Q2 Report 2021

Interim CEO & Commercial Director
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August 19th, 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.

Q2 2021 Highlights

- Sedaconda launch well on track - European approval of Sedaconda (isoflurane) received & first national approval achieved in France
  - Appr. 1-3 months to receive approval in the 15 individual countries.
  - Appr. 3 months to products on shelf following national marketing authorisation
- Increased use of our therapy to ”non covid” patients in Germany and other European countries, number of ICU customers continues to grow at a rate of 1/day
- Strong sales in Germany despite decreasing number of COVID-19 patients.
- Covid pandemic trends, decrease in Europe and increase in Latin America. Mexico second largest market in sales during Q2.
- US Clinical studies well on track, subsidiary established and first Sedana Medical staff to join in Q3.
- Continued build-up of organisation for future growth.

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Our Purpose

To improve life during and beyond sedation

Our Vision

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

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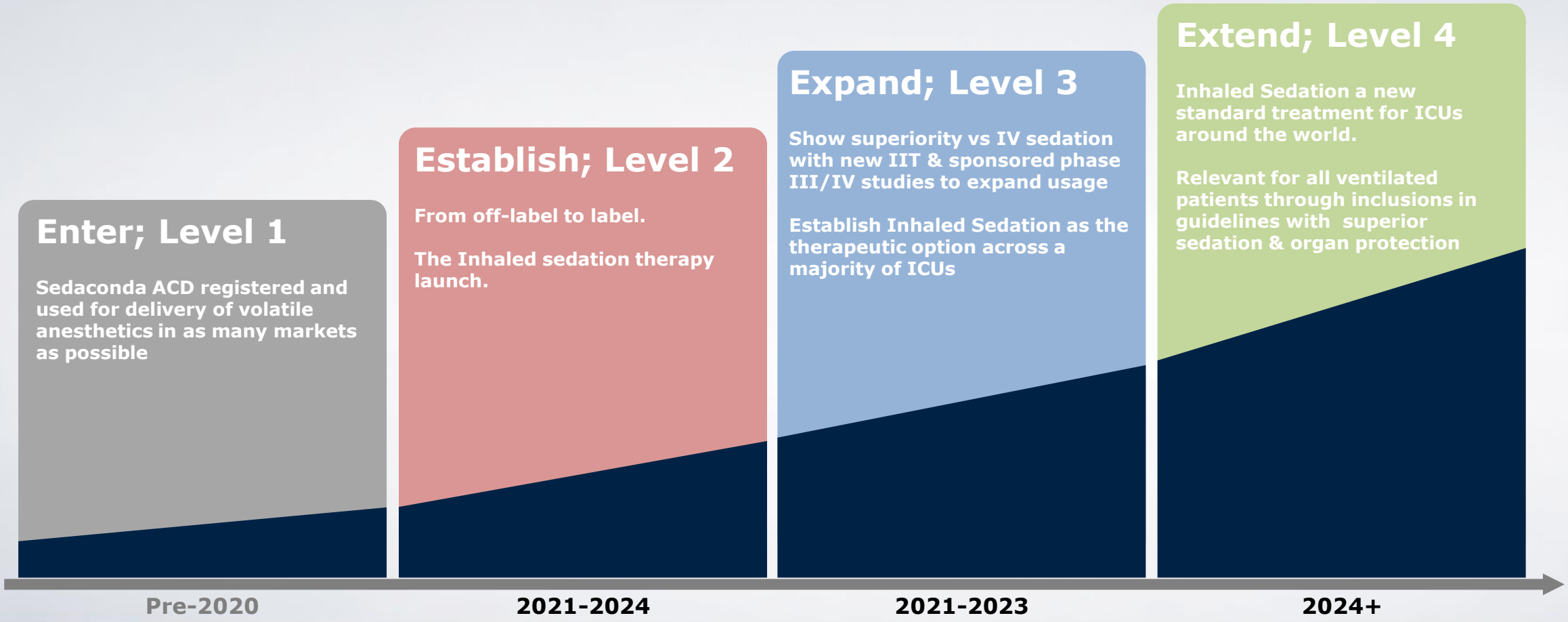
A new tagline & symbol to signal the significance of our journey

Sedana Medical Vision & Strategic Evolution

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



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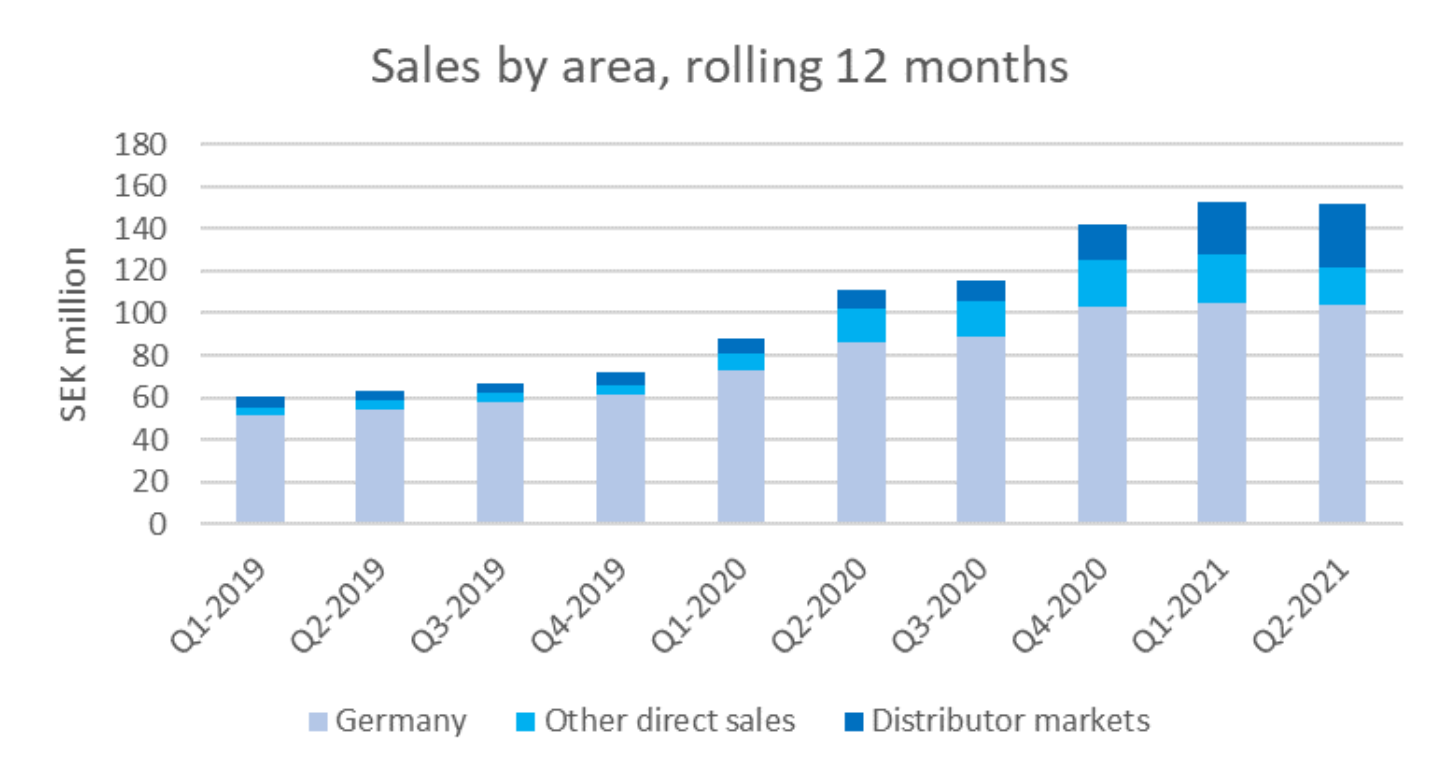
Sales Development Q2 2021



