

# SEDANA MEDICAL

Pioneering volatile anaesthetic delivery

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Q4 and Year-End Report 2020

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25th February 2021  
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# 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.

# 2020 a year strongly influenced by Covid-19





## **Our Purpose**

*To improve life during and beyond sedation*

## **Vision**

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

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# Sedaconda®/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>

## Sedaconda®/AnaConDa

10-20 min

4-16 days

10-35 min

2 of 10 patients

2.7 mg/hour

40%

50%

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

## IV sedation

90 min – 130 h

6-27 days

150-600 min

5 of 7 patients

4.2 mg/hour

63%

70%

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

Price per day

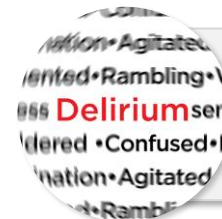
EUR 100\*

EUR 20-300\*\*\*



EUR 1-3k

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

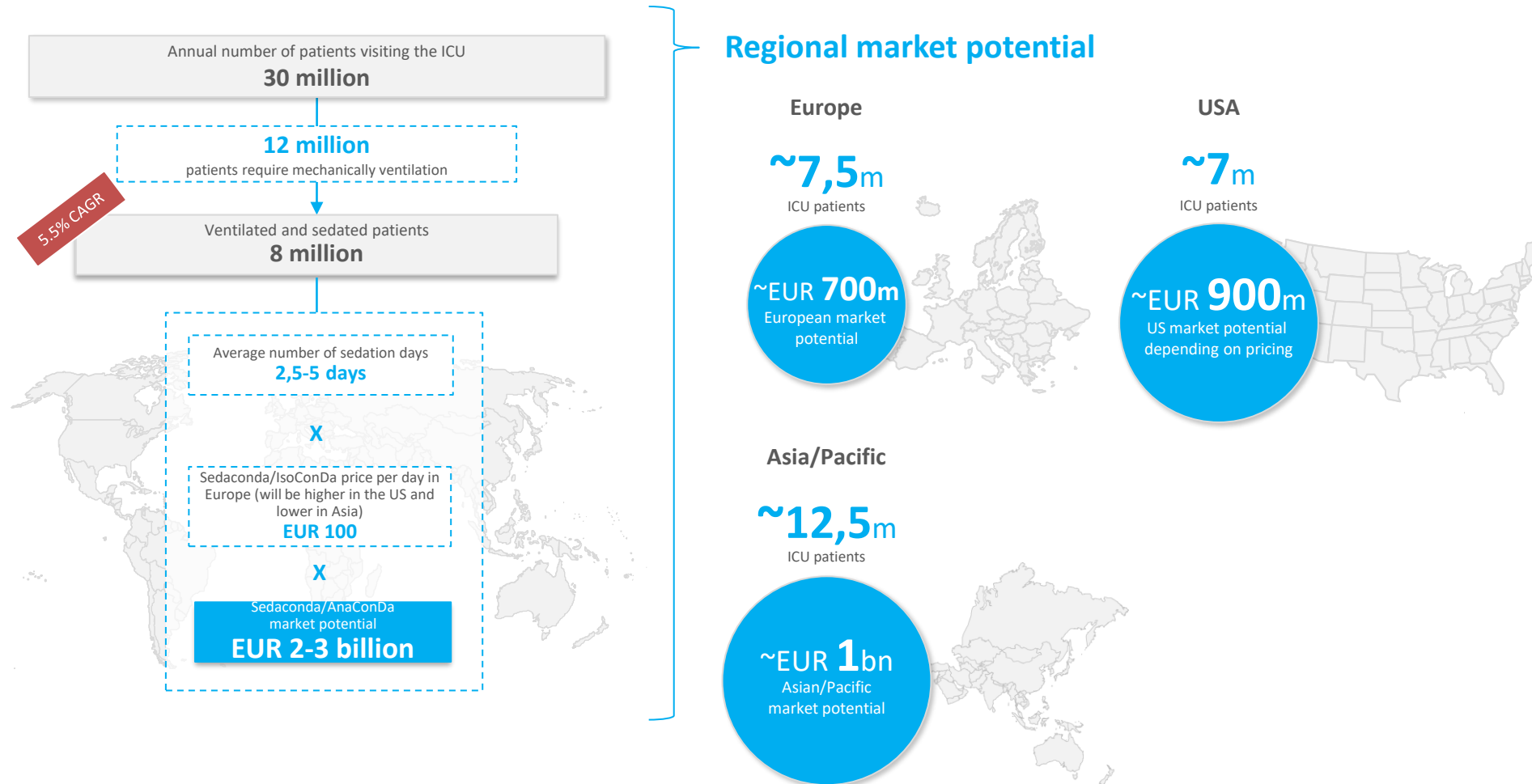


\$4-16bn

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

# Blockbuster market potential for Sedaconda/AnaConDa

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



# Strategic priorities and financial objectives longterm

## Strategic priorities

1

### Development and commercialisation: Europe

- Registration of the pharmaceutical candidate Sedaconda (isoflurane) in 2HY 2021
- Ensure solid growth of AnaConDa sales and prepare for launch and launch of Sedaconda in 2021

2

### Development and commercialisation: USA

- Development of registration work in USA with both Sedaconda and AnaConDa for NDA approval in 2024
- Preparation of Commercialisation strategy for USA to be decided ~2022.

