

# Acacia Pharma Group plc Interim Results Presentation

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# Introduction to Acacia Pharma, PONV and BARHEMSYS®



## Building US hospital sales organisation

- ~80% of surgeries carried out in 1,600 hospitals
- 30-40 field reps can address ~50% of the largest, 60-80 can address > 75%
- Core team in place to enable effective US launch once BARHEMSYS is approved

## Significant US market opportunity in PONV

- ~49m patients p.a. get preventative antiemetics
- ~16m of these patients still develop PONV and need rescue treatment with a different mechanism
  - Patients receive on average 2 doses of current rescue treatments
  - **15% of this market at price of \$80 would represent ~ \$380m annual opportunity**
- ~18m of these patients are high-risk and eligible for combination prophylaxis
  - **10% of this market at \$40 price would add a further ~\$80m**

## BARHEMSYS® A new option in PONV

- Differentiated antiemetic mechanism (dopamine D<sub>2</sub>/D<sub>3</sub>)
- Clinically proven in 4 pivotal PONV trials
- Seeking to be the first drug approved for rescue treatment of PONV following failed prophylaxis with standard of care
- Expect NDA resubmission completed this month, and PDUFA date Q1 2020

## Strong patent protection

- Market exclusivity in US – minimum 5 years
- Initial patent term to 2031 with likely extension, additional patent applications filed – potential term to 2038

## Operational Highlights

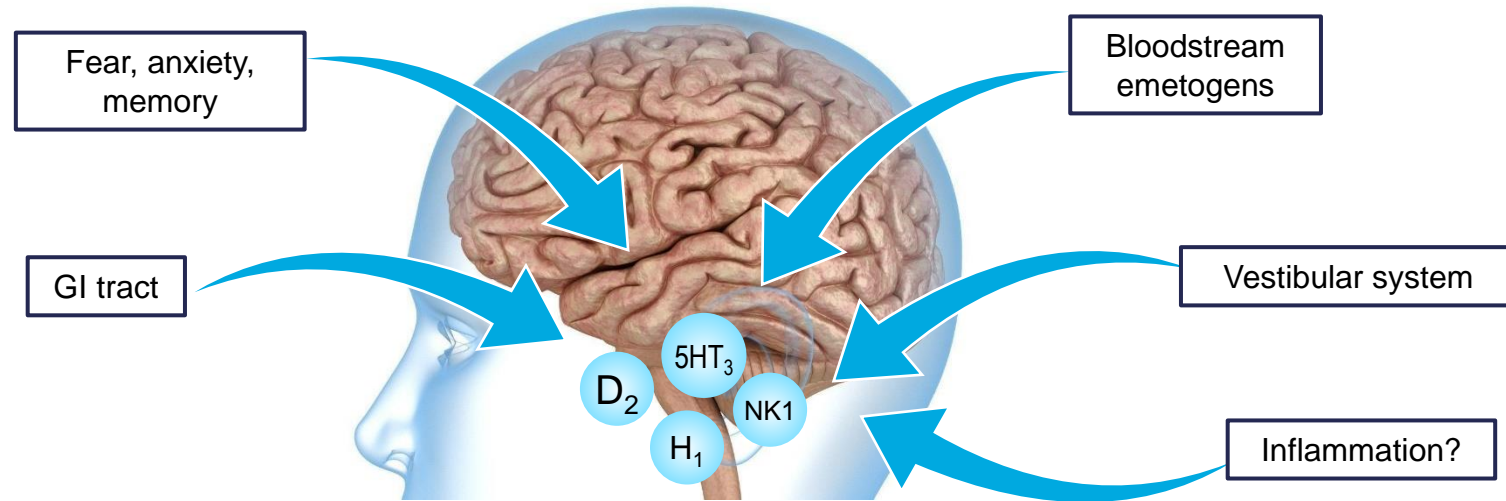
- On-track to complete resubmission of NDA for BARHEMSYS® to the FDA later this month
  - FDA raised no concerns in the Complete Response Letters (CRL) on clinical or safety data in the NDA
  - Alternative supplier of amisulpride has been qualified for nomination in the resubmission
- Anticipate Q1 2020 PDUFA target date assuming timely acceptance of NDA and a Class 2 resubmission
- Good operational progress in creating awareness of clinical need
  - US team in place and laying a solid foundation for launch
  - Phase 3 clinical study results of BARHEMSYS in PONV published in leading peer-reviewed publications