3%
Sales growth YoY
in local currencies

37%
Sales growth
12 months rolling in local currencies

- Sales 40 (41) MSEK, 3% sales growth YoY in local currencies, *(-2% in reported numbers)*
- Substantial growth in Latin America, Mexico second largest market in Q2, increase in COVID-19 patients in Latin America
- Continued strong sales in Germany despite a decrease in COVID-19 patients in Europe

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Rapidly increasing adoption and usage despite off-label status

Case study: AnaConDa/Sedaconda ACD 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 guidelines together with positive statements from a number of German KOLs have led to extensive use of AnaConDa/Sedaconda ACD 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.

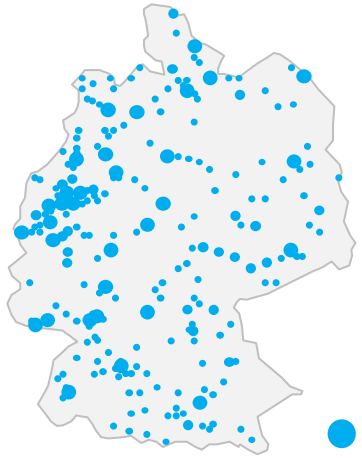
AnaConDa/Sedaconda ACD in Germany

>900

ICUs use AnaConDa

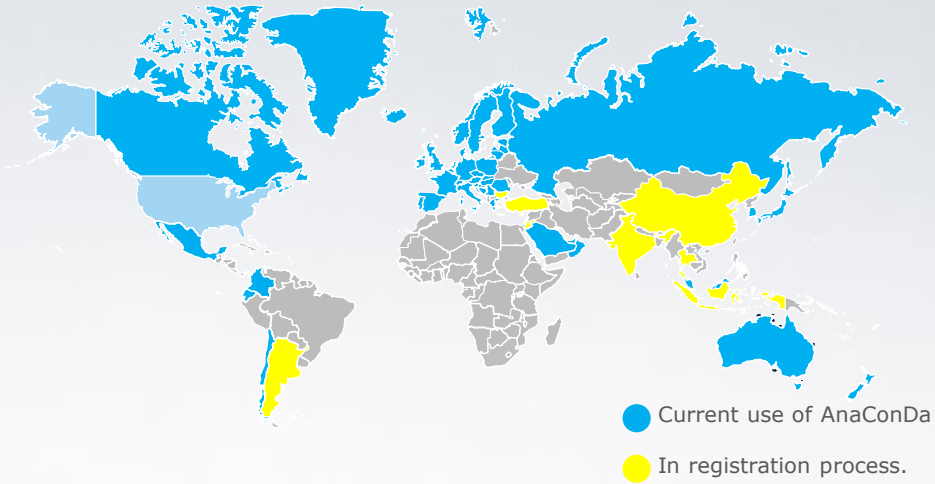
7-9%

of total market potential



Clinics actively using AnaConDa/ Sedaconda ACD

Increasing use globally



Proven in clinical practice

H1
1 NEW ICU/day
in Direct sales Markets

Q2
Mexico 2nd largest market

Q2
151% sales growth
in Distributor Markets

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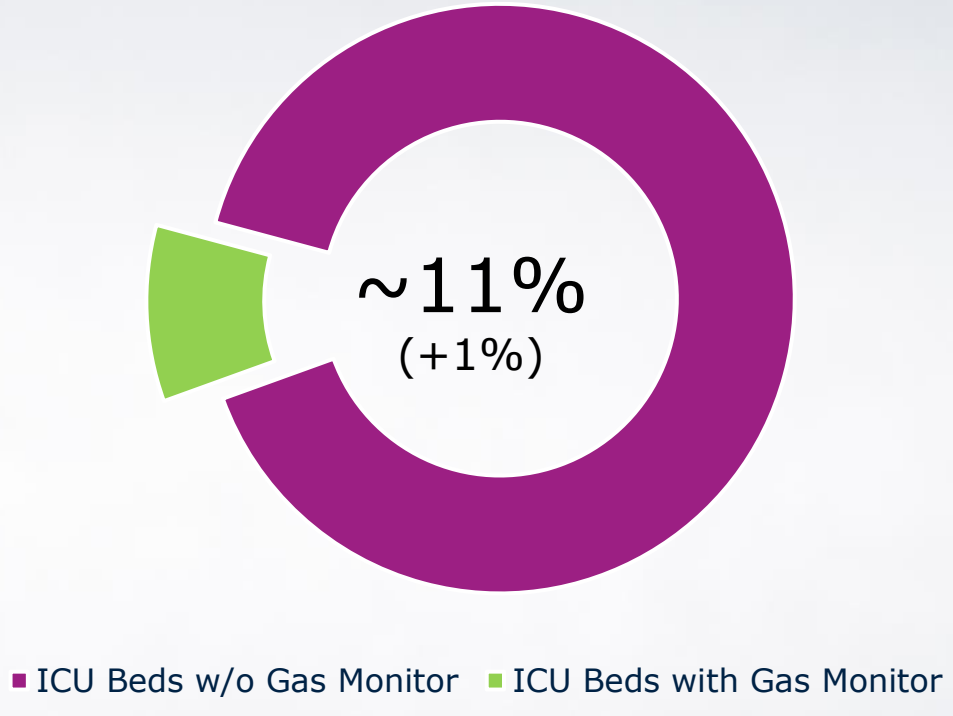
Continued influx of new customers during Q2 despite signs of ”COVID-fatigue” & more ICU beds being equipped with Gas Monitors

