

# Remimazolam ein neues Anästhetikum, das Kombinationsmöglichkeiten mit Medizinprodukten bietet

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# Corporate overview

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PAION AG is a specialty pharma company with a focus on anesthesia products



Remimazolam, PAION's lead drug candidate, in Phase III development



Six regional partnerships for Remimazolam in China, South Korea, Canada, Russia (CIS), Turkey and MENA region



Headcount of 44 (incl. Mgmt Board), HQ in Aachen, Germany: PAION AG with subsidiaries in

Cambridge (UK): PAION UK Ltd

New Jersey (USA): PAION, Inc.



~ EUR 41 million cash and cash equivalents (End of Q3 2015) Sufficient funds for Phase III program with Remimazolam in the U.S.



## Supervisory Board

Dr. Jörg Spiekerkötter (Chairman)

Background: Former CFO, Schering AG, Organon

Dr. Karin Dorrepaal

Background: Former Schering AG Board Member

John Dawson

Background: CEO Oxford BioMedica



## Management

Dr. Wolfgang Söhngen

Title: CEO, Founder

Abdelghani Omari

Title: CFO

Dr. Juergen Rath

Title: COO

# PAION's lead product Remimazolam

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## Product

- Ultra-short-acting anesthetic/sedative

## Trials

- More than 1,000 volunteers/patients have received Remimazolam in trials
- Current focus is conducting Phase III trials

## Market

- Market exclusivity expected until at least 2027 (2031 in the U.S.)
- Attractive peak sales potential of ~US\$ 500m worldwide per year in each indication



# Remimazolam – U.S. Strategy

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# U.S. – Launch indication targets growing outpatient colonoscopy screening market

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**Hospital**

**ICU  
Sedation**

**Surgical General  
Anesthesia**

**Procedural  
Sedation  
(eg. day cases)**



**Out-Patient**

**Remimazolam**

**Procedural  
Sedation**

# Remimazolam – U.S. program procedural sedation

## Pivotal Studies

- Colonoscopy: Remimazolam (n=300) vs. placebo (n=60) and midazolam (n=100)  
Started in March 2015 – Completion expected in Q1 2016
- Bronchoscopy: Remimazolam (n=300) vs. placebo (n=60) and midazolam (n=100)  
Started in June 2015 – Completion expected in 2016/2017

## Safety Studies

- Colonoscopy ASA III/IV patients  
(Remimazolam n=30 vs. midazolam n=30 vs. placebo n=15)  
Started in December 2015 – Completion expected in 2016
- Phase I Studies  
Thorough QT Study, Renal Impairment, Abuse Liability

## Pediatric Study

- After filing  
Pediatric Plan agreed with FDA

## Labeling comparable to midazolam

- primary goal

**Filing scheduled in 2017**

# Remimazolam – EU Program

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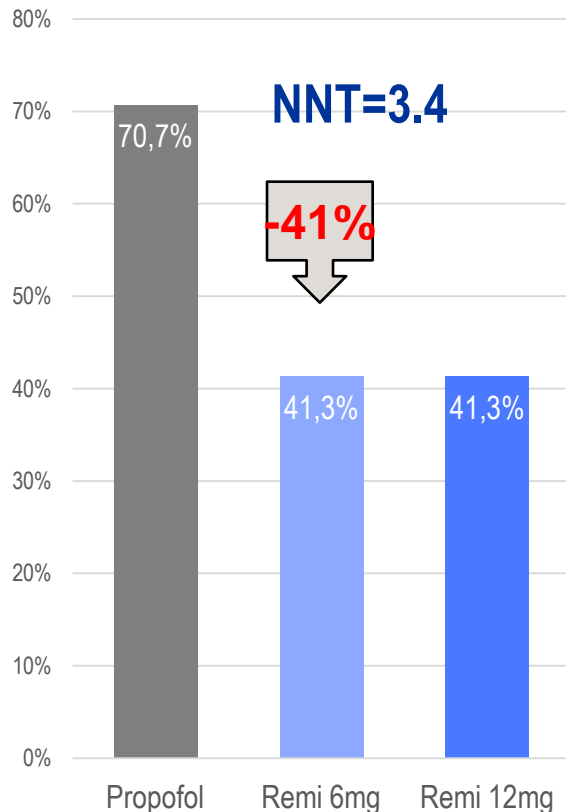