## Financial Summary

- Presentation currency changed from Pounds Sterling to US dollars as at 1 January 2019
- Cash and cash equivalents were \$22.7m at 30 June 2019
  - 31 December 2018: \$37.4m, 30 June 2018: \$47.2m
  - Steps taken to reduce expenditure and conserve cash resources
- Operating loss for the period increased to \$12.8m (H1 2018: \$6.3m) as the Group transitions from an R&D-led business towards the launch and commercialisation of BARHEMSYS
  - Sales and marketing costs for H1 2019 were up \$6.8m to \$8.1m (H1 2018: \$1.3m) as a result of the addition of our new employees and activities.
  - G&A costs decreased \$1.4m in H1 2019 to \$2.2m (H1 2018: \$3.6m). Previous year costs included an approximately \$1.7m one-off expense incurred in bringing the Group to its Euronext listing in March 2018.
  - R&D costs in the H1 2019 increased to \$2.5m (H1 2018: \$1.5m) attributed to activities preparing the NDA for BARHEMSYS and progressing towards its launch
- Basic loss per share \$0.2469 (H1 2018: \$0.2213)

# Nausea and vomiting is a complex process

- managed by combinations of antiemetics targeting multiple mechanisms – dopamine antagonism not addressed



- Multiple pathways involved, including:
  - Serotonin ( $5-HT_3$ )
  - Dopamine ( $D_2$ )
  - Inflammatory mediators
  - Substance P ( $NK1$ )

- Previous gold standard in PONV was  $D_2$  antagonist droperidol, now rarely used due to safety issues

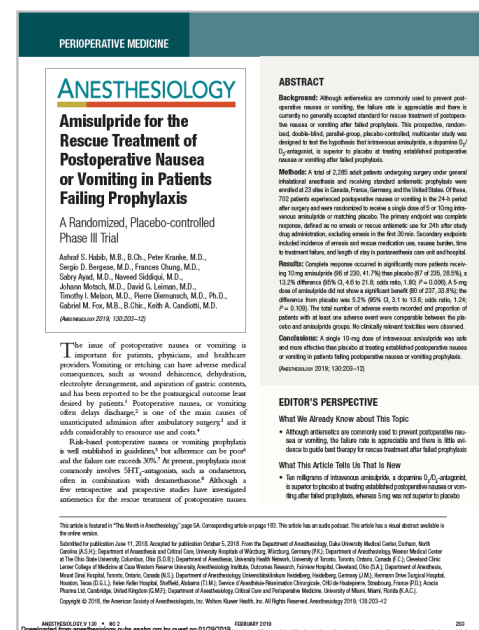
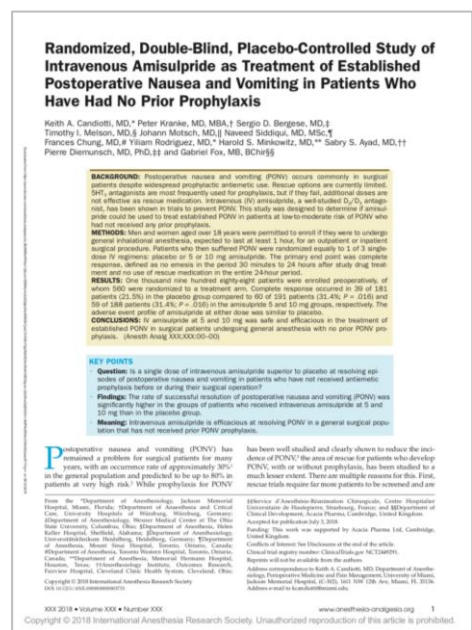
- Current standard-of-care:  $5-HT_3s \pm$  corticosteroids
- $NK1s$  added in CINV

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



# Comprehensive clinical trials package completed in PONV

- 8 clinical trials – 3,313 patients enrolled of whom 1,924 received BARHEMSYS
- All 4 pivotal trials are published in the peer reviewed literature

