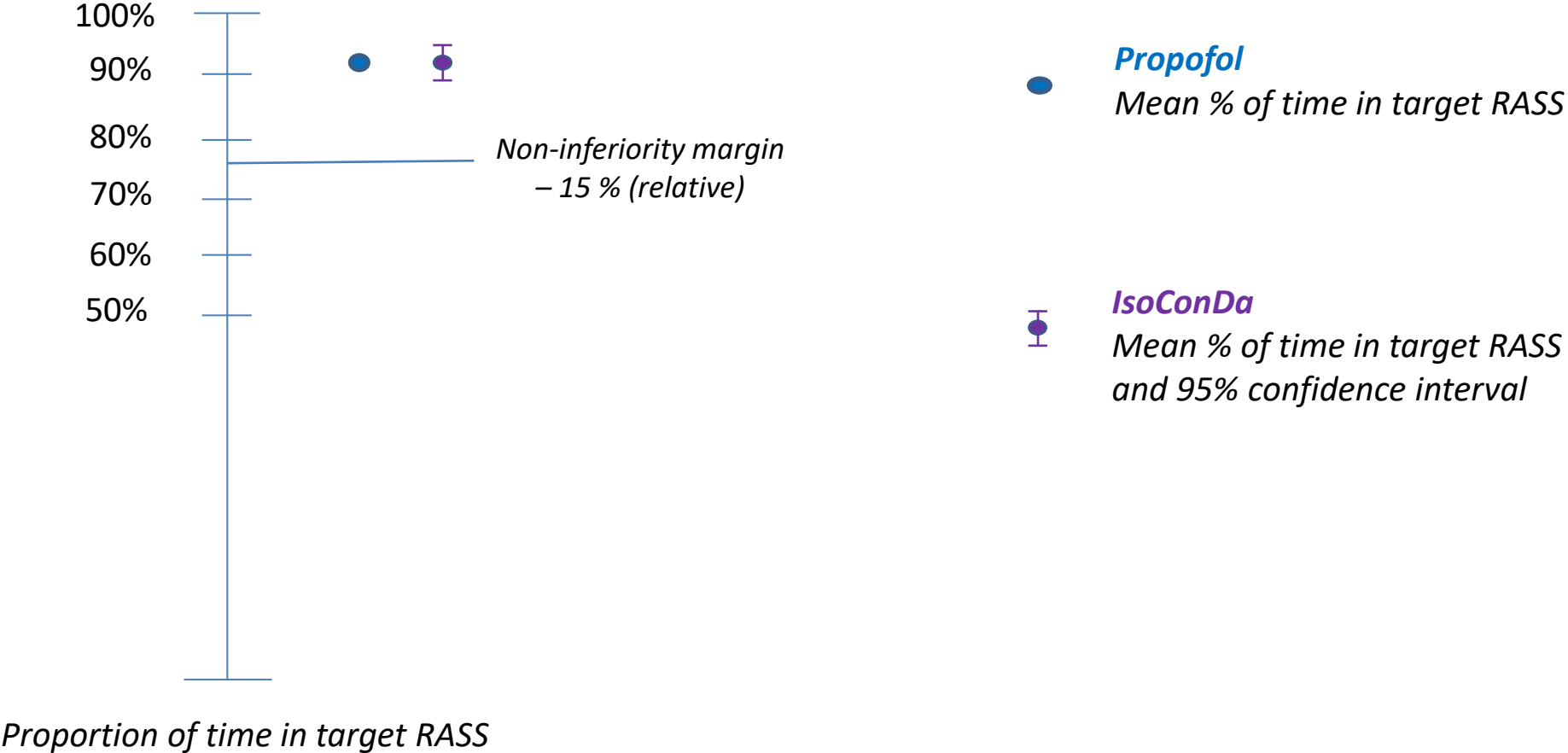


**SEDANA**MEDICAL



Topline results from IsoConDa study

# IsoConDa sedation efficacy non-inferior to propofol



## Safety

**SAEs**

Few serious adverse events in both groups despite critically ill patient population

**No safety or tolerability concerns**

Adverse events generally unrelated to sedation or device

## Secondary and exploratory endpoints

**Under analysis**

Will be communicated together with primary endpoint and safety in peer reviewed publication

**SEDANA**MEDICAL

.....

