Acacia Pharma Group plc
Presentation

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Overview

Acacia Pharma	Hospital pharmaceutical group based in Cambridge UK and Indianapolis US developing & commercialising new nausea & vomiting products
Pipeline	BARHEMSYS™ PONV NDA accepted for filing and under review by FDA APD403 CINV completed one Phase 2 study
Milestones	BARHEMSYS PONV PDUFA date October 5 2018 Launch targeted 2Q 2019 APD403 CINV second Phase 2 1H 2019
Financial	IPO March 2018 Euronext Belgium : ACPH Raised €40m to fund PONV pre-launch activities Market cap ~ €190m

Nausea & vomiting and BARHEMSYS™

- Post-operative nausea & vomiting (PONV) is a large, concentrated, US hospital opportunity which can be addressed efficiently
- Rescue treatment of PONV is a major unmet need
- Opportunity to improve patient outcomes
- Significant pharmacoeconomic incentives to better manage PONV

- BARHEMSYS (intravenous amisulpride) can provide the solution
- NDA accepted for filing; PDUFA date 5th October 2018
- Broad label sought; including rescue treatment and high risk combination prophylaxis

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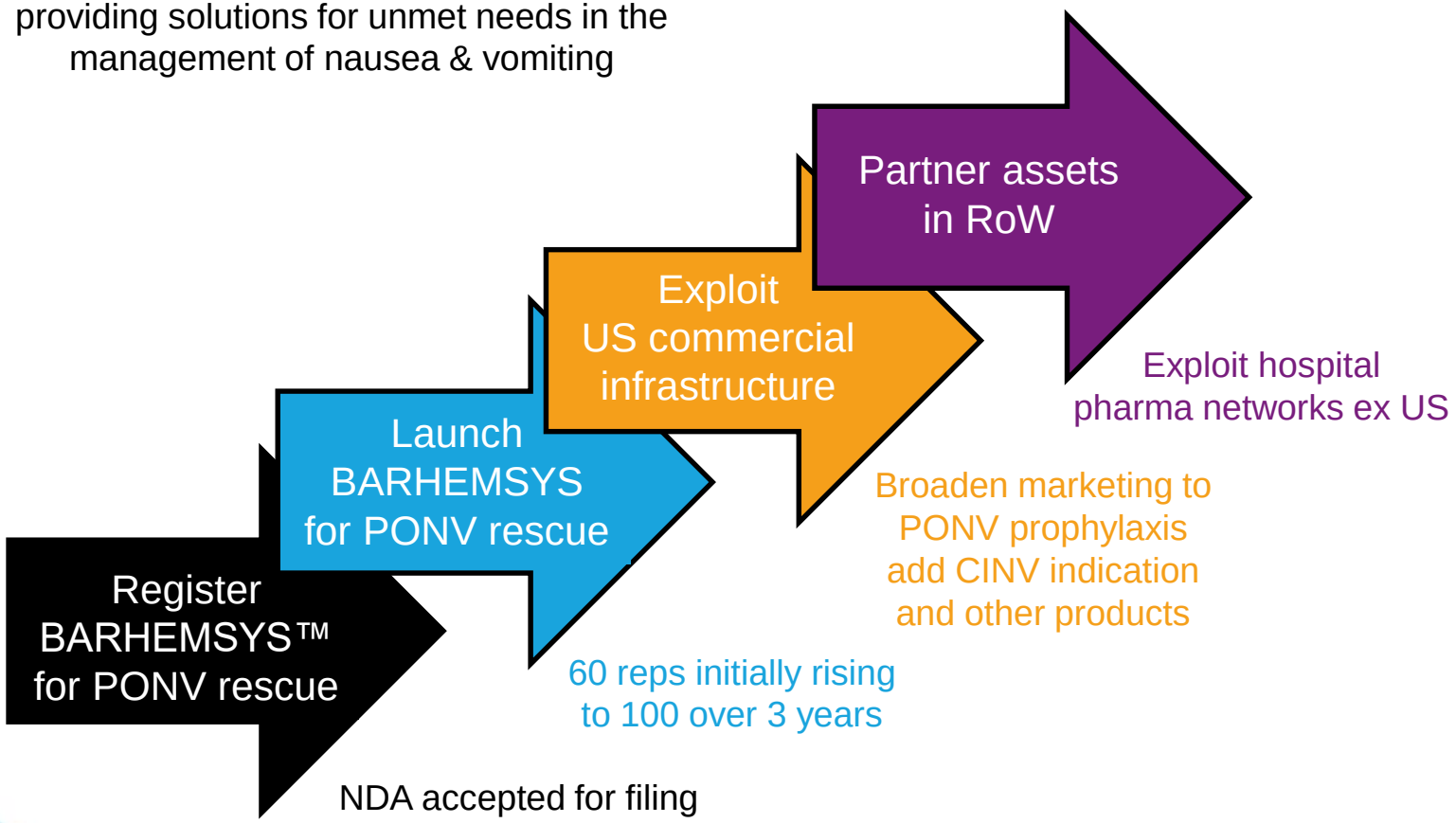
- Second indication in chemotherapy induced nausea & vomiting (CINV)
- Phase 2 proof of concept in delayed CINV completed
- Opportunity size similar to PONV