of new ICU customers during Q2 in Direct Sales Markets

Share of ICU Beds in Direct Sales Markets with Gas Monitor



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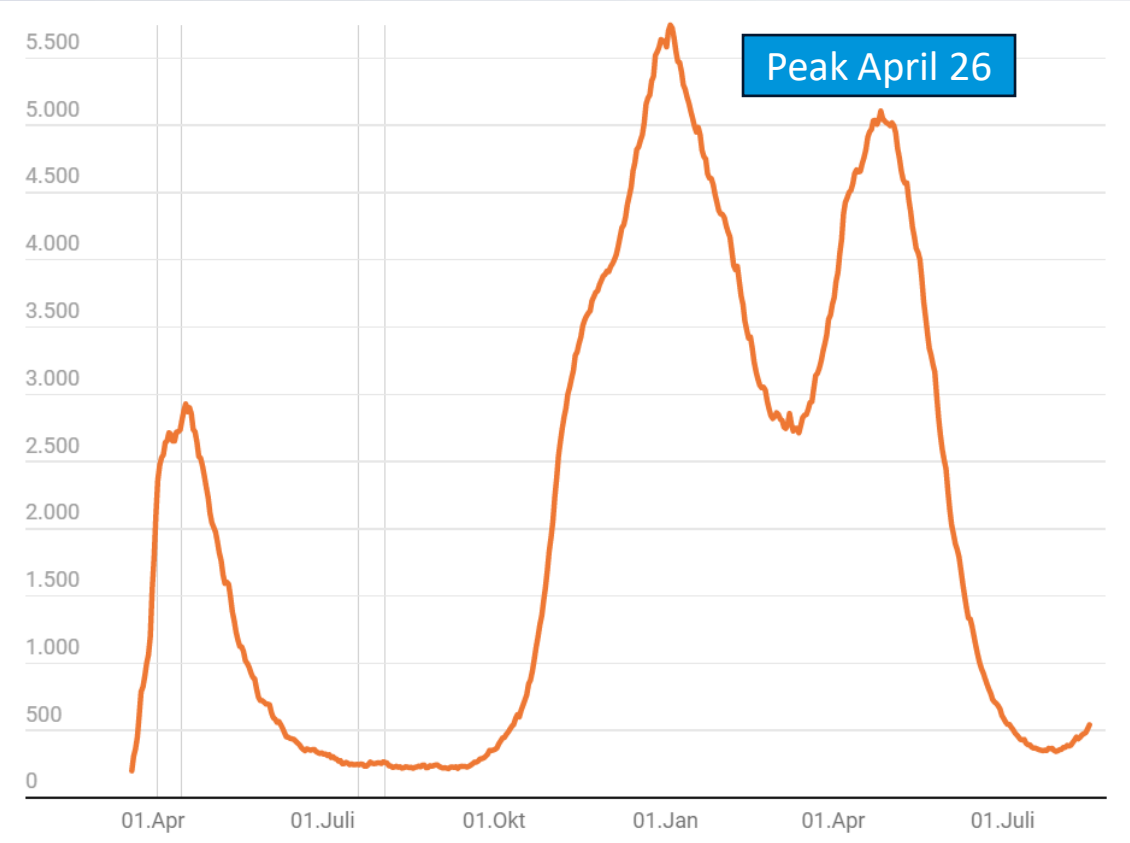
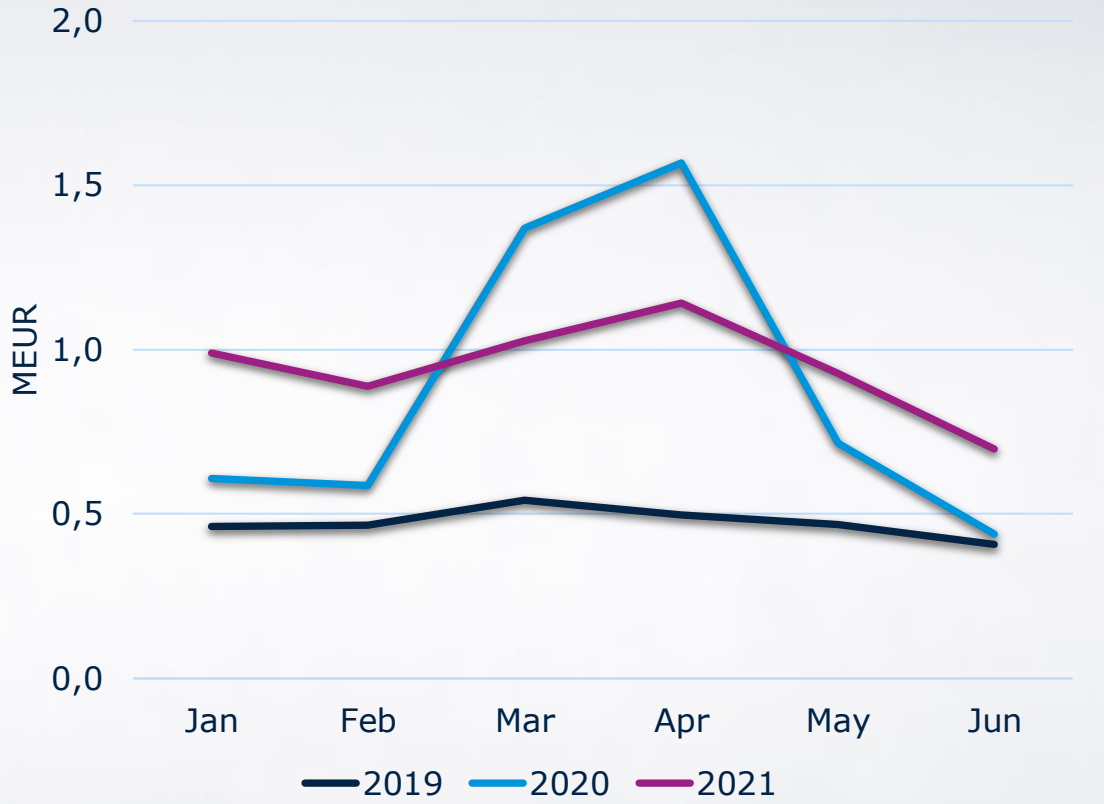
1H 21 sales in Germany much less dependent on COVID-19 than in 1H 20 with stable sales doubled vs 1H 19