**Clinical Development  
USA**

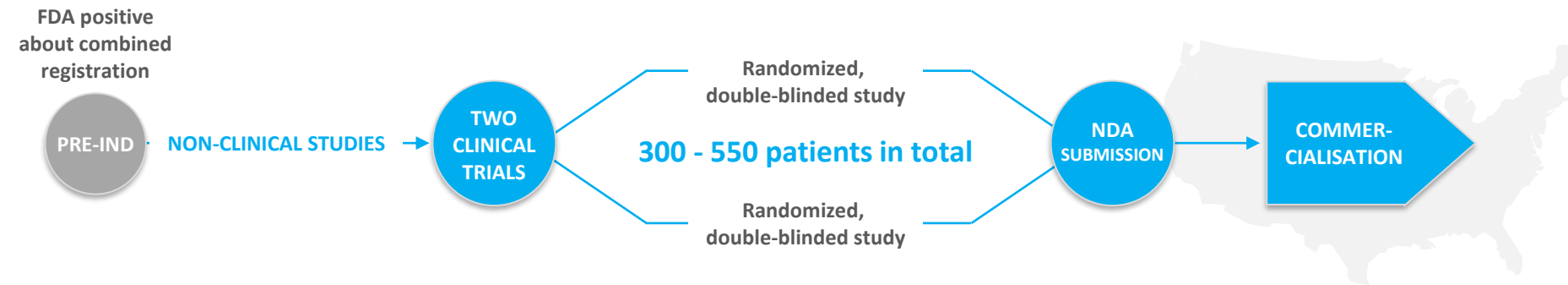


# Combination registration of AnaConDa & IsoConDa in USA



## 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.



### NON-CLINICAL DATA

Current documentation to be complemented with more data, to be approved by FDA:

- Toxicity studies – animal and PPND\* - ongoing
- Human factors validation - ongoing

### CLINICAL STUDIES

Two clinical, randomized and double-blinded studies to be conducted to confirm efficacy and safety.