3

### Development and commercialisation: RoW

- Register AnaConDa and Sedaconda in relevant markets in Asia, such as Japan and China

## Financial objectives

### Pre-registration

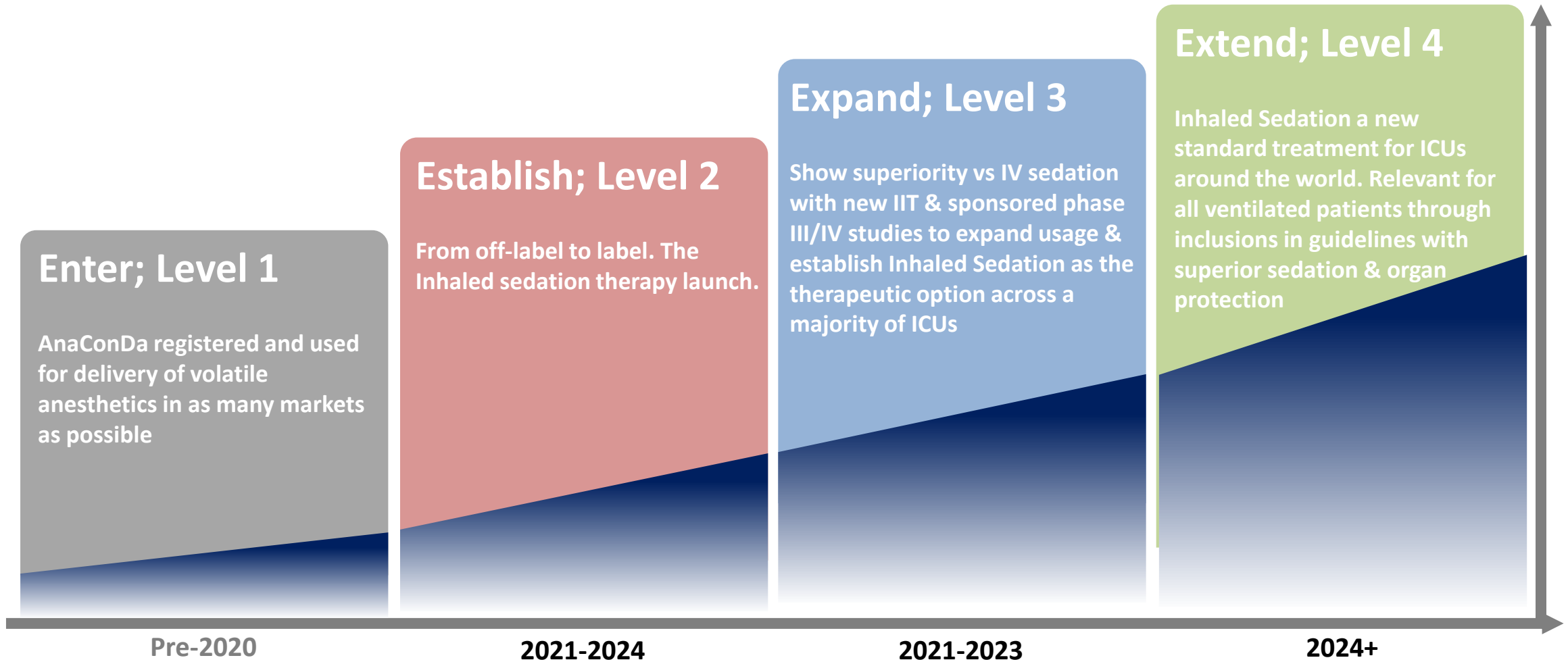
During the period up until the approval of Sedaconda is obtained, the Company's goal is to increase sales with an average of over 20 per cent per year, in parallel to building up a larger sales and market organization.

### Post-registration

Provided that an approval of Sedaconda in Europe is obtained, the Company's target is to reach a turnover in EU exceeding 500 million SEK and an EBITDA margin of 40 percent three years after approval.