of ICU Patients in Germany with COVID-19 from outbreak



Monthly sales in Germany



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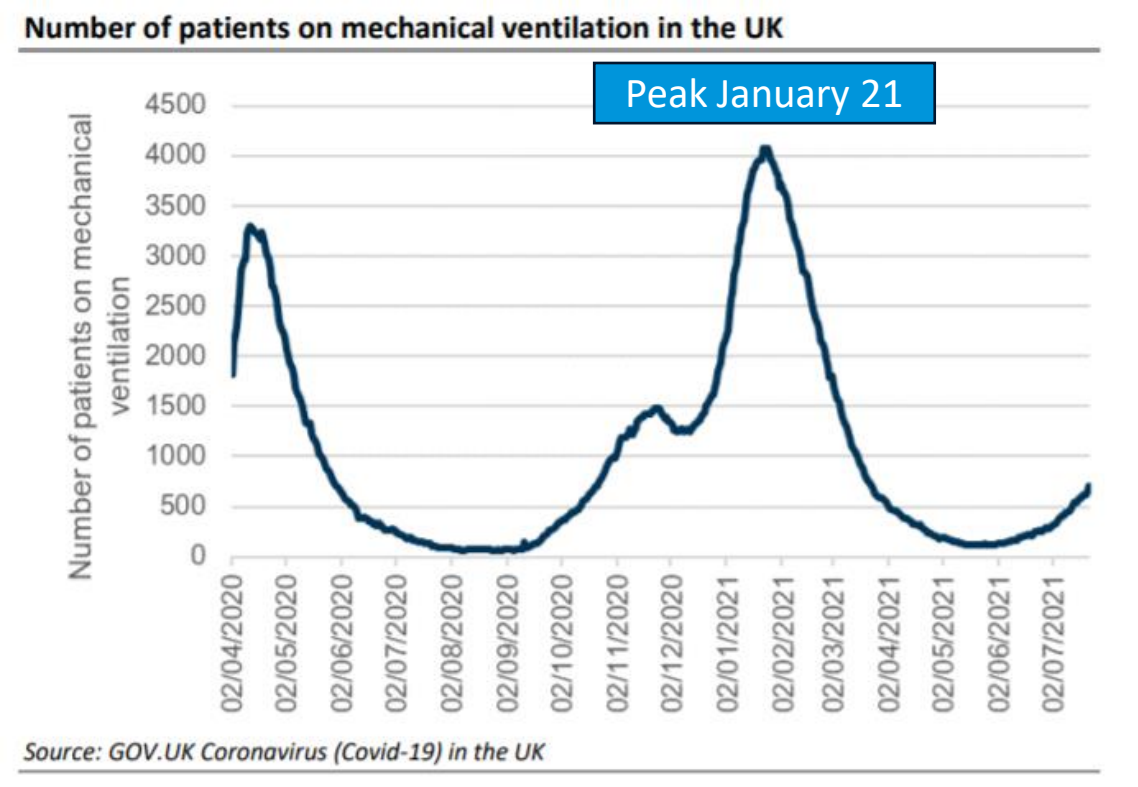
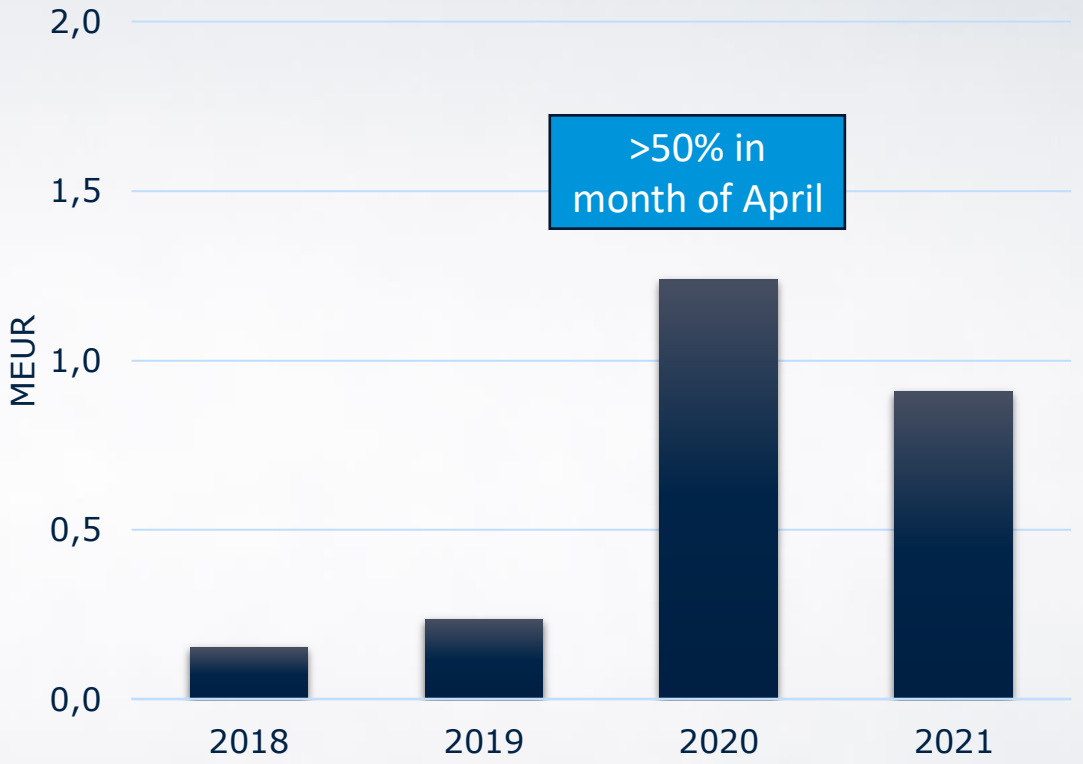
1H 21 sales below 1H 20 sales in other Direct sales markets but importantly, more than 3 times higher than same periods 2019

of ventilated patients in UK from outbreak



1H Sales in Other Direct sales Markets (excl Germany)



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Sedaconda achieving regulatory approvals faster than expected with strong product label support

DCP approval achieved in 200 days, significantly faster than normal review process

First market authorisation achieved in France just over 20 days after DCP approval

Label approved for Sedaconda/ Sedaconda ACD only without time limitation & strong supporting claims of rapid & predictable wake-up and cognitive recovery

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Inhaled Sedation
with Sedaconda® is here

Sedaconda, delivered via the Sedaconda ACD, is the only approved inhaled sedation therapy for use during intensive care.

- Fast and effective sedation
- Hepatic and renal independent elimination
- Rapid and predictable wake-up

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First Sedaconda on shelf anticipated Nov/Dec with price & reimbursement processes adding some launch delay in select markets

National Approvals
Aug/Sep

Sedaconda on shelf first markets
~Nov/Dec

Price & reimbursement processes finalised
~Q1

Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar

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Sales organisation buildup in preparation for regulatory approvals

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 EUROPE

- Submission in 15 EU countries November 2020
- Expected approval and launch 2H 2021
- Submission Switzerland & UK Q1 2021
  Expected approval and Launch 1H 2022
- Price & reimbursement submissions across EU markets Q3 2021
- 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