### SAFETY DATABASE

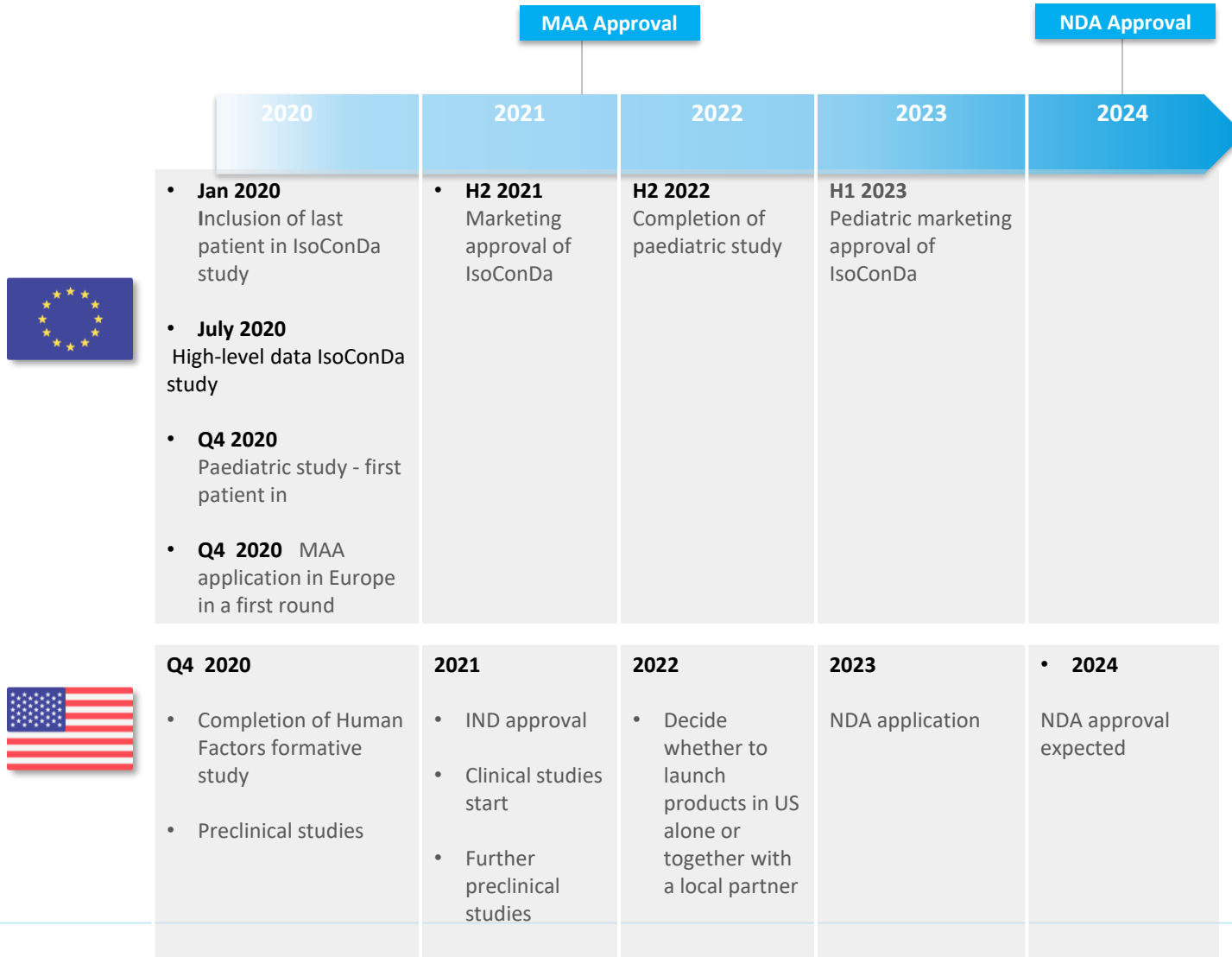
Patients from these clinical studies, as well as patients from the European study will be included in the safety database of 500 isoflurane patients.

### COMMERCIALISATION

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



# Timeline – registration activities in Europe and US



MAA Approval

NDA Approval

**SEDANA**MEDICAL



**Financial highlights**

# Financial highlights

## Q3 -2020

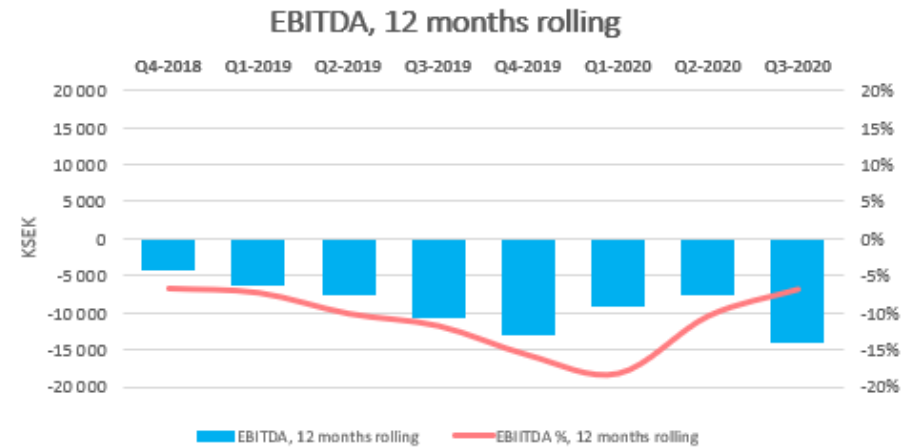
- **Net sales** of 21,4 MSEK vs. 16,4 MSEK in Q3 2019, 31% growth individual quarter YoY and 86% YTD YoY.
- **Gross margin** of 14,3 MSEK or 67% vs. 12,0 MSEK or 73 % in Q3 2019.
- **EBITDA** -10,4 MSEK or -48,6% vs. -4,0 MSEK or -24,5% in Q3 2019.
- **OPEX** increased with 48% vs Q3 2019 due to build up of European organisation and preparation for IsoConDa launch which means continued sales and market, medical affairs, regulatory affairs and quality functions investments during Q3.
- **58 employees** in average vs. 40 employees Q3 2019 for the group in total.
- **Cash flow from operations** before change in working capital was -8,5 MSEK.
- **Cash flow from operations** including change in working capital was -5,3 MSEK.
- **Cash flow from investments** was -22,0 MSEK of which -18,3 MSEK concern product development.
- **Total cash flow** for the group in Q3 was -27,4 MSEK.