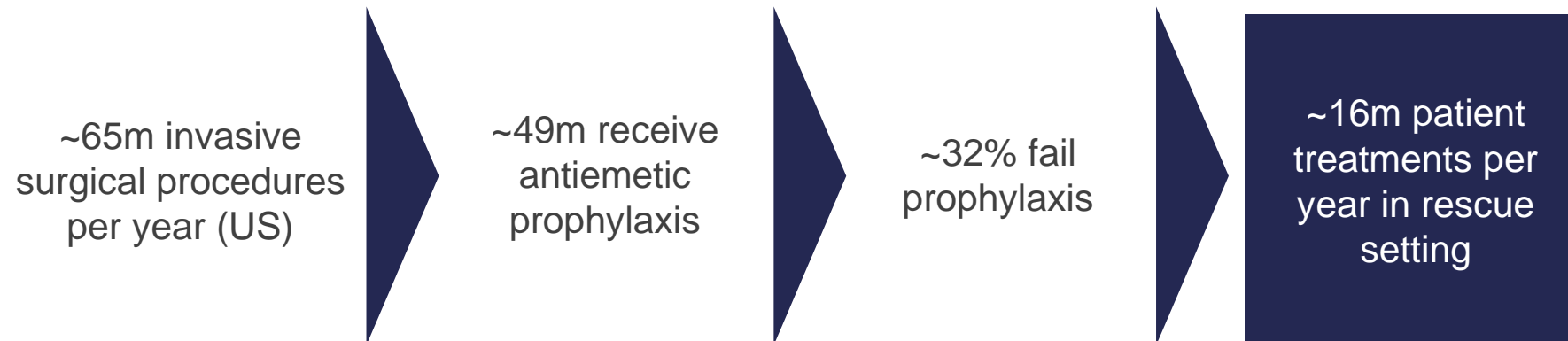


- BARHEMSYS would be the first drug to be approved for rescue treatment following failed standard of care prophylaxis
- Studies show a use of BARHEMSYS can save time in PACU and overall length of stay providing a net saving of ~\$670 per rescue patient dosed\*

References – 1) Kranke P, et al. (2013) Br J Anaesth 111(6): 938-945; 2) Kranke P, et al. (2018). Anesthesiology 128(6): 1099-1106; 3) Candiotti KA, et al. (2018). Anesth Analg doi: 10.1213/ANE.0000000000003733; 4) Habib AS, et al. (2019). Anesthesiology, 130:203-212

\* Assuming a price of \$80 per 10 mg rescue dose

## **We are focused on Rescue treatment – not addressed adequately and offering a significant commercial opportunity**



Patients currently receive 2 rescue doses on average giving rescue market of up to ~32 million doses

Assuming a price of \$80 per 10 mg rescue dose, this equates to a total addressable market of > \$2 billion



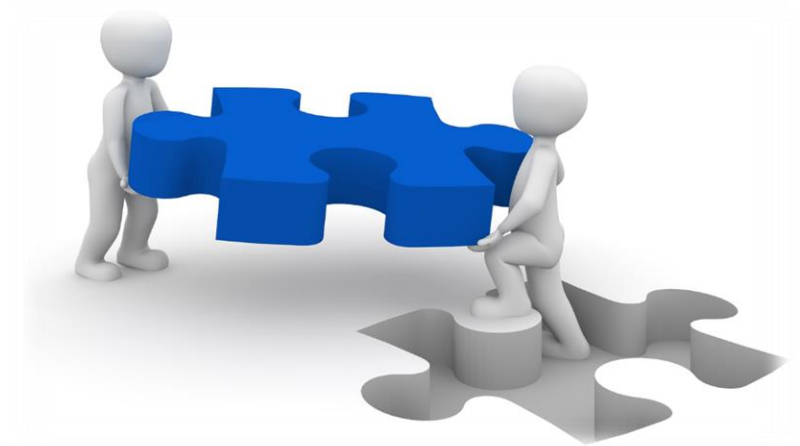
# Educating the market on the current unmet needs in PONV is the key to laying a solid foundation for launch

