# **Acacia Pharma Group plc**

Jefferies London Healthcare Conference Presentation November 2021

> Delivering innovative products to enhance surgical patients' recovery



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## Acacia Pharma Group – Overview

### **BARHEMSYS® – FDA approved for PONV, launched late 2020**

- Broad label for prevention and treatment of Post-Operative Nausea and Vomiting (PONV)
- Only agent approved for 'Rescue' of ~16m patients p.a. in US with PONV after generic antiemetics fail
- PONV "rescue" is an estimated \$2.7 billion annual total addressable market<sup>2</sup>

### BYFAVO<sup>®</sup> – In-licensed, FDA approved for procedural sedation, launched Jan 2021

- Indicated for procedural sedation in adults launch benefitting from shared value proposition
- Key target: 40m procedures a year in US, including 25m GI procedures<sup>3</sup>
- Estimated >\$1.5 billion annual total addressable market<sup>4</sup>

### Commercialization and engagement with KOLs showing good progress

- Strong, experienced team has effectively engaged with customers both virtually and live when possible
- Customers have provided very positive feedback on their initial experiences with the products
- Initiated the Byfavo pediatric study and have seen significant KOL interest in further studying Byfavo
- Partnering with key institutions to begin the Barhemsys PROMPT study to gather real-world evidence

1 Calculations based on available procedural data, applied Compound Annual Growth Rate and quantitative market research responses as follows: National Hospital Discharge Survey, 2006; National Survey of Ambulatory Surgery, 2006 (as revised in 2009); Source Healthcare; NCHS 2005; Life Science Strategy Group, LLC Market Research; Apfel et al.,2004. 2 Based on the calculations in (1) multiplied by the number of doses per patient at a WAC price of \$85 per 10mg dose. 3 iData Research, US Market Report Procedure Numbers for Gastrointestinal Endoscopic Devices February 2019; American Society of Anesthesiologists, Practice Guidelines for Moderate Procedural Sedation and Analgesia 2018; and Quantitative Market Research prepared by The Link Group for Cosmo Technologies (March 2019). 4 Based on the calculation in (4) multiplied by the number of doses per patient at a WAC price of \$39 per dose.



## Leadership Team with Experience to Deliver the Vision

Mike Bolinder CEO	<ul> <li>Joined 2015, became CEO 1 August 2019</li> <li>20 years experience in life sciences</li> <li>Relevant commercial experience with OFIRMEV<sup>®</sup> at Cadence/Mallinckrodt</li> </ul>	Killy Mallinckrodt
Gary Gemignani <i>CFO</i>	<ul> <li>Joined as CFO January 2020</li> <li>30+ years finance experience in healthcare</li> <li>Relevant CFO experience in early commercial stage pharma</li> </ul>	HARMACEUTICALS HARMACEUTICALS NOVARTIS Wyeth
Deb Hussain CCO	<ul> <li>Joined as CCO May 2021</li> <li>20+ years in pharma sales &amp; marketing</li> <li>Relevant commercial launch experience with multiple pharma brands</li> </ul>	<b>Silly</b> <b>Riley Hospital for Children</b> Indiana University Health
Dr Gabriel Fox <i>CMO</i>	<ul> <li>Joined as CMO 2008</li> <li>24 years in pharmaceutical medicine</li> <li>Relevant development and medical- marketing experience in repurposed drugs</li> </ul>	GILEAD Roche



We have been able to make significant progress in a very challenging operational environment caused by the global pandemic

66	The OR accounts for up to 65% of hospital				
	profit margin, so this missing volume is cutting deeply into cash flow and net income. – Becker's Hospital Review <sup>1</sup>	<b>?</b> ,			