## Slightly lower gross profit



## Positive EBITDA



# Financial results Q3 2020 vs. Q3 2019

(MSEK)

## P&L

	Q3	
	2020	2019
<b>Revenues</b>		
Net sales	21,4	16,4
Capitalized development expenses	0,0	0,0
Other operating income	2,0	0,9
	<b>23,5</b>	<b>17,3</b>
<b>Operating cost and expenses</b>		
Cost of goods sold	-7,1	-4,4
External expenses	-9,8	-7,1
Personnel expenses	-14,5	-9,3
Depreciation and amortisation	-1,3	-1,1
Other operating expenses	-2	0
<b>Operating income</b>	<b>-11,7</b>	<b>-5,1</b>
<b>Income from financial items</b>		
Result from securities and long term receivables	0,0	0,0
Financial income	1,2	0,8
Financial expenses	-1,0	0,0
<b>Income after financial items</b>	<b>-11,4</b>	<b>-4,3</b>
<b>Income before taxes</b>	<b>-11,4</b>	<b>-4,3</b>
Taxes	-2,0	-0,7
<b>Net Income</b>	<b>-13,4</b>	<b>-4,9</b>
<b>Gross Margin</b>	<b>14,3</b>	<b>12,0</b>
%	<b>66,7%</b>	<b>73,2%</b>
<b>EBITDA</b>	<b>-10,4</b>	<b>-4,0</b>
%	<b>-48,6%</b>	<b>-24,5%</b>

## Balance Sheet

	30 September	
	2020	2019
<b>ASSETS</b>		
Intangible assets	145,4	84,2
Tangible assets	6,5	5,3
Financial assets	1,1	1,3
<b>Total Fixed assets</b>	<b>153,0</b>	<b>90,8</b>
Inventory	0,0	0,0
Receivables	21,5	12,4
Cash and cash equivalents	406,3	122,2
<b>Total current assets</b>	<b>427,9</b>	<b>134,6</b>
<b>TOTAL ASSETS</b>	<b>580,9</b>	<b>225,4</b>
<b>EQUITY &amp; LIABILITIES</b>		
Share capital	2,3	2,0
Other equity	560,1	207,4
<b>Total equity</b>	<b>562,4</b>	<b>209,4</b>
<b>Long term liabilities</b>	<b>0,0</b>	<b>0,0</b>
<b>Current liabilities</b>	<b>30,7</b>	<b>21,8</b>
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>593,1</b>	<b>231,3</b>

## Cash Flow

	Q3	
	2020	2019
Cash flow from operations bef. change in w.c.	-8,5	-3,9
Change in w.c.	3,1	0,5
<b>Cash flow from operations after change in w.c.</b>	<b>-5,3</b>	<b>-3,4</b>
Cash flow from investment activities	-22,0	-12,7
Cash flow from financing activities	0,0	0,9
<b>Cash flow for the period</b>	<b>-27,4</b>	<b>-15,3</b>