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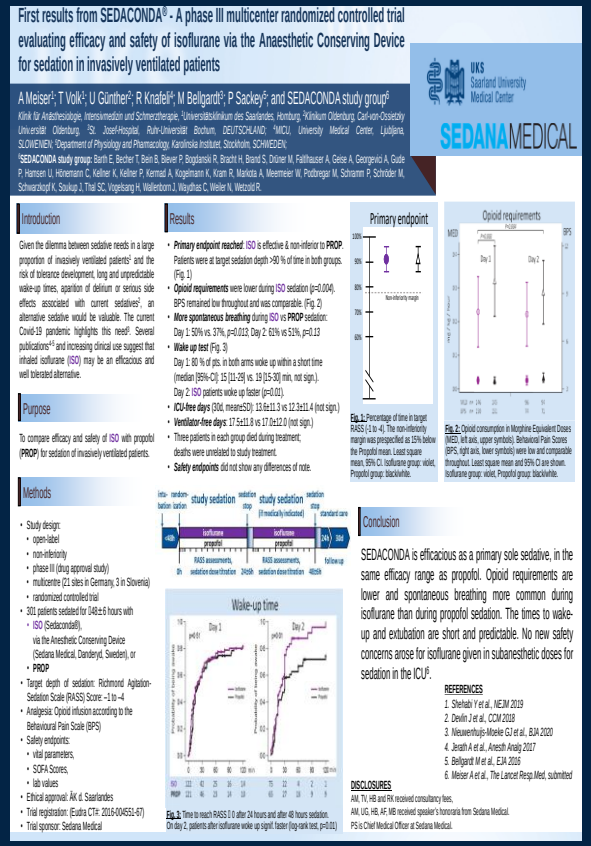
MEDICAL HIGHLIGHTS

THE SEDACONDA STUDY (SED001)

DATA FROM AWARD-WINNING POSTER AT THE GERMAN AND AUSTRIAN CRITICAL CARE ANNUAL JOINT MEETING 2021



First results from SEDACONDA® - A phase III multicenter randomized controlled trial evaluating efficacy and safety of isoflurane via the Anaesthetic Conserving Device for sedation in invasively ventilated patients

A Meiser[1]; T Volk[2]; U Günther[3]; R Knafelj[4]; M Bellgardt[5]; P Sackey[6]; and SEDACONDA study group[6]

Introduction

Given the dilemma between sedative needs in a large proportion of invasively ventilated patients[1] and the risk of tolerance development, long and unpredictable wake-up times, spanition of delirium or serious side effects associated with current sedatives[2], an alternative sedative would be valuable. The current Covid-19 pandemic highlights this need[3]. Several publications[4,5] and increasing clinical use suggest that inhaled isoflurane (ISO) may be an efficacious and well tolerated alternative.

Purpose

To compare efficacy and safety of ISO with propofol (PROP) for sedation of invasively ventilated patients.

Methods

- Study design:
  - open-label
  - non-inferiority
  - phase III (drug approval study)
  - multicentre (21 sites in Germany, 3 in Slovenia)
  - randomized controlled trial
- 301 patients sedated for 048±6 hours with
  - ISO (Sedaconda®), via the Anesthetic Conserving Device (Sedana Medical, Danderyd, Sweden), or
  - PROP
- Target depth of sedation: Richmond Agitation-Sedation Scale (RASS) Score -1 to -4
- Analgesia: Opioid infusion according to the Behavioural Pain Scale (BPS)
- Safety endpoints:
  - vital parameters,
  - SOFA Scores,
  - lab values
- Ethical approval: ÄK d. Saarlandes
- Trial registration: (Eudra CT#: 2016-004551-67)
- Trial sponsor: Sedana Medical

Results

- **Primary endpoint reached**: ISO is effective & non-inferior to PROP
  Patients were at target sedation depth >90 % of time in both groups. (Fig. 1)
- **Opioid requirements** were lower during ISO sedation (p=0.004). BPS remained low throughout and was comparable. (Fig. 2)
- **More spontaneous breathing** during ISO vs PROP sedation:
  Day 1: 50% vs. 37%, p=0.012; Day 2: 61% vs 51%, p=0.13
- **Wake up test** (Fig. 3)
  Day 1: 80 % of pts. in both arms woke up within a short time (median [95%-CI]: 15 [11-29] vs. 19 [15-30] min, not sign.).
  Day 2: ISO patients woke up faster (p<0.01).
- **ICU-free days** (30d, mean±SD): 13.6±11.3 vs 12.3±11.4 (not sign.)
- **Ventilator-free days**: 17.5±11.8 vs 17.0±12.0 (not sign.)
- Three patients in each group died during treatment; deaths were unrelated to study treatment.
- **Safety endpoints** did not show any differences of note.

Primary endpoint

Fig. 1: Percentage of time in target RASS (-3 to -4). The non-inferiority margin was prespecified as 15% below the Propofol mean. Least square mean, 95% CI. Isoflurane group: violet, Propofol group: black/white.

Opioid requirements

Fig. 2: Opioid consumption in Morphine-Equivalent Doses (MED, left axis, upper symbols). Behavioral Pain Scores (BPS, right axis, lower symbols) were low and comparable throughout. Least square mean and 95% CI are shown. Isoflurane group: violet, Propofol group: black/white.

Wake-up time

Fig. 3: Time to reach RASS 0 after 24 hours and after 48 hours sedation. On day 2, patients after isoflurane woke up signif. faster (log-rank test, p<0.01)

Conclusion

SEDACONDA is efficacious as a primary sole sedative, in the same efficacy range as propofol. Opioid requirements are lower and spontaneous breathing more common during isoflurane than during propofol sedation. The times to wake-up and extubation are short and predictable. No new safety concerns arose for isoflurane given in subanesthetic doses for sedation in the ICU[6].

REFERENCES

1. Shehabi Y et al., NEJM 2019
2. Devlin J et al., CCM 2018
3. Nieuwenhuijs-Moeke GJ et al., BJA 2020
4. Jerath A et al., Anesth Analg 2017
5. Bellgardt M et al., EJA 2016
6. Meiser A et al., The Lancet Resp.Med, submitted

DISCLOSURES

AM, TV, HB and RK received consultancy fees.
AM, UG, HB, AF, MB received speaker's honoraria from Sedana Medical.
PS is Chief Medical Officer at Sedana Medical.

EudraCT No:2016-004551-67
Submitted for publication, under review

Primary Endpoint: Sedation Efficacy

Comparable time spent in the target RASS range without rescue sedation

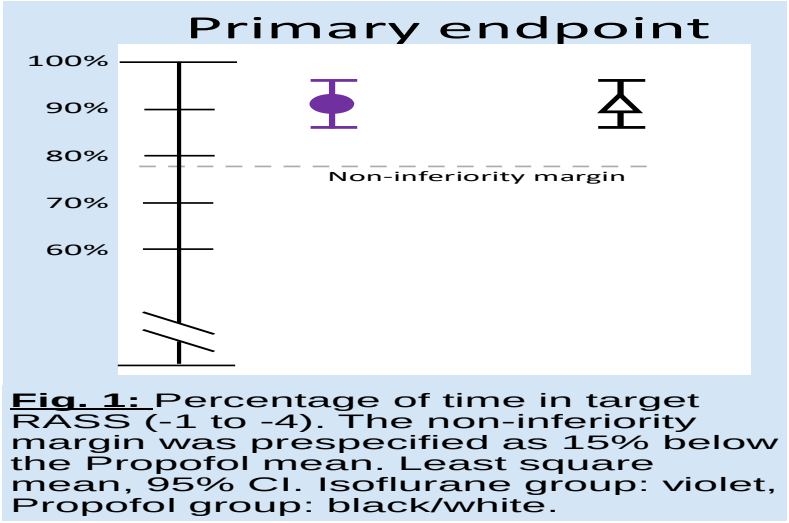


Fig. 1: Percentage of time in target RASS (-1 to -4). The non-inferiority margin was prespecified as 15% below the Propofol mean. Least square mean, 95% CI. Isoflurane group: violet, Propofol group: black/white.