# Our Mission in General Anesthesia: Reducing the detrimental effects of

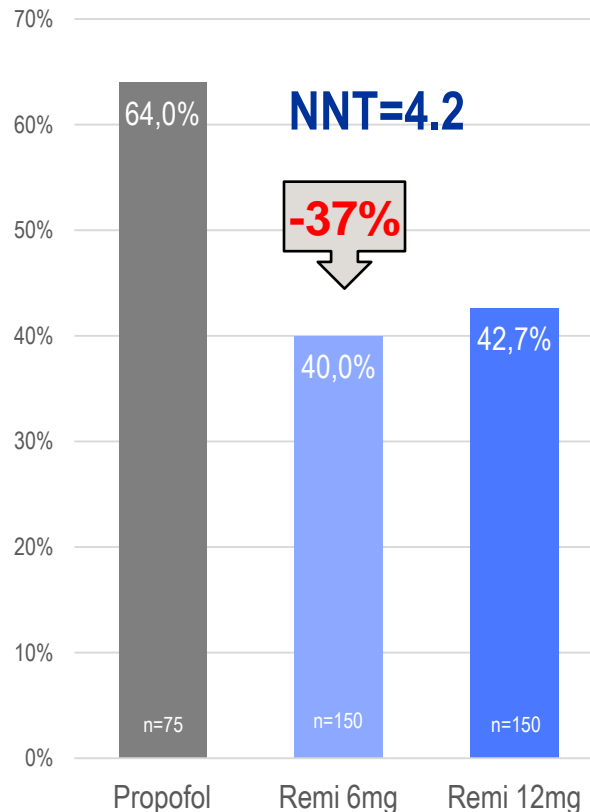
## Hypotension

Patients with APM  
< 60 mm Hg  
First hour after intubation



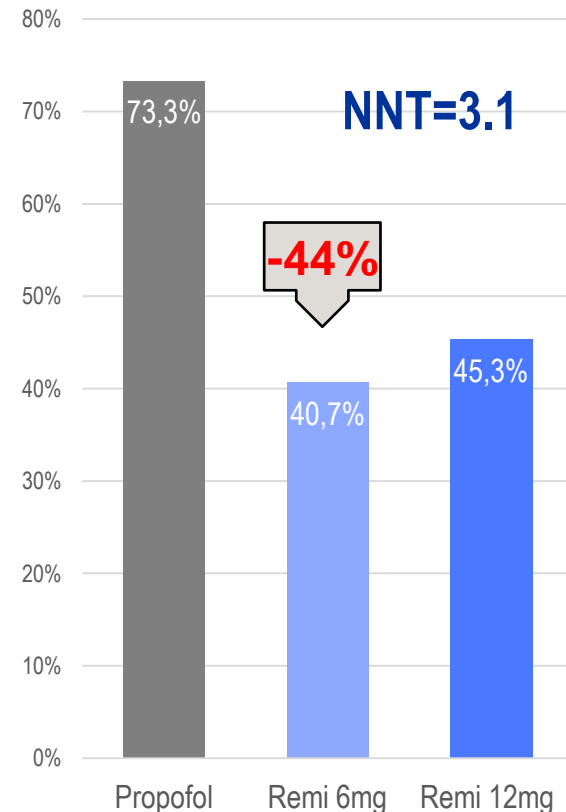
## Need for Vasopressors

Share of Patients with any  
vasopressor  
entire study



## Too deep sedation

Share of patients with BIS  
score below 40 until 1 h after  
intubation



# Remimazolam – Strategy Japan / Asia

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# Remimazolam Japan – filing ahead

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- Remimazolam rights for Japan returned from Ono to PAION in July 2015
- Know-how transfer (ONO -> PAION) completed
- Data from six clinical trials (Phase I-III) and preclinical studies will now be integrated into PAION's database
- PAION has been contacted by parties interested in Japan – Partnering process for a Remimazolam license for Japan ongoing
- KOLs confirmed that Remimazolam is regarded a needed innovation for the Japanese anesthesia market
- PMDA: PAION applied for a Pre-NDA meeting
  - Positive PMDA feedback:
    - Product produced in Europe can be used for commercialization in Japan
    - PMDA regards clinical and non-clinical data sets as complete for filing in the indication “Induction and maintenance of general anesthesia”
    - Filing of Remimazolam is mainly subject to the time point of partnering or a PAION decision to file without a partner

# Upcoming milestones

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# Potential Cooperations

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- Administration of the drug
  - Drug delivery
  - Reconstitution devices
  - Non aqueous liquid formulations
  - Machine controlled sedation



**Thank you very much  
for your attention!**

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