# Largest shareholders at the end of September 2020

	Number of shares	Share (%)
Handelsbanken Funds	2 213 763	9,61%
Swedbank Robur Funds	2 035 895	8,83%
Linc AB	1 899 701	8,24%
Anders Walldov direct and indirect (Brohuvudet AB)	1 650 000	7,16%
Sten Gibeck	1 219 944	5,29%
Ola Magnusson direct and indirect (Magiola AB)	1 157 246	5,02%
Öhman Funds	743 416	3,23%
Berenberg Funds	697 004	3,02%
Tredje AP-fund	515 000	2,23%
Michael Ryan	476 478	2,07%
Nordnet Pensionsförsäkring	465 591	2,02%
Avanza Pension	452 608	1,96%
Tedsalus AB (Thomas Eklund)	416 616	1,81%
Highclere International Investors LLP	364 798	1,58%
Philip Earle	304 751	1,32%
Fifteen largest shareholders	14 612 811	63,41%
<i>Others</i> *	8 433 929	36,59%
<b>Total</b>	<b>23 046 740</b>	<b>100,00%</b>

\* CEO's ownership is 259 000 shares.



# 2020 a year strongly influenced by Covid-19





**SEDANA**MEDICAL

.....

**Questions**

# **SEDANA**MEDICAL

Appendix



# Q3 2020 Highlights

## Significant events during the period

- On July 1, Sedana Medical announced that it had received market approval in Saudi Arabia for its medical device AnaConDa, and that distribution agreements had been concluded with distributors in Saudi Arabia, the United Arab Emirates and Oman. Sales are expected to begin shortly in Saudi Arabia and within a few months in the other countries.
- On July 10, Sedana Medical announced top line result for the company's registration-based phase 3 study for the drug IsoConDa. The study reached its primary endpoint; to show that IsoConDa (isoflurane), administered with AnaConDa, is an effective sedation method, for ventilator-intensive care patients, which is non-inferior to propofol.
- On August 19, the company announced that it has signed a distribution agreement for sales in Australia and New Zealand with the distributor Device Technologies. As the AnaConDa already has market approval in both markets, sales can start immediately.

## Significant events after the period

- Sedana Medical announced in October that Susanne Andersson has been appointed new CFO of the company and will start during the first quarter of 2021. Susanne Andersson succeeds Maria Engström, who on her own initiative has chosen to leave the CFO position. Maria Engström will transfer to an advisory role for Sedana Medical's management team when Susanne Andersson has started.
- Sedana Medical announced in the beginning of October that the UK's National Institute for Health and Care Excellence (NICE) has issued a Medtech innovation briefing (MIB) on the use of AnaConDa as an alternative to intravenous sedation in intensive care.

## Therapeutical benefits by using inhaled anaesthetics



**Pulmonary therapeutic effects for patients with impaired gas exchange<sup>11</sup>**

- ✓ Improved oxygenation
- ✓ Reduction of pulmonary inflammatory response
- ✓ Bronchodilatory effect



**On-off effects and reliable wake-up with inhaled sedation<sup>12</sup>**

- ✓ Shorter time to extubation...
- ✓ Shorter time to cooperation...
- ✓ Shorter ventilator time and ICU stay...  
...when compared with intravenous sedation