# Sedana Medical Vision & Strategic Evolution

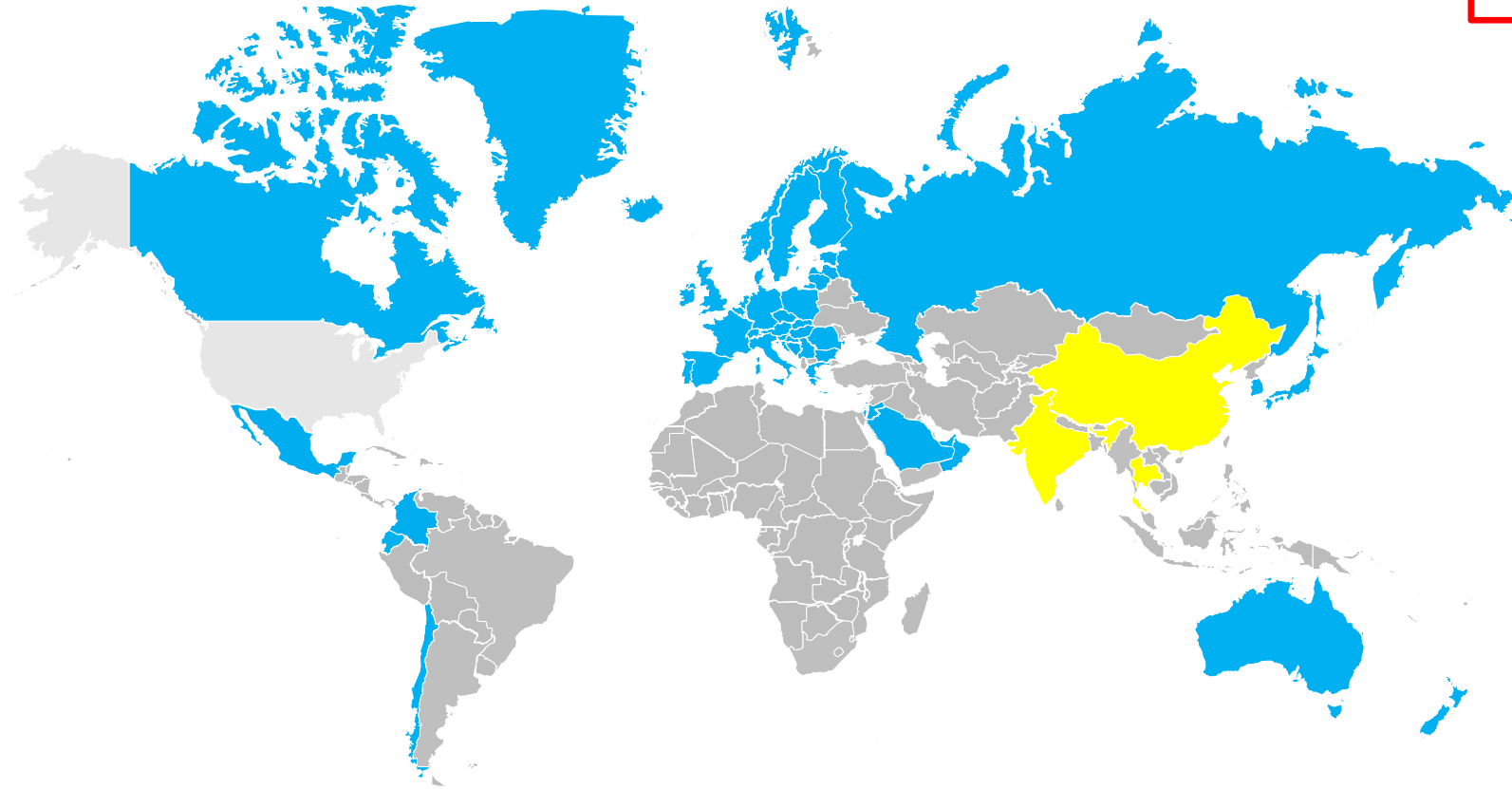
To make inhaled sedation (Sedaconda and AnaConDa),  
a global standard therapy for critical care patients





# Approved AnaConDa Markets

Level 1



- Existing Registered AnaConDa markets
- In registration process.

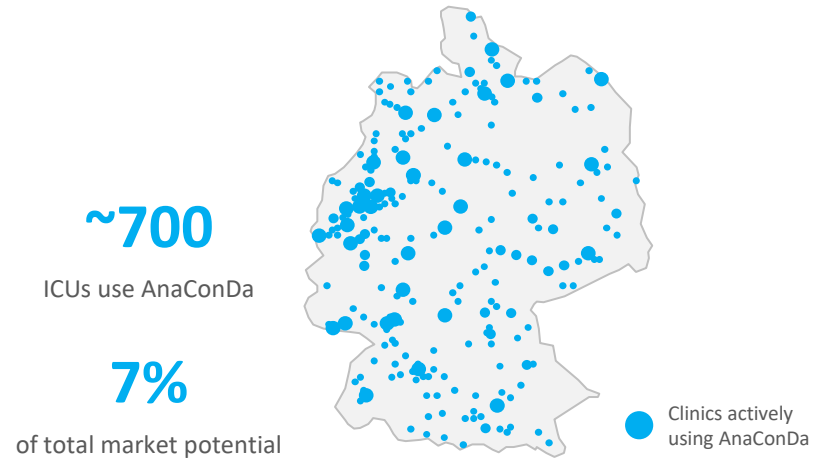
# Rapidly increasing adoption and usage despite off-label status