COVID-19 impact on hospitals and surgical centers	<ul> <li>Non-essential surgeries cancelled creating a significant backlog</li> <li>Physical access to hospital decision-makers even more restricted</li> </ul>
Hospital profits have suffered and need to be restored quickly	<ul> <li>Surgeries and procedures are major contributors to hospital profits</li> <li>Providers need to dramatically increase throughput to regain lost profits</li> </ul>
We believe our products and team are ideally positioned to help	<ul> <li>BARHEMSYS and BYFAVO can help improve patient throughput – both are now even more relevant and of greater interest to customers due to COVID</li> <li>Our strong relationships are helping us gain access to key decision-makers</li> </ul>



# **BARHEMSYS**®

(amisulpride for injection)

# The first and only FDA-approved product for PONV rescue treatment<sup>1</sup>

1 FDA labels for other recommended treatments do not include treatment after failed prophylaxis. Treatment agents recommended by Society for Ambulatory Anesthesiology Consensus Guidelines (2014). Habib et al (2019): no agent has previously been shown in a prospective trial to be more effective than a placebo for treating PONV for patients who have failed prophylaxis.



## **BARHEMSYS®** and the PONV Commercial Opportunity

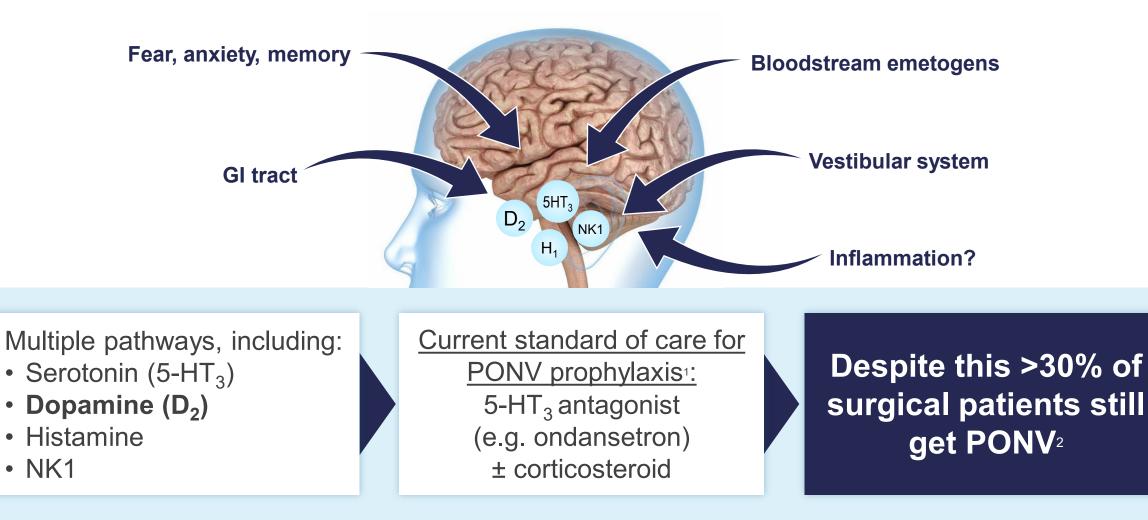
BARHEMSYS Addresses the major unmet need in PONV	<ul> <li>BARHEMSYS is the only FDA-approved drug for PONV rescue after failed prophylaxis<sup>1</sup></li> <li>Dopamine D<sub>2</sub>/D<sub>3</sub> antagonist with broad, differentiated label</li> <li>Offers significant economic savings to hospital vs current standard of care</li> </ul>
Large but concentrated US market opportunity in PONV <sup>2</sup>	<ul> <li>Estimated ~65m eligible surgeries annually, ~49m patients receive preventative antiemetics<sup>3</sup></li> <li>Total addressable PONV rescue market estimated at ~\$2.7 billion/year<sup>4</sup></li> <li>Estimated 80% of surgeries carried out in ~1,200 hospitals<sup>5</sup></li> </ul>
High gross profit, secure supply chain and worldwide rights	<ul> <li>Cost of goods ~10% of sale price</li> <li>Substantial product inventory to minimize supply risk</li> <li>Worldwide rights and exploring out-licensing opportunities in OUS markets</li> </ul>
Can help with COVID surgical backlogs	<ul> <li>"The OR accounts for up to 65% of hospital profit margin" – Becker's Hospital Review<sup>6</sup></li> <li>Non-essential surgery cancellations create significant backlogs</li> <li>Shorter time in PACU (recovery room) can help increase surgical throughput</li> </ul>