**Reliable effect and safety with inhaled sedation for the distressed patient<sup>13</sup>**

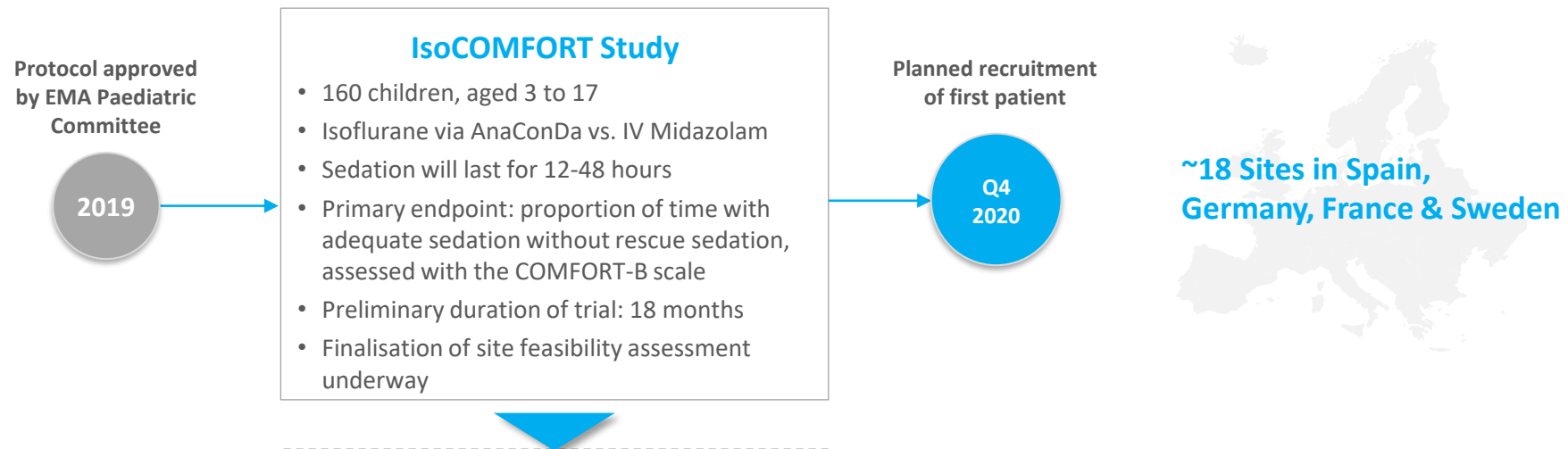
- ✓ Works in all patients – full range sedative
- ✓ No need for polypharmacy
- ✓ Few problems after wake-up
- ✓ Patients are more lucid and calm with less hallucinations and delusions
- ✓ No/low risk of tolerance development, ceiling effect and withdrawal symptoms
- ✓ Reduction of opioid use

# The IsoCOMFORT study for EU and USA



## Approved paediatric investigation plan

A complete Marketing Authorization Application (MAA) for drugs in EU must include a PDCO-approved study plan for children, a so-called PIP (Paediatric Investigation Plan).