Level 1

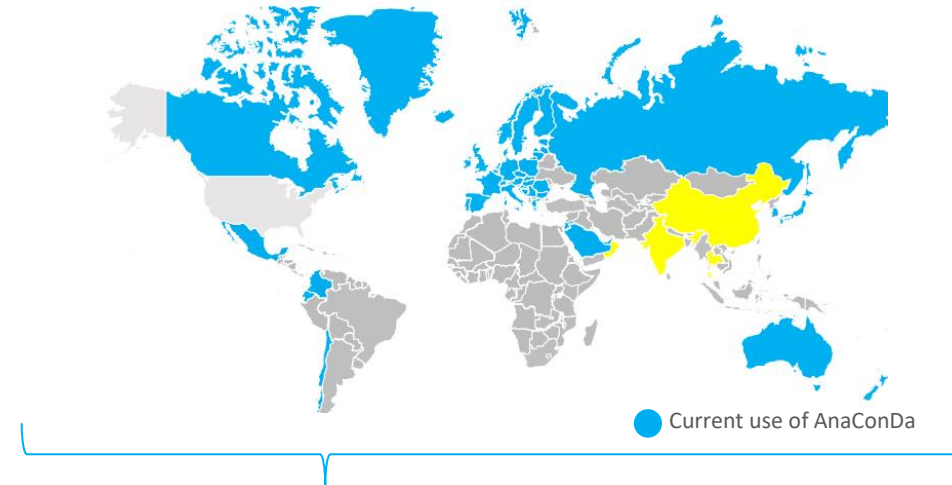
## Case study: AnaConDa in Germany

- 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



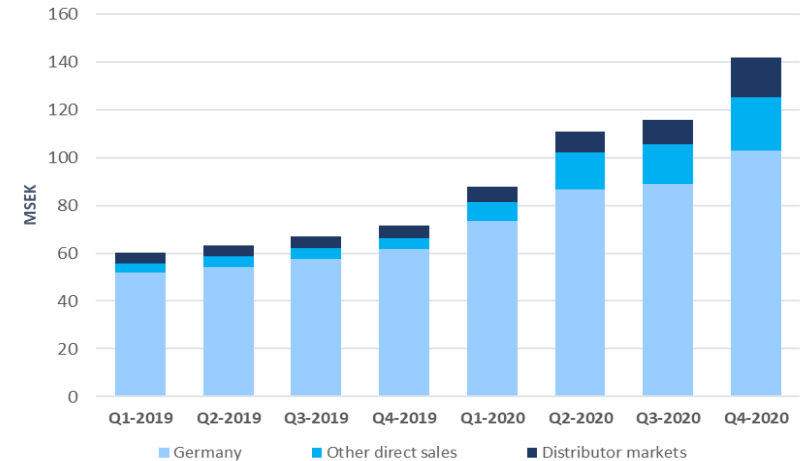
## Increasing use globally



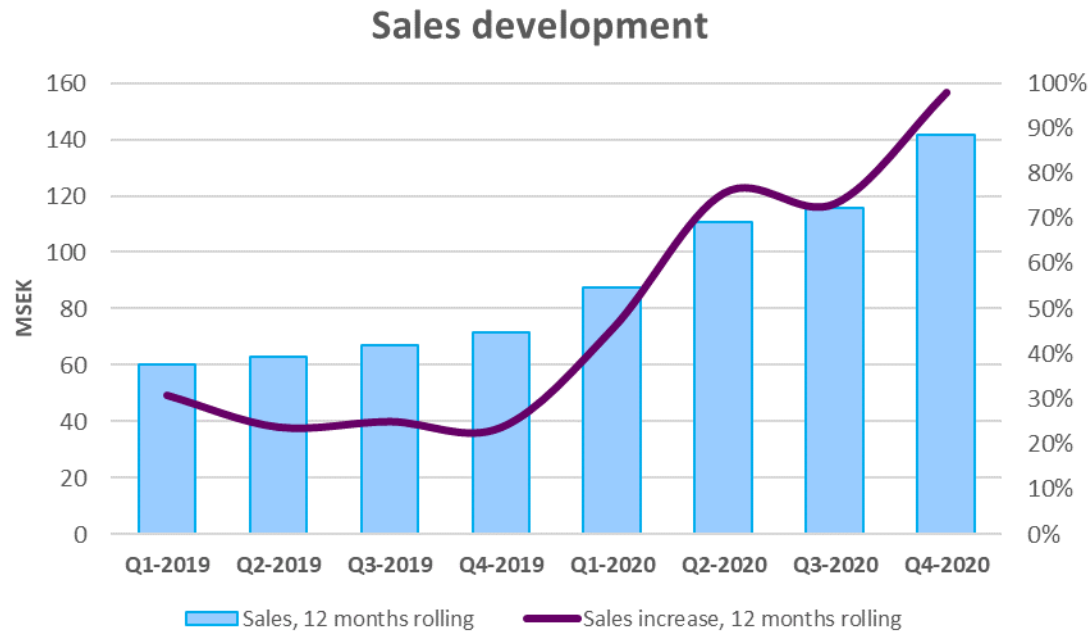
98%  
12 months rolling  
Sales growth  
December 2020