Company vision

To build a US hospital pharmaceutical company providing solutions for unmet needs in the management of nausea & vomiting



Led by an experienced team based in Cambridge UK and Indianapolis IN

Dr Julian Gilbert
CEO & Co-founder

Co-founder Arakis
Repurposing & supportive care Arakis & Mundipharma
Partnering/licensing

Christine Soden
CFO & CoSec

CFO BTG & Optos
Transition from development to US sales

Dr Gabriel Fox
CMO

Repurposing NeXstar
Oncology & supportive care
Hoffmann La Roche

Mike Bolinder
CCO Acacia Pharma Inc

Head of Hospital Marketing at Cadence/Mallinckrodt
Led commercialisation of OFIRMEV® to anaesthetists

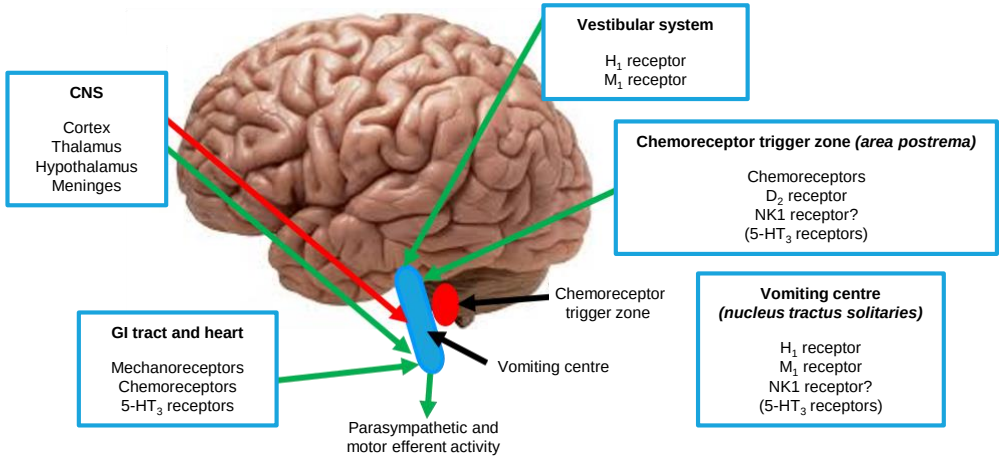
Dr Patrick Vink
Chairman

COO Cubist
Hospital pharma commercial & technical

Scott Byrd
Non-executive Director

CCO Cadence
Launched OFIRMEV® to anaesthetists and built infrastructure

Nausea & vomiting is a complex process managed with combinations of antiemetics



- Multiple pathways involved
- In particular:
  - Serotonin (5-HT_3)
  - Substance P (NK1)
  - Dopamine (D_2)

- Combinations of antiemetics with different mechanisms of action are used

- Current standard-of-care
  - 5-HT_3s and corticosteroids
  - NK1s added in cancer

- Despite this
  - ~32% of surgical patients still get PONV
  - Up to 50% of cancer patients get CINV

High incidence of PONV increases morbidity, & hospital costs, reducing income potential

Common complication of surgery (30-80%)

Increases morbidity and is a driver for ERAS protocols to improve mobilisation

25%

increase in length of stay

Increases hospital costs

Unanticipated & extended in-patient hospital stays and extended time in PACU

~$2,300

per day

Distressing to patients

Patient satisfaction linked to income and used as a marketing tool

1st

over pain

Better PONV management can therefore
reduce morbidity & hospital costs and optimise hospital income

Management of PONV & unmet need

PREVENTION

Prophylaxis

Assess risk factors: Female, Prior history, Non-smoker, Opioid pain control

Low risk (0/1)	Medium risk (2)	High risk (3 or 4)
No antiemetic "Wait & see" and treat if needed	Give one antiemetic	Give multiple antiemetics from different mechanisms of action