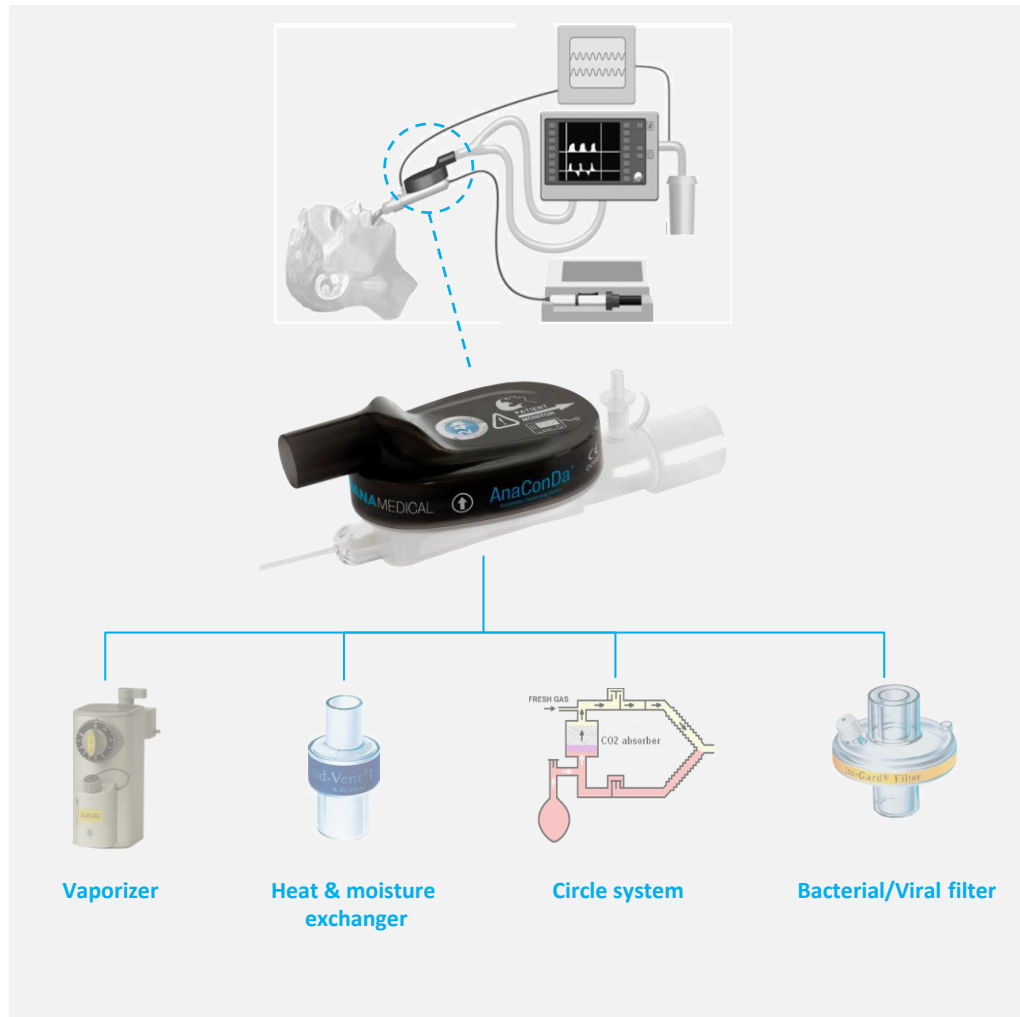


The outcome of the study is not a requirement for obtaining an authorization for use in adults, so **the timetable for approval of IsoConDa is not affected** by this decision.

Since the filed registration documentation will now be complete – i.e. also covers children – **an approval means Sedana Medical will receive ten years of market exclusivity** in Europe for the use of isoflurane in sedation in intensive care.

# AnaConDa – making inhaled sedation possible in the ICU

Compact device encompassing the most important elements for ICU use



## AnaConDa

- **Simple and convenient to administer** – can be administered by a nurse
- **Low cost disposable system** for administration of inhaled sedatives
- **Accurate patient dosing** minimizing over and under sedation
- **Compact size and convenient design** – Seamless integration into clinical workflow
- **Low consumption of sedative agent** – >90% recirculated to patient
- **Proven safety with no workplace pollution** in the ICU
- **Combines 4 functions** (vaporizing, reflecting, humidifying and filtering) disposable delivery system - no electricity or maintenance
- **CE marked** with strong sales growth in Europe, patent possible until 2036



# IsoConDa® – a superior inhaled sedative for use in the ICU

Safe and proven inhaled sedative administered by a practical and cost effective delivery system



## IsoConDa® (Isoflurane)

- **Significant reduction in mortality<sup>4</sup>**
- **Potential for reduced ICU stay duration:** No development of tolerance, dependence, withdrawal symptoms and/or delirium and fewer hospital acquired infections (HAI): expected to lead to shorter ICU stays
- **Organ protective\*:** Inhaled sedatives have potentially cardio-, neuro- and lung-protective properties<sup>7</sup>
- **Eliminated through the lungs** (IV drugs are metabolised in the liver and eliminated through the kidneys): isoflurane is almost 100% eliminated through the lungs
- **Bronchodilator effect:** Improves lung function for patients with COPD, ARDS, Asthma etc.<sup>8</sup>
- **Reduction of opiate dependency:** Reduces the need for analgesics such as remifentanyl and other opioids by >35% compared to when using IV sedation, with benefits to the associated cost of sedation<sup>9</sup>