Proven in clinical practice

### Sales by area, rolling 12 months



# Sales Development Q4 2020



**129%**  
Sales  
increase  
vs. Q4 2019

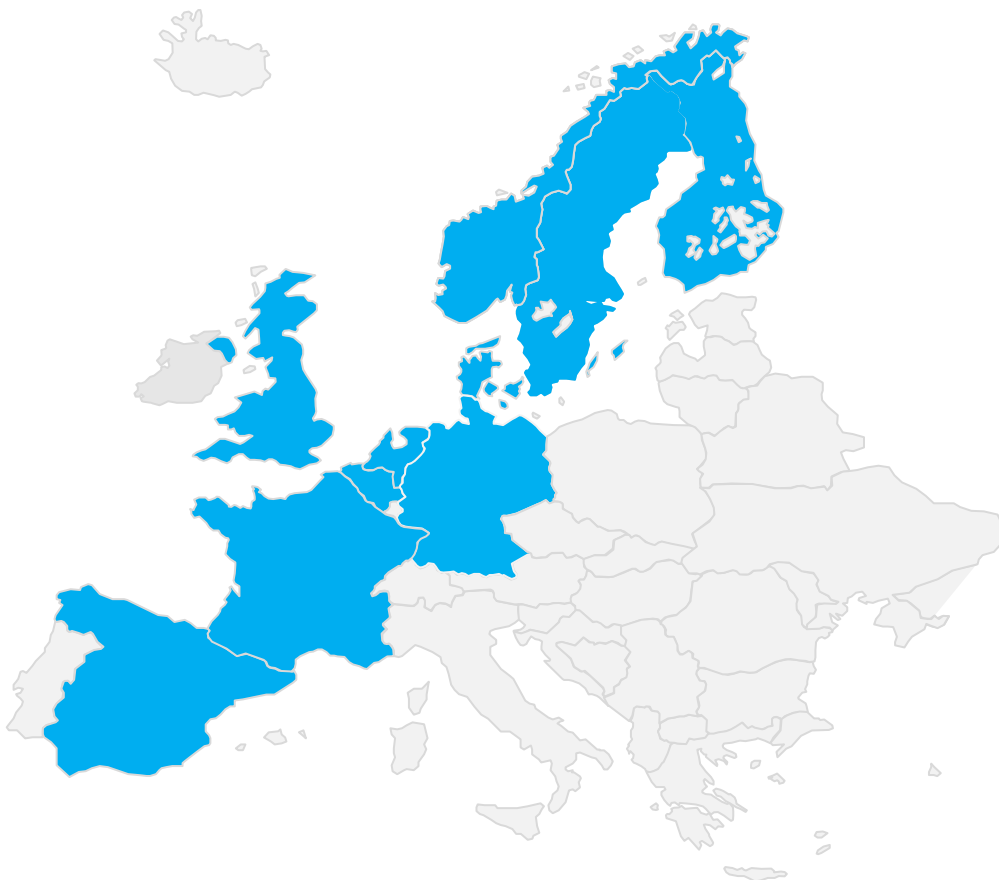
**98%**  
Sales  
increase  
vs. FY 2019

- Sales of 46 MSEK Q4 2020, 129% sales growth vs Q4 2019 (137% in local currencies)
- Sales of 142 MSEK FY 2020, 98% growth vs FY 2019 (100% in local currencies)

# 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



## SEDACONDA LAUNCH EUROPÉ

- Submission in 15 EU countries November 2020
- Expected approval and launch 2HY 2021
- Submission Switzerland & UK Q1 2021  
Expected approval and Launch 1HY 2022
- Second wave submission in EU after first wave approval and expected launch 6-8 months after submission.
- Investigation ongoing for additional registration countries to be added based on the European dossier.

15  
COUNTRIES



# 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

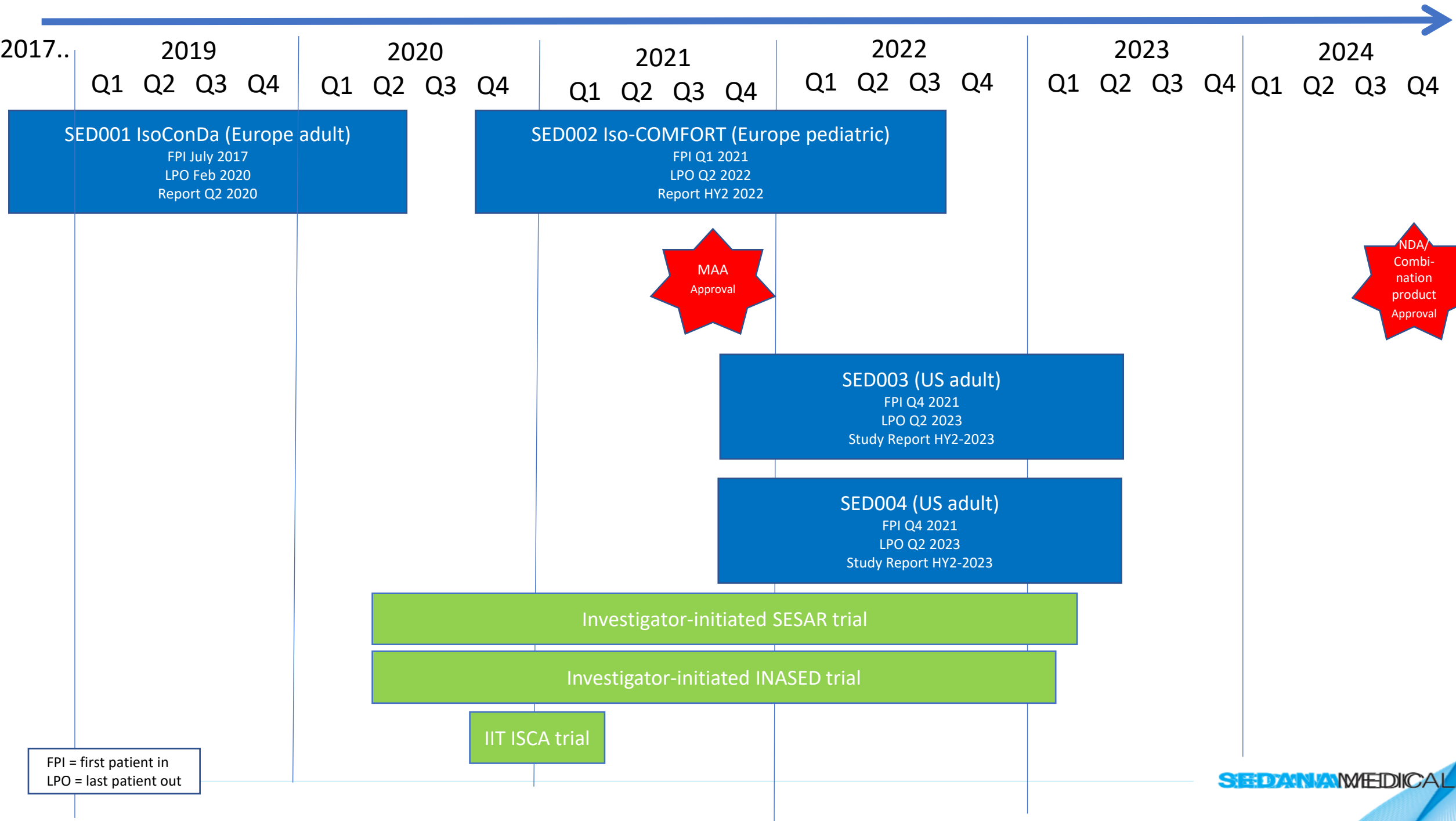
Medtech innovation briefing

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).