## Why?

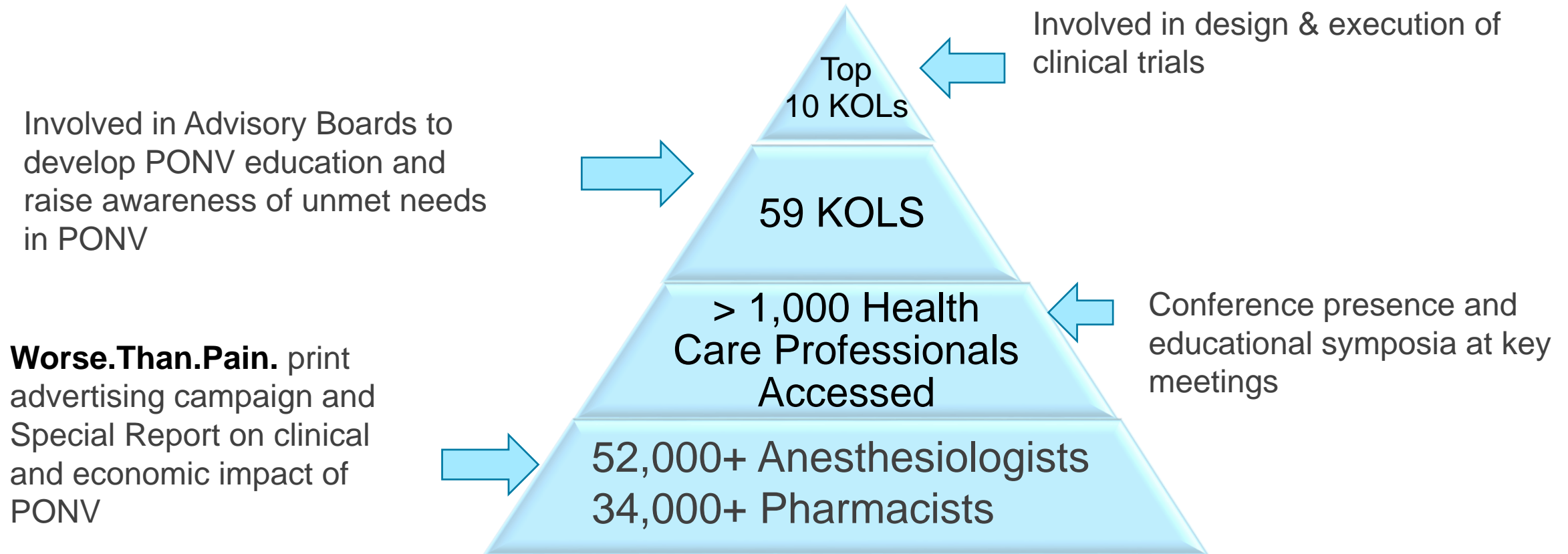
- No promotion or education in this space in over a decade
- Current practice for rescue contrary to guidelines

## How?

- Disease state campaign that highlights:
  - Current clinical and economic impact
  - Need for different options
  - Need for different mechanism in rescue