~90% of patients get 5-HT_3, ~80% 2nd drug get steroid

TREATMENT

Treatment

~32% of surgical patients get PONV after prophylaxis ~16 million pts a year in US

No prophylaxis given	Prophylaxis given but patient suffers PONV
Treat with any available antiemetic	Treat using an antiemetic from a mechanism that has not been given prophylactically

Can't use 5-HT_3s, can't use steroids too slow

Management of PONV & unmet need

PREVENTION

Prophylaxis

Assess risk factors: Female, Prior history, Non-smoker, Opioid pain control

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TREATMENT

Treatment

~32% of surgical patients get PONV after prophylaxis ~16 million pts a year in US

No prophylaxis given	Rescue treatment - the major unmet need
Treat with any available antiemetic	

Can't use 5-HT_3s, can't use steroids too slow

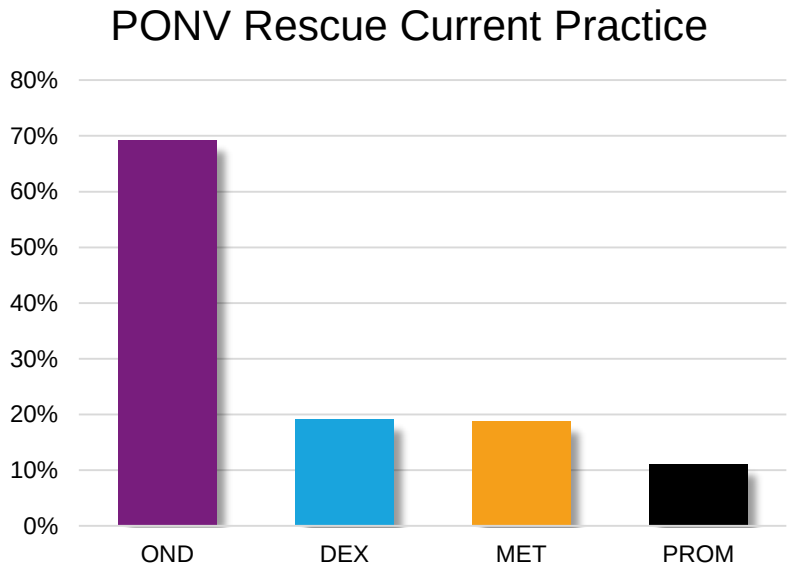
Current options for rescue treatment are unsuitable

"When rescue therapy is required, the antiemetic should be chosen from a **different therapeutic class** than the drugs used for prophylaxis" (Consensus Guidelines)

- 90% of US prophylaxis includes a 5-HT_3 antagonist

And yet

- 69% rescue patients receive a 5-HT_3 (against guidelines, contrary to label)
- 20% receive a steroid that takes 2 hours to work
- Metoclopramide and promethazine weak antiemetics and have side effect issues

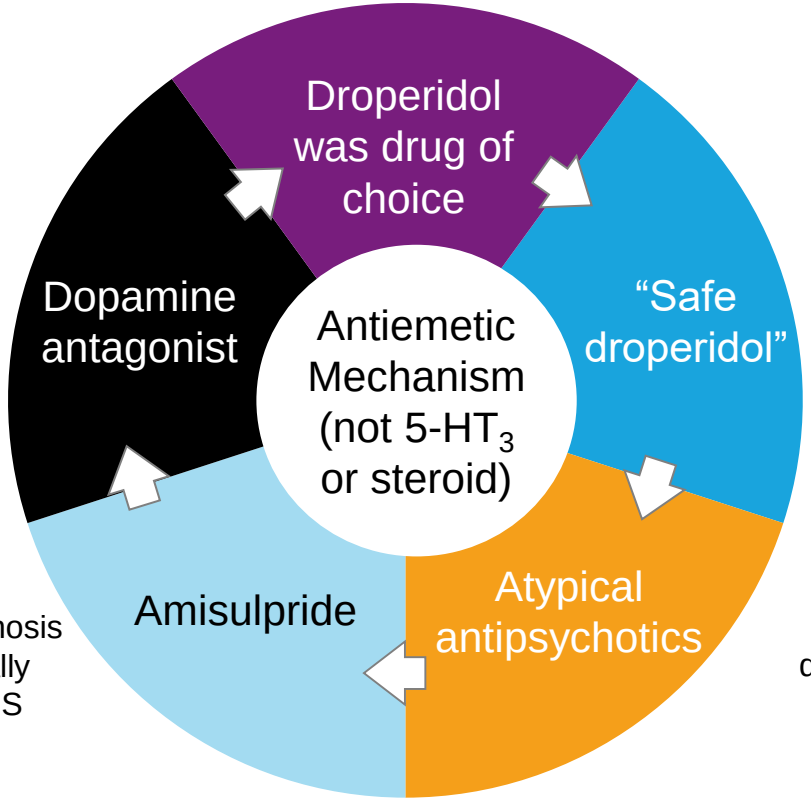


No drug currently indicated for rescue treatment of PONV

A real need for a safe and effective antiemetic from a different therapeutic class