1 FDA labels for other recommended treatments do not include treatment after failed prophylaxis, 2 This is the belief of the Company. 3 Company market size estimates based upon: 2006 National Hospital Discharge Survey; National Survey of Ambulatory Surgery, 2006 (as revised in 2009); LSSG Quantitative Research November 2014; Apfel, NEJM 2004. Calculations based on available procedural data, applied Compound Annual Growth Rate and quantitative market research responses. 4 Based upon WAC price of \$85 per 10mg rescue dose with, on average, 2 rescue doses per patient, and the above estimates. 5 Symphony Health, Source Non Retail, August 2017 - July 2018. estimates 6 How to rebuild surgical revenue after COVID-19, Becker's Hospital Review, accessed via <a href="https://www.beckershospitalreview.com/strategy/how-to-rebuild-surgical-revenue-after-covid-19-even-if-you-just-lost-60-of-your-or-volume.html">https://www.beckershospitalreview.com/strategy/how-to-rebuild-surgical-revenue-after-covid-19-even-if-you-just-lost-60-of-your-or-volume.html</a>



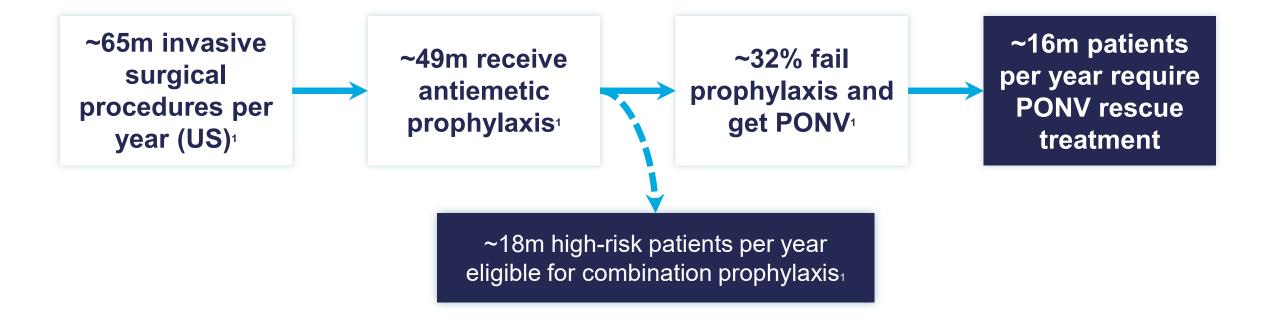
## **Nausea and Vomiting is a Complex Process**

Managed by combinations of antiemetics targeting multiple mechanisms





## **Targeting PONV Rescue Market**



## Total estimated addressable market in PONV rescue ≈ \$2.7B per year

Secondary market in combination prophylaxis in highest-risk patients, estimated to be worth \$765M per year<sup>2</sup>

1 Company market size estimates based upon: 2006 National Hospital Discharge Survey; National Survey of Ambulatory Surgery, 2006 (as revised in 2009); LSSG Quantitative Research November 2014; Apfel et al, 2004. Calculations based on available procedural data, applied Compound Annual Growth Rate and quantitative market research responses. 2 Based on WAC price of \$85 per 10 mg rescue dose and average 2 rescue doses per patient; \$42.50 per 5 mg prophylaxis dose.



## **BARHEMSYS<sup>®</sup>** is the Only FDA-Approved Product for PONV Rescue

When PONV prophylaxis has failed, patients should receive antiemetic treatment from a different pharmacological class to the PONV prophylaxis – Consensus Guidelines





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1 Fourth Consensus Guidelines for the Management of Postoperative Nausea and Vomiting. 2 Wang et al (2000). 3 BARHEMSYS label prescribing information. 4 LSSG quantitative market research among 