## How? – We can leverage close relationships with key opinion leaders to educate the market on unmet needs in PONV



# We have built an experienced team with demonstrated hospital success, aligned to drive efficiencies at launch

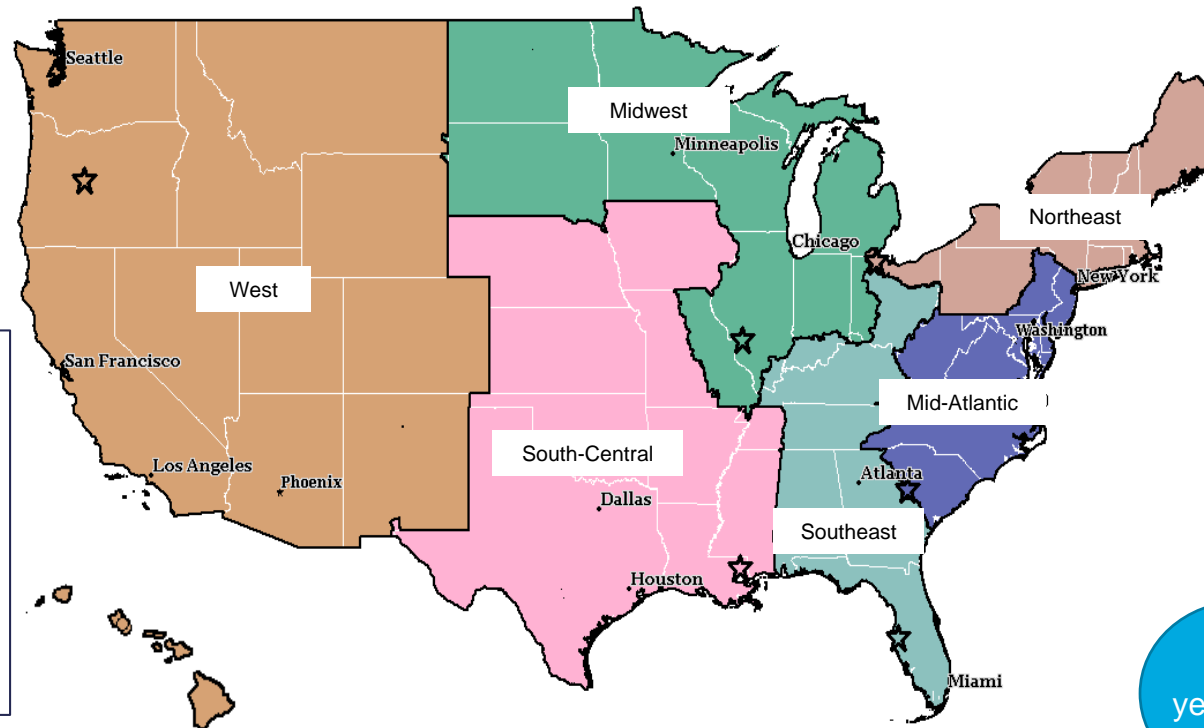
## Commercial Leadership Team

25+  
years avg  
industry

60+  
launches

### Initial Field Force Design

- 1 VP of Sales
- 1 National Accounts Group Leader
- 1 National MSL Group Leader
- 6 Sales Regions each with:
  - 1 RBD
  - 1 MSL
  - 1 National Account Director
  - 5-10 Hospital Territory Managers