BARHEMSYS™ (amisulpride) designed to provide the solution for PONV

Boxed warning in 2001 for QT prolongation
Also extrapyramidals and sedation



Can follow 5-HT$_3$s and corticosteroids

Dopamine antagonist without cardiac, sedation and extrapyramidal issues

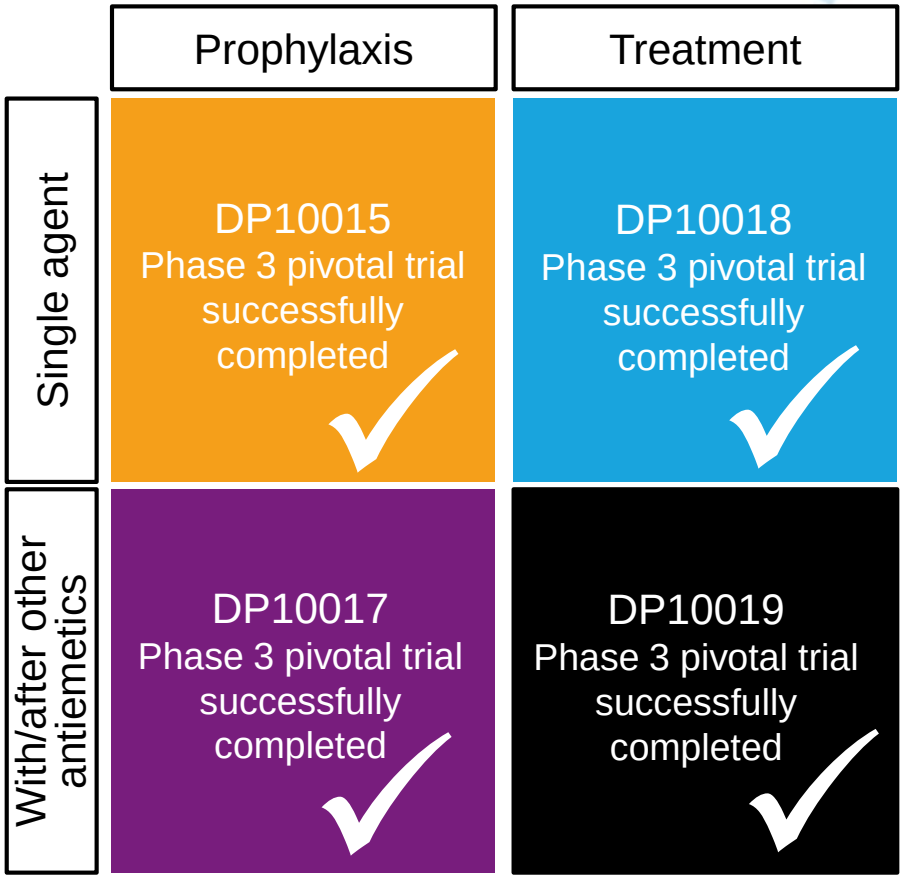
30 years of safe use in psychosis
High doses given chronically
Never been launched in US

Lack of "old style" dopamine side effects

BARHEMSYS could be the first drug registered for rescue treatment

BARHEMSYS™ NDA under review by the FDA

- NDA accepted by FDA for filing; PDUFA date 5th October 2018
- Broad and unique proposed label:
  - Treatment of established PONV (including after failed 5-HT_3 prophylaxis) with 10 mg single dose
  - Prophylaxis of PONV (alone or in combination) with 5 mg single dose
- Comprehensive and robust NDA package of 8 clinical trials, 4 of which are pivotal, conducted in US & Europe
- Extensive database:
  - ~3,000 patients of whom ~2,000 received BARHEMSYS