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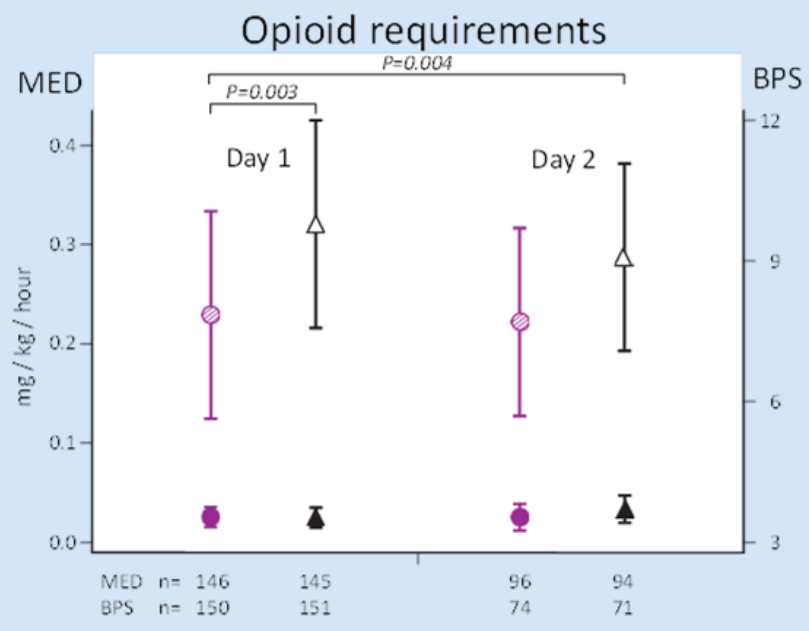
Lower opioid requirements with isoflurane, with similar pain scores in both groups & shorter and more predictable wake-up time

Morphine equivalent dose intensity and BPS during study sedation



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Shorter and more predictable wake-up time with isoflurane

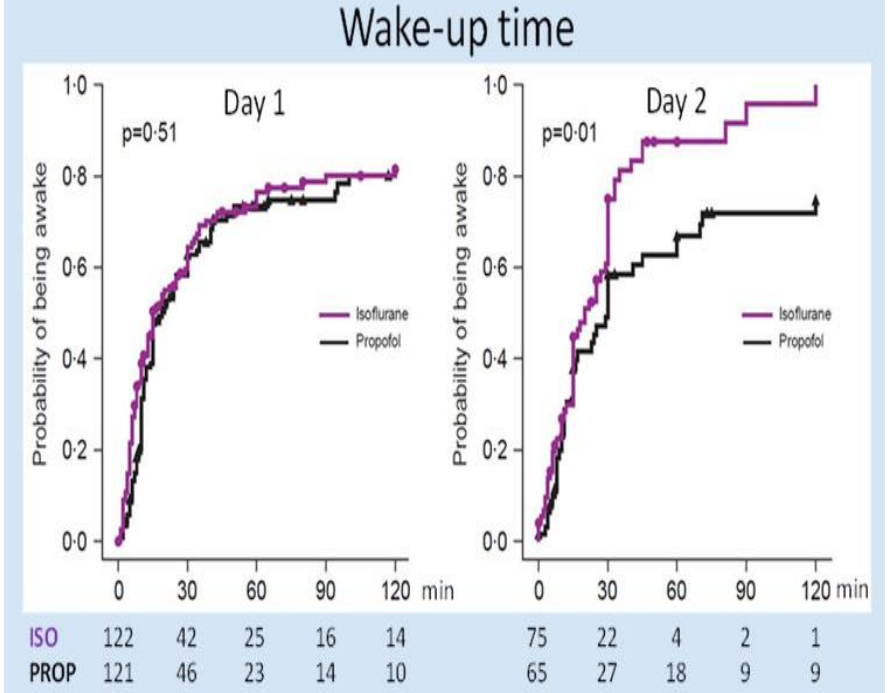

Fig. 3: Time to reach RASS 0 after 24 hours and after 48 hours sedation. On day 2, patients after isoflurane woke up signif. faster (log-rank test, p=0.01)

MED: Morphine Equivalent Dose

BPS: Behavioural Pain Scale

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Spontaneous breathing more common with isoflurane

Estimated rate of spontaneous breathing

Day 1:
- Isoflurane 50.3%
- Propofol 37.0% (p=0.013)

Day 2:
- Difference not statistically significant (p=0.131)

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Adverse Events

- Almost all events of hypertension, delirium, and agitation occurred shortly after stopping study sedation, deemed to be related to the rapid washout of the drug.

- 17 Serious Adverse Events (SAEs) reported in 15 patients:
  - 9 isoflurane patients – 3 deaths
  - 6 propofol patients – 3 deaths

- No SAE deemed as treatment-related

Most common AEs	Isoflurane	Propofol
Hypertension	6.7%	1.3%
Delirium	5.3%	4.6%
Oliguria	4.7%	4%
Atrial fibrillation	3.3%	2.6%

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Summary of findings

- Time spent in the target RASS range without rescue sedation was similar in isoflurane and propofol groups
- Opioid requirements were lower with isoflurane (with no indication of increased pain as shown by BPS scores)
- Spontaneous breathing was more frequent in isoflurane group
- Wake-up times were shorter and more predictable with isoflurane
- Isoflurane via Sedaconda ACD was well tolerated when given in subanaesthetic doses for sedation in the ICU

A strong SmPC, the foundation for all promotional communication

- No 48 hour limitation
-  Sedaconda ACD the only approved device in combination with Sedaconda
- "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 and 60 minutes after end of isoflurane administration"