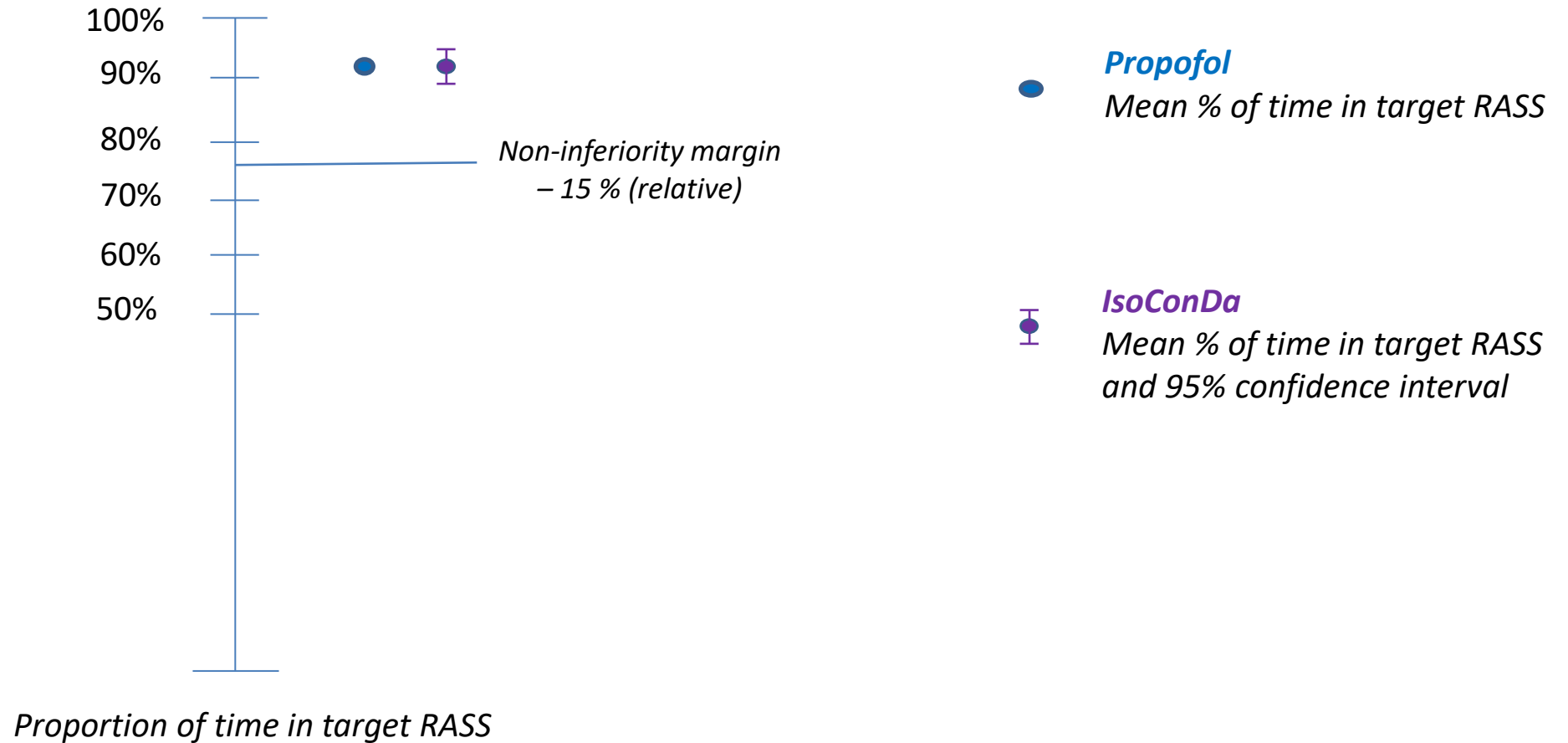
FPI = first patient in  
 LPO = last patient out

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Topline results from SED001 IsoConDa study

# Sedaconda 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 endpoints SED001

### Presented at European Society of Intensive Care Medicine 2020

1. Lower opioid requirement during sedation with isoflurane\*
2. Higher proportion of spontaneous breathing with isoflurane\*
3. Wake-up times
  - No difference in time to wake-up after 24 hours
  - Significantly shorter time to wake-up after 48 hours\*

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**Clinical Development  
USA**