BARHEMSYS™ shown to prevent and treat PONV, alone and in combination

BARHEMSYS 10mg rescues patients who have failed prior prophylaxis	DP10019 Phase 3 pivotal rescue treatment study in 705 patients Significantly improved the complete response rate Placebo 28.5% vs BARHEMSYS 41.7% (p=0.003)
BARHEMSYS 5mg is additive in combination preventing PONV in high risk patients	DP10017 Phase 3 pivotal combination prophylaxis study in 1147 patients Significantly improved the complete response rate Placebo 46.6% vs BARHEMSYS 57.7% (p=0.0002)
BARHEMSYS 5mg prevents PONV	DP10015 Phase 3 pivotal monotherapy prophylaxis study in 342 patients Significantly improved complete response rate Placebo 32.5% vs BARHEMSYS 44.3% (p=0.034)
BARHEMSYS 10mg treats PONV	DP10018 Phase 3 pivotal treatment study in 560 patients Significantly improved complete response rate Placebo 21.5% vs BARHEMSYS 31.4% (p=0.016)

BARHEMSYS™ has important safety benefits

- Excellent safety profile in all clinical trials
  - Number of adverse events generally lower with BARHEMSYS than placebo
  - Consistent with large published literature on high-dose oral amisulpride use
- Absence of the key toxicities which limit use of other antiemetics:
  - No cardiac toxicity (unlike droperidol, haloperidol)
  - No extrapyramidal side effects (unlike droperidol, metoclopramide, prochlorperazine, etc)
  - No sedation (unlike older D_2 antagonists, anti-histamines)
  - No tissue damage on infusion (unlike promethazine)
  - No anticholinergic effects eg dry mouth (unlike transdermal scopolamine patch, promethazine)
- Effect on QT interval below 10 ms threshold of FDA concern
  - Maximal QT prolongation with 5 mg BARHEMSYS dose = 5.0 ms (upper bound of CI: 7.1 ms)
  - Standard extrapolation of 10 mg treatment dose: maximal prolongation = 7.9 ms (upper bound of CI: 9.1 ms)

BARHEMSYS offers the benefits of a dopamine antagonist without the risks

BARHEMSYS™ is an effective, safe antiemetic with a unique proposed label

BARHEMSYS shown to be an effective dopamine antiemetic

- Works in both rescue treatment and combination prophylaxis
- Unique profile in rescuing patients after failure of prophylaxis with other antiemetics
- Effectiveness translates into faster mobilisation and discharge from PACU and hospital

BARHEMSYS shown to be a safe dopamine antiemetic

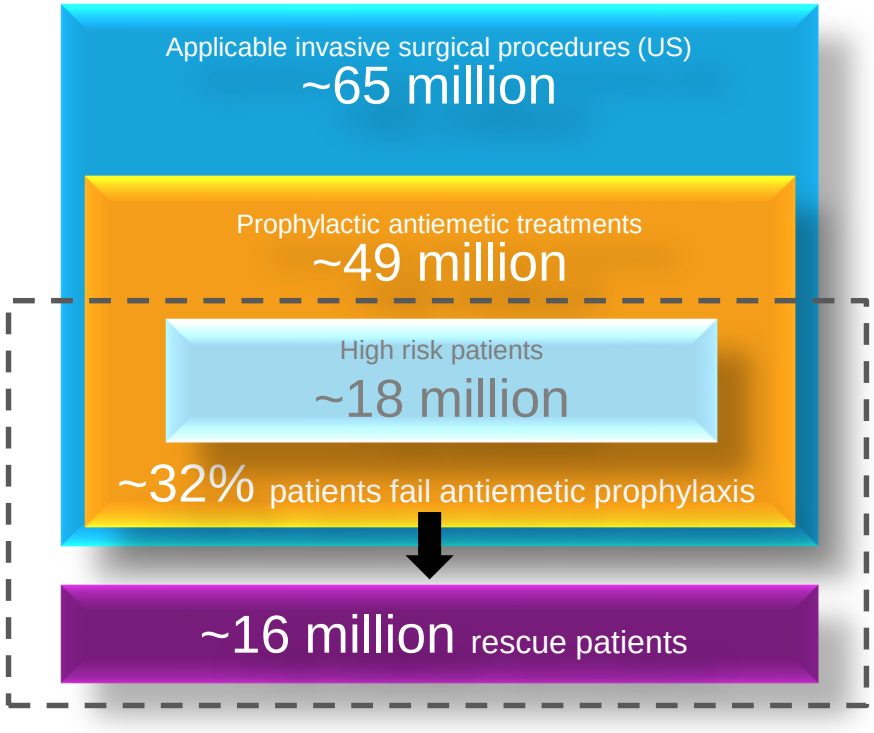
- Absence of “old style” D_2 side effect problems – QT, EPS & sedation
- Extremely low incidence of the side effects that have limited the use of antiemetics such as scopolamine, metoclopramide, promethazine, etc