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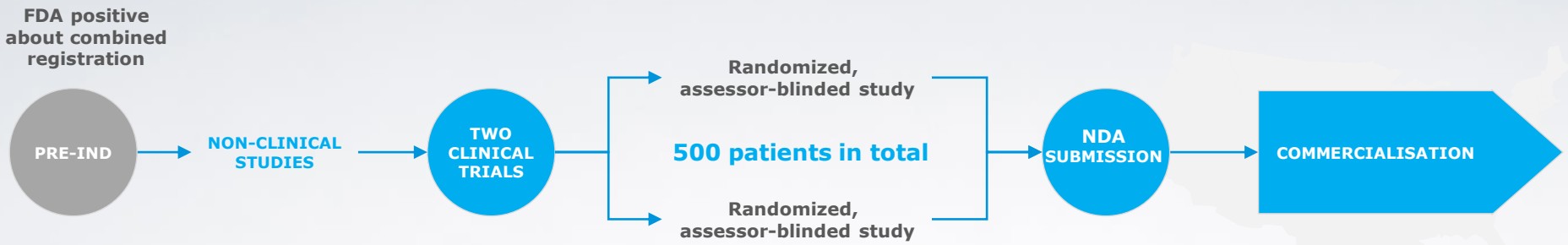
CLINICAL DEVELOPMENT

Combination registration of Sedaconda 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 program - ongoing

CLINICAL STUDIES

Two clinical, randomized, assessor-blinded studies to be conducted to confirm the efficacy and safety of Sedaconda.

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.

* PPND: pre- and post-natal development.

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Non-clinical program for US IND and NDA

1. Long-term (rodent and non-rodent) exposure studies prior to IND
    - No findings of concern to date
    - Studies on track for IND Q4 2021

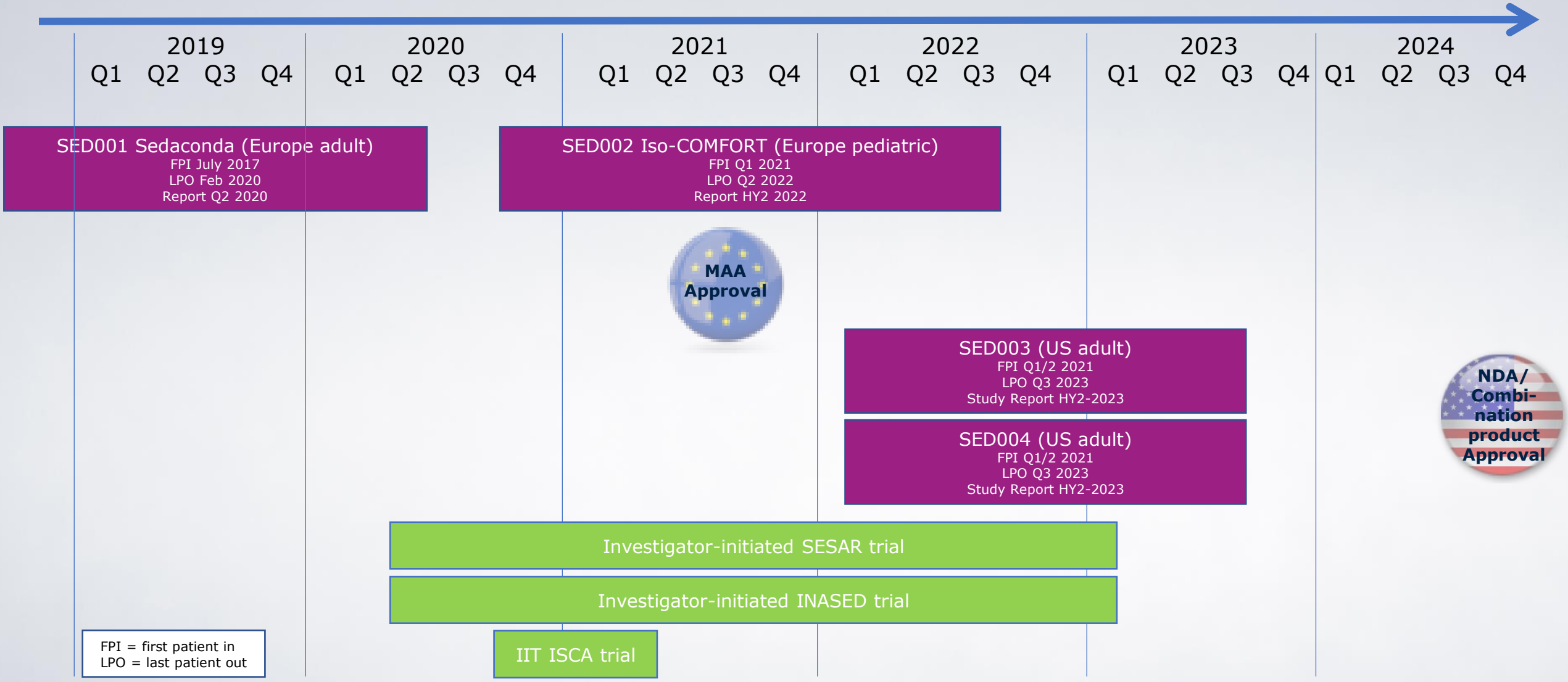
2. Studies for NDA
    - Pre- and Post-natal Development study – ongoing
    - 28-day (rodent, non-rodent) repeated exposure studies in planning

US Human factors program for IND and NDA

1. Formative phase (requirement for to IND)
    - First formative study completed spring 2021
    - Second formative study September 2021

2. Validation phase (after IND), planned for spring 2022
    - Based on findings from the formative phase
    - Not mandatory for IND and preferred to be done closer to NDA

Development programme to support regulatory approvals



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Timeline – registration activities in Europe and US

MAA Approval

NDA/ Combi-nation product Approval

	2021	2022	2023	2024
	• Marketing approval of Sedaconda in 15 countries • IsoCOMFORT (paediatric study) recruitment ongoing	• Completion of IsoCOMFORT • Second round of MAA in European countries not included in first round	• Pediatric European marketing approval of Sedaconda	
	• EOP2 meeting • Preclinical studies • Human Factors formative testing • Site recruitment • Sedana Medical Inc • Employment of Sedana Medical Clinical Educators • IND	• Clinical studies start (Q1/early Q2) • Human Factors validation testing • Plan launch in US - alone or together with a local partner	• Completion of US Clinical Studies • NDA application	• NDA approval expected

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Preliminary study site map US Clinical Trials

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FINANCIAL HIGHLIGHTS

Financial results [1)]

Investing for future

Net sales Q2'21: 40 (41) MSEK, -2% YoY, +3% in local currencies
Net sales 1H'21: 85 (74) MSEK, +14% YoY, +20% in local currencies

Gross Profit Q2'21: 26 (26) MSEK
Gross Margin Q2'21: 66 (64) %

- Improved margin due to larger proportion of sea freight in the quarter. Prices for freight costs estimated to continue high during the Covid-19 pandemic.
- Sales mix, increased sales in distributors markets with somewhat lower margins.