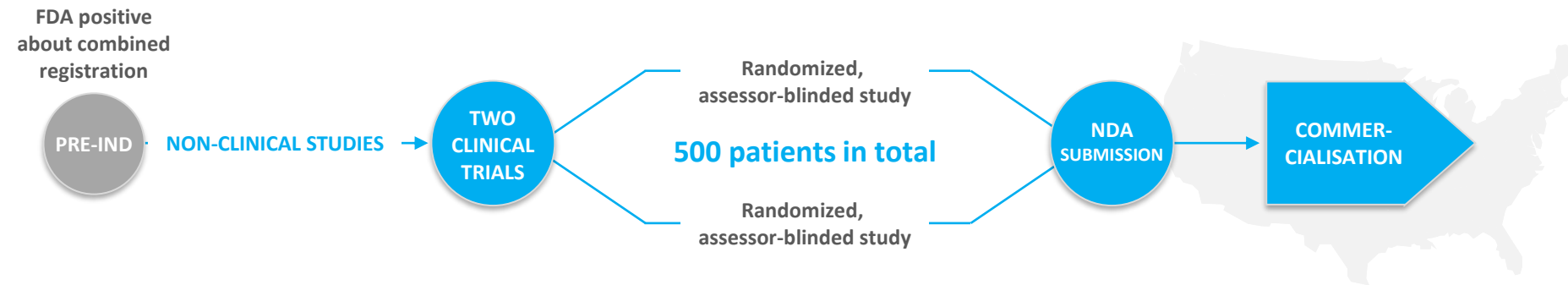


# Combination registration of Sedaconda & AnaConDa in USA



## 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.

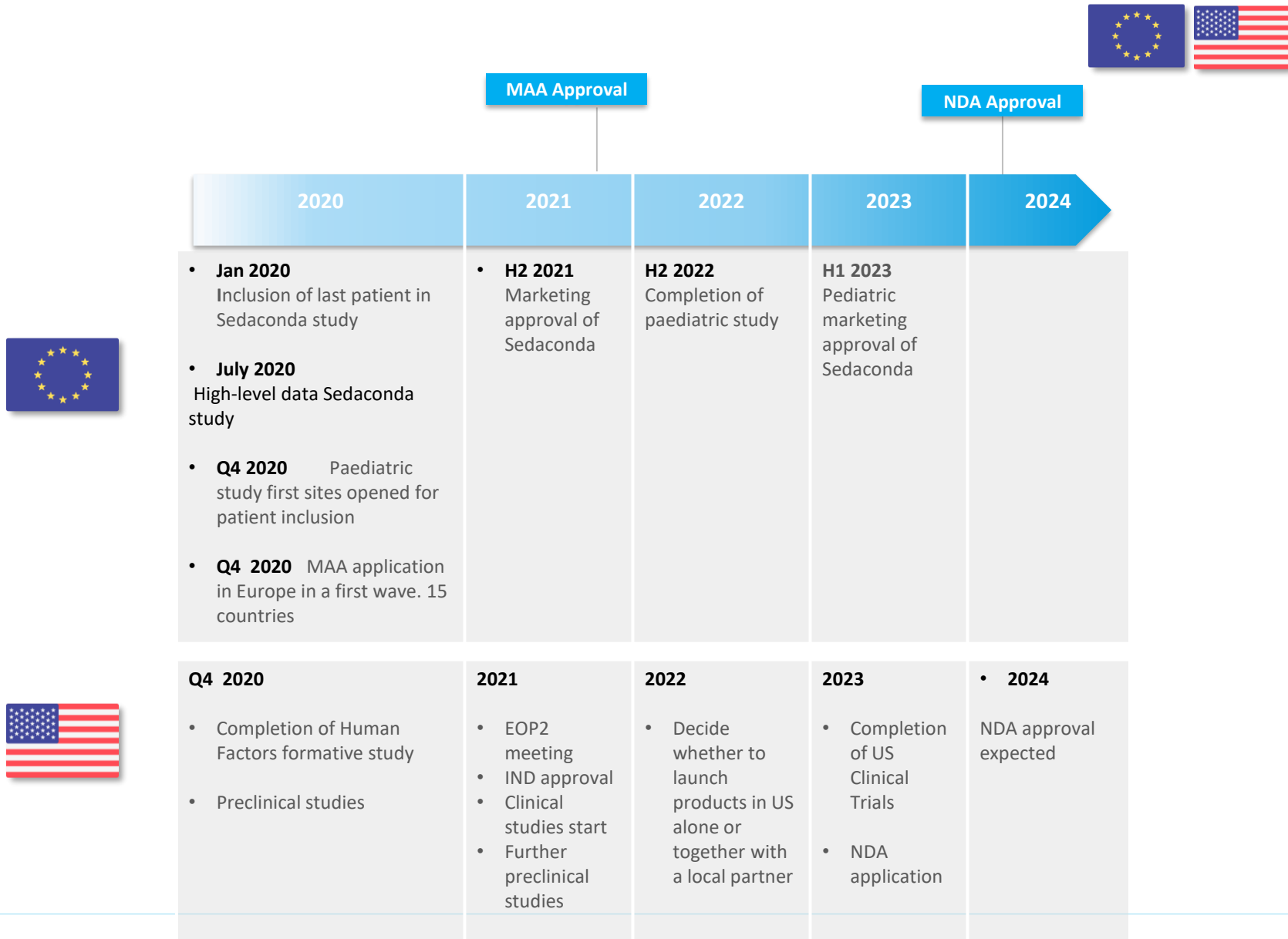
### SAFETY DATABASE

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



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**Financial highlights**

# Financial results <sup>1)</sup>

## Improved results. Investing for future.

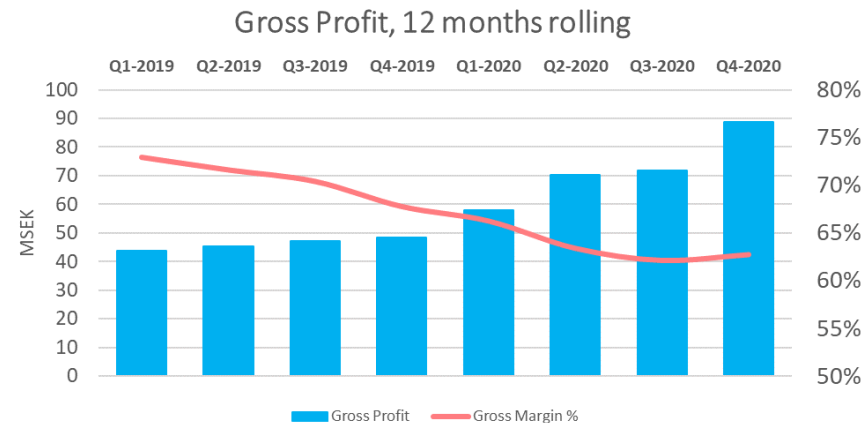
- **Net sales Q4'20:** 46 (20) MSEK, +129% YoY  
**Net sales FY'20:** 142 (72) MSEK, +98% YoY

- **Gross Profit FY'20:** 89 (49) MSEK, +83% YoY  
**Gross Margin FY'20:** 63 (68) %

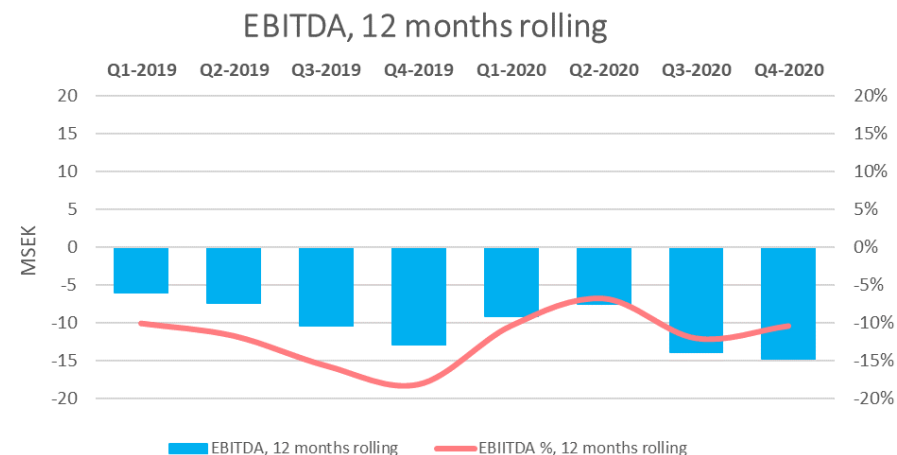
Strong development throughout the year, but certain decline in gross margin due to higher freight costs during the Covid-19 pandemic.

- **EBITDA FY'20:** -14 (-13) MSEK  
**EBITDA Margin FY'20:** -10 (-18) %
- **Investing now for future growth.** Build up of organisation and preparation for SedaConDa launch results in increased OPEX and number of staff.
- **Staff, incl consultants, per 31<sup>st</sup> Dec 2020/2019:** 83 (46)

## Gross profit development



## EBITDA development



<sup>1)</sup> Numbers are restated according to IFRS and from a P/L by cost type to function type.

# Financial balances and Cash<sup>1)</sup>

- **Cash flow from operations Q4'20:** 3 (-4) MSEK  