BARHEMSYS has a unique proposed label

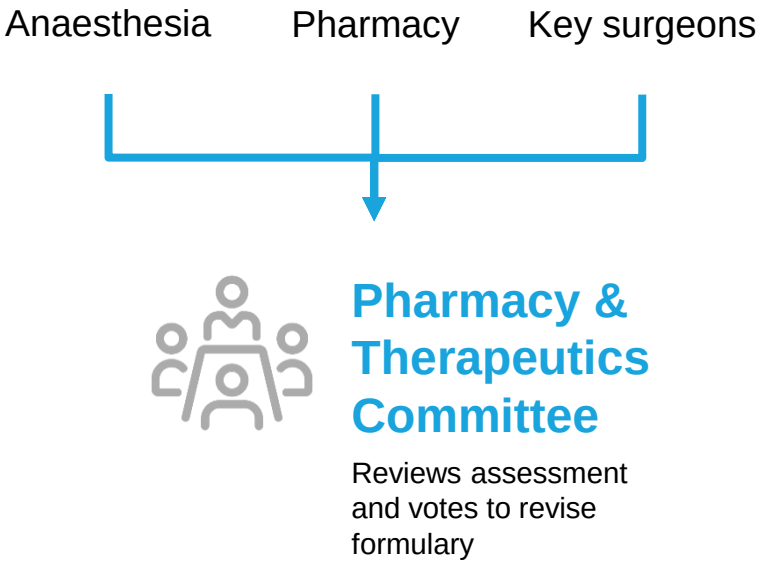
- No other antiemetic has rescue treatment claim after failed prophylaxis
- No other antiemetic has combination use claim in prophylaxis

BARHEMSYS™ provides significant commercial opportunity

- Large hospital market opportunity in US
  - ~32m rescue treatment events a year
  - ~18m high risk prophylaxis events a year
- Highly concentrated, addressable, profitable opportunity
  - ~1,600 US hospitals; 80% of surgical procedures
  - Address with 60 reps initially, rising to 100
  - Favourable cost of goods
- Unmet need exists for an effective antiemetic with a different mechanism
  - US research indicates physicians intend to use BARHEMSYS in ~60% of their patients
  - Rescue treatment for failed prophylaxis represents the greatest unmet need