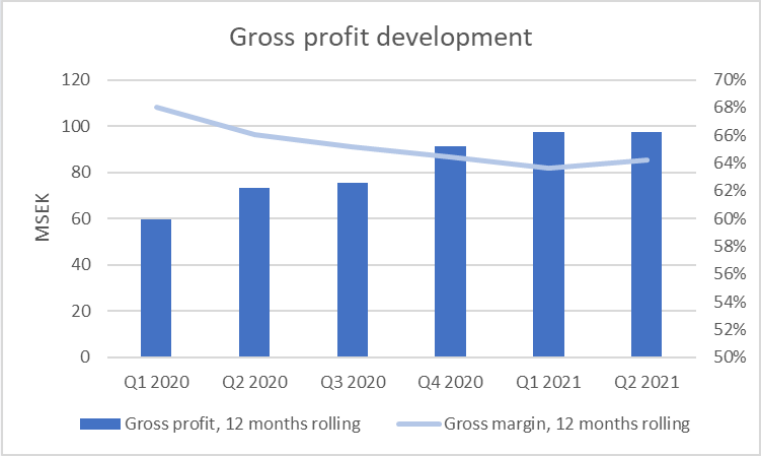
	Q2	Jan-Jun
EBITDA:	-14 (0) MSEK	-23 (1) MSEK
EBITDA Margin:	-36 (-1) %	-27 (2) %

Investing now for future growth

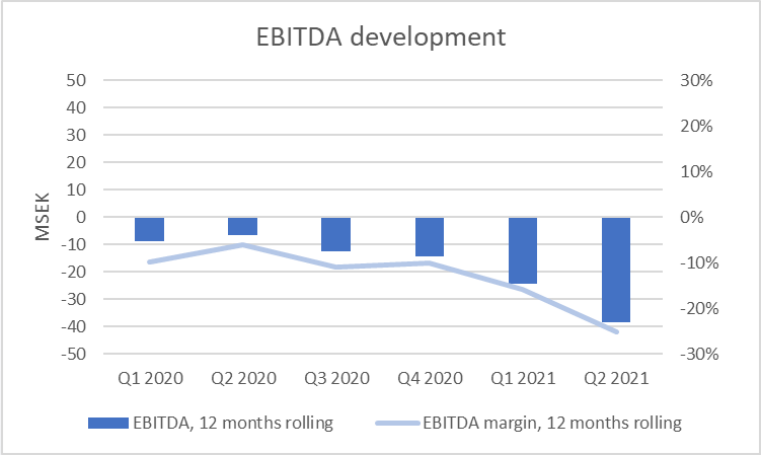
- Preparation for Sedaconda launch, including MDR-approval, results in increased OPEX, ca 6 MSEK in Q2'21 and ca 8 MSEK 1H'21.
- Build up of organisation. Some overlap in staff costs also in Q2.

Staff, incl consultants, per Jun 30, 2021: 91 (64)

Gross profit development



EBITDA development



[1)] 2020 numbers are restated according to IFRS and from a P/L by cost type to function type.

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Financial balances and Cash [1)]

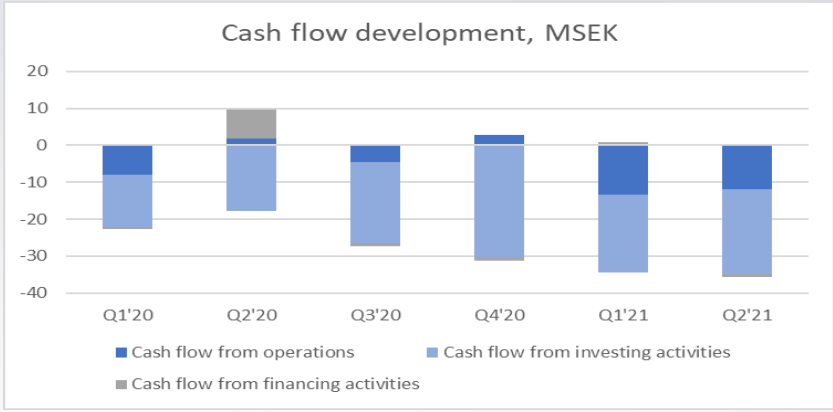
- **Cash flow from operations Q2'21:** -12 (2) MSEK
  Cash flow from operations 1H'21: -25 (-6) MSEK

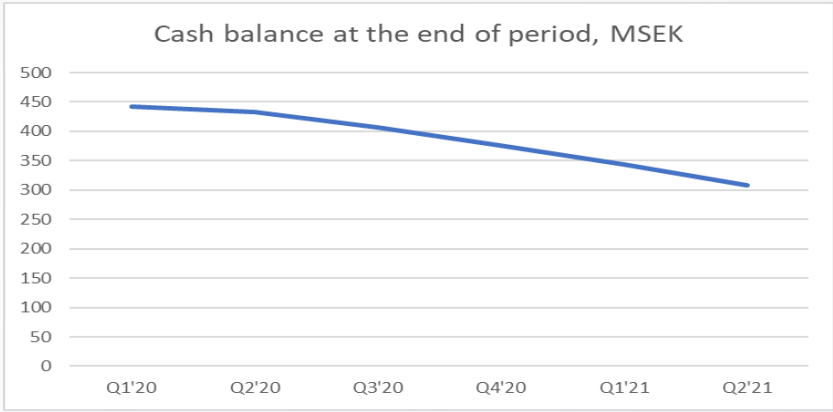
- **Cash flow from investment Q2'21:** -23 (-18) MSEK
  Cash flow from investment 1H'21: -44 (-32) MSEK
  of which the vast majority is related to product development.

- **Cash flow for the period Q2'21:** -36 (-8)
  Cash flow for the period 1H'21: -69 (-31)

- **Cash balance per Jun 30, 2021: 308 (344) MSEK**

- **No long-term financial debts / Debt free company**





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Largest shareholders June 30, 2021

	No of share	Share
Handelsbanken Funds	8 495 052	9,2%
Swedbank Robur Funds	8 314 933	9,0%
Linc AB	7 598 804	8,2%
Anders Walldov direct and indirect (Brohuvudet AB)	7 100 000	7,7%
Ola Magnusson direct and indirect (Magiola AB)	4 613 728	5,0%
Sten Gibeck	4 279 776	4,6%
Öhman Fonder	3 902 588	4,2%
Berenberg Funds	2 162 344	2,3%
Avanza Pension	1 947 394	2,1%
Tredje AP-fonden	1 900 000	2,1%
Nordnet Pensionsförsäkring	1 840 198	2,0%
Tedsalus AB (Thomas Eklund)	1 666 464	1,8%
Highclere International Investors LLP	1 626 060	1,8%
Philip Earle	1 010 000	1,1%
DNCA Finance S.A	975 980	1,1%
Fifteen largets shareholders	57 433 321	62,3%
Others	*34 753 639*	*37,7%*
Total	**92 186 960**	**100,0%**

A split (4:1) was made at the end of May 2021

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QUESTIONS