**Cash flow from operations FY'20:** -8 (-7) MSEK
- **Cash flow from investment Q4'20:** -31 (-17) MSEK  
**Cash flow from investments FY'20:** -85 (-54) MSEK  
of which the vast majority is related to product development.
- **Cash flow for the period Q4'20:** -29 (342)\*  
**Cash flow for the period FY'20:** -87 (305)\*  
\* A directed new share issue of 375 MSEK concluded in Oct 2019.
- **Cash balance per 31<sup>st</sup> Dec 2020:** 376 (465) MSEK
- **No long-term financial debts / Debt free company**

<sup>1)</sup> Numbers are restated according to IFRS and from a P/L by cost type to function type.





# Largest shareholders at 31<sup>st</sup> December 2020

	Number of shares	Share (%)
Handelsbanken Funds	2 173 763	9,61%
Swedbank Robur Funds	2 110 895	8,83%
Linc AB	1 899 701	8,24%
Anders Walldov direct and indirect (Brohuvudet AB)	1 690 000	7,16%
Sten Gibeck	1 219 944	5,29%
Ola Magnusson direct and indirect (Magiola AB)	1 153 432	5,02%
Öhman Funds	743 416	3,23%
Berenberg Funds	697 004	3,02%
Nordnet Pensionsförsäkring	501 422	2,23%
Tredje AP-fund	475 000	2,07%
Avanza Pension	471 331	2,02%
Tedsalus AB (Thomas Eklund)	416 616	1,96%
Highclere International Investors LLP	364 798	1,81%
Christer Ahlberg	259 000	1,58%
Philip Earle	257 500	1,32%
Fifteen largest shareholders	14 433 822	62,63%
<i>Others</i> *	8 612 918	37,37%
<b>Total</b>	<b>23 046 740</b>	<b>100,00%</b>

\* CEO's ownership is 259 000 shares.

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**Questions**