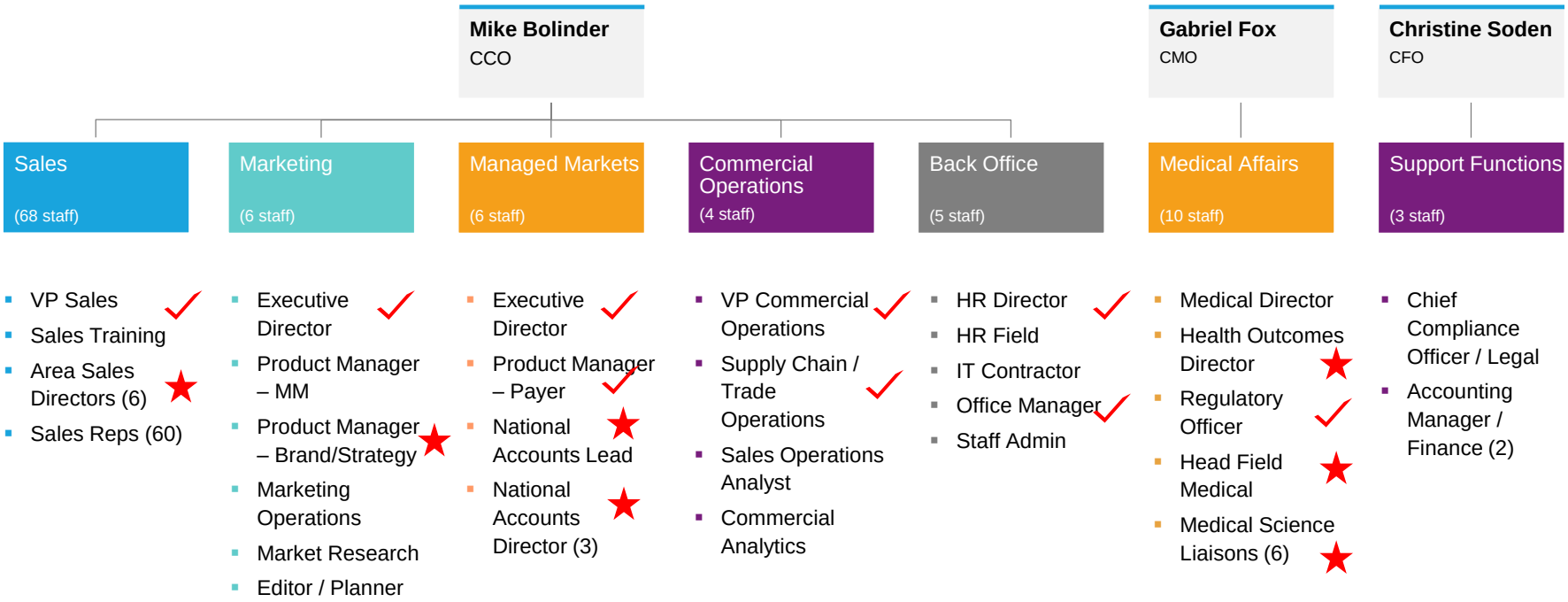


Price BARHEMSYS™ to optimise access in US hospitals

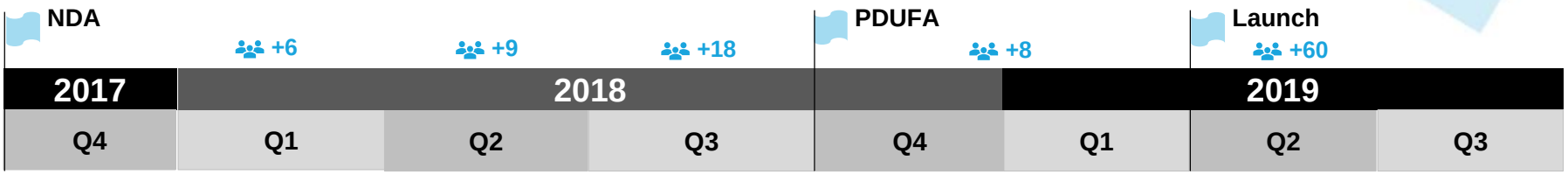


- Real unmet need
  - No drug approved for rescue treatment
- Paid for through capitated fixed fee for surgical procedure - “the DRG”
- Key to demonstrate pharmacoeconomic benefit
  - ~¼ day saving in length of stay ~$750
- Key to have appropriate restrictions on use
  - Use following failed standard of care
- Price for access on >80% of hospital formularies

Key US commercial leadership already in place, other positions in process



BARHEMSYS™ US launch readiness plan



Commercial Planning & Strategy ✓

- Commercial Leadership ✓
- Brand Strategy & Positioning ✓
- Distribution Strategy ✓
- Publication Planning ✓
- KOL Engagement ✓
- Medical Meetings & Education ✓

Market Research & Commercial Systems ★

- Marketing & Med Affairs Teams ★
- Infrastructure, Systems ★
- Messaging/Brand Development ★
- Launch Marketing Materials
- Final Pricing Research
- Hospital Budget Impact Model ★
- AMCP Dossier
- Sales Force Plan/Targeting ★
- Medical Communications

Market Engagement & Production

- Commercial Manufacturing
- National Accounts
- Initiate Launch Programs
- GPO Contracting
- Key Account Engagement
- Sales Rep Identification

Product Introduction

- Sales Representatives
- National Distribution
- Hospital P&T Process

Key launch workstreams completed and ongoing

APD403 for CINV

- Chemotherapy induced nausea & vomiting (CINV) common with many chemotherapy drugs
  - Highly emetogenic (HEC) >90%, moderately emetogenic (MEC) 30-90%
  - Two phases of CINV, acute (day 1) and delayed (days 2-5)
- Guidelines recommend triple therapy
  - $5HT_3$ + NK1 + steroid
- Unmet medical is delayed CINV where up to 50% of patients are not controlled
  - Predominant issue is delayed nausea

- APD403 (intravenous and oral amisulpride) shown to have a profound effect on delayed CINV and particularly nausea in Phase 2
  - 32% relative risk reduction

- Commercial opportunity similar to BARHEMSYS PONV
- Potential launch in 2022

>90%

Patients get CINV when receiving **HEC**

Two phases of CINV:

Acute
(Day 1)

Delayed
(Day 2-5)

Delayed

CINV

Is the **unmet medical need**

Potential launch in:

2022

32%

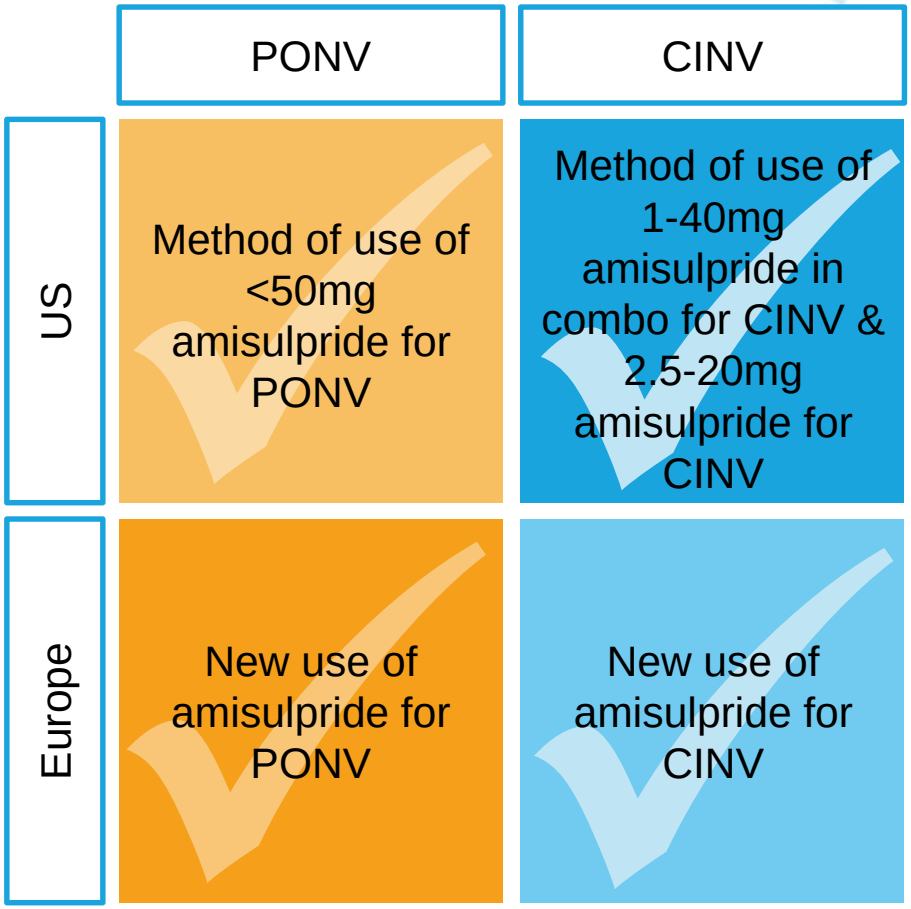
relative risk reduction of delayed CINV

Commercial opportunity similar size to

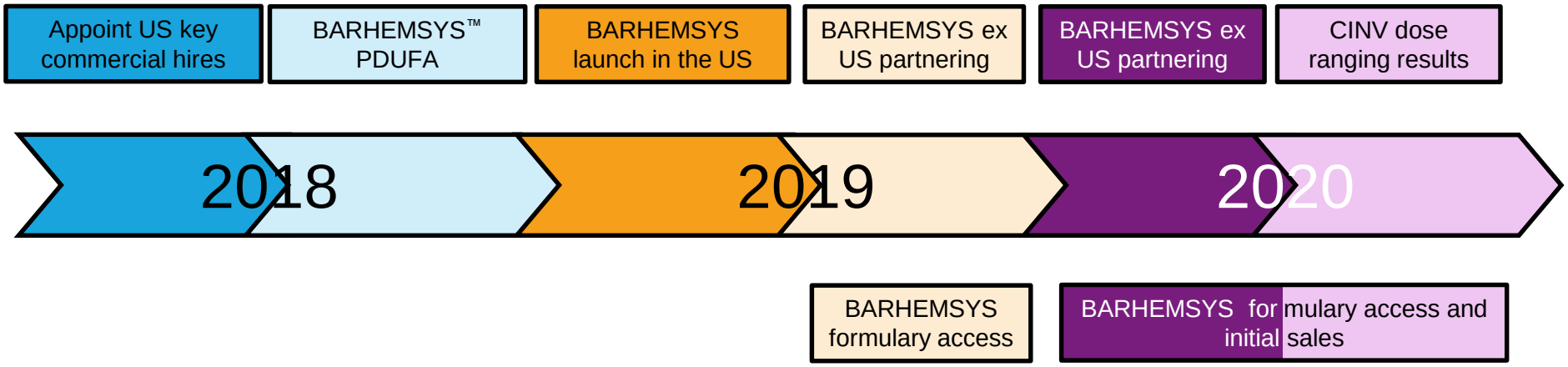
BARHEMSYS™ PONV

Commercial franchise patent protected to 2031

- Method of use patents allowed/ granted widely for BARHEMSYS™ and APD403, including Japan, US China and Europe
  - Initial patent term to March 2031
  - Patent extensions likely
  - Patents can be listed in Orange Book in the US
  - Additional selection applications filed



Short term news flow on lead assets



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