## Sales Leadership Team

21  
years avg  
industry

17+  
years  
hospital

## National Accounts Team

23  
years avg  
industry

20+  
years  
hospital

## Medical Science Liaison Team

22  
years avg  
industry

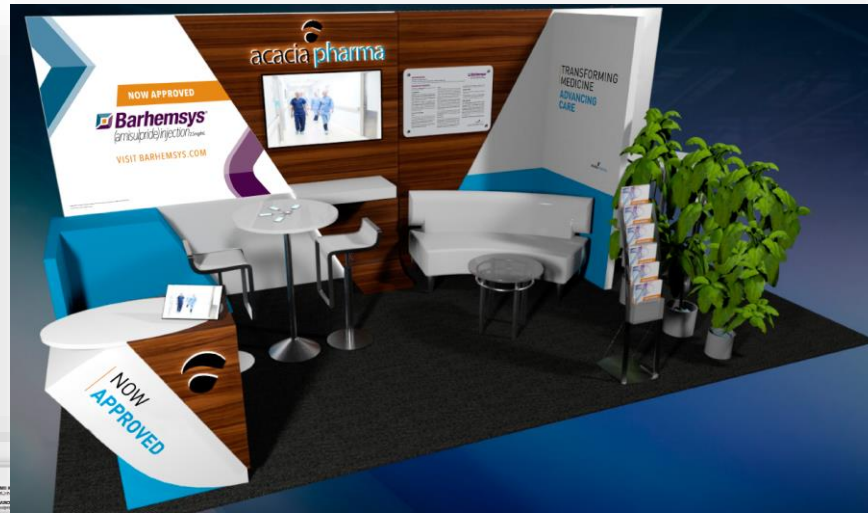
10+  
years as  
MSL



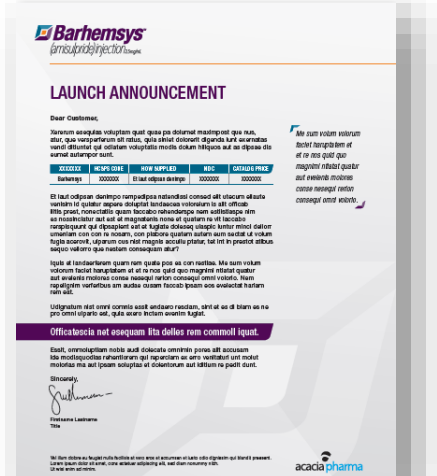


# Prepared resources to differentiate BARHEMSYS® and drive utilisation

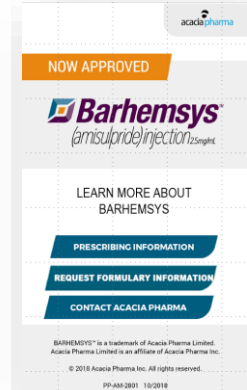
## Conference booth



## Announcement letter

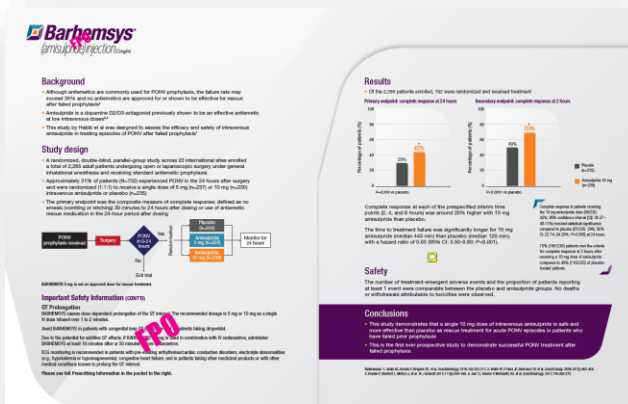


## Website

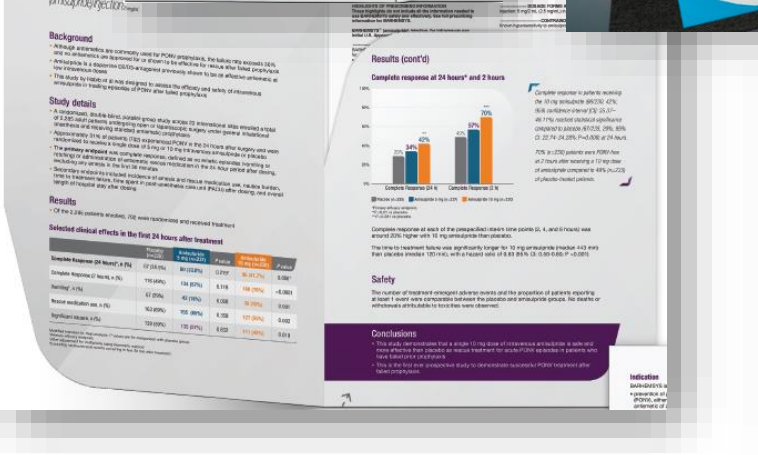
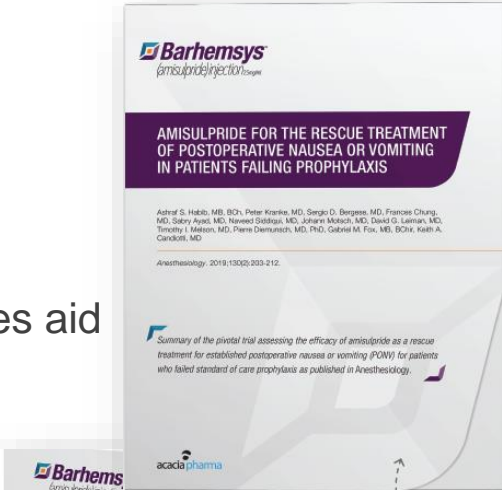


## Branded campaign

## Reprint and carrier



## Sales aid



## Summary

- We are on track to have our NDA resubmission accepted this month
  - No issues cited in CRL with respect to BARHEMSYS safety or efficacy or proposed label
- We expect a Class 2 designation which would lead to Q1 2020 PDUFA date
- We can use the next 6 months to further prepare for the most effective launch once BARHEMSYS is approved
  - We will educate leading surgery centres, group purchasing organisations and integrated delivery networks
  - We will maintain presence at key medical meetings such as ASA, ASHP, PGA
- Experienced sales leadership team in place
  - Team can initiate launch ahead of securing finance to recruit field sales team
- Significant US revenue opportunity
  - Large market opportunity in rescue and prophylaxis
  - Addressable by small, focused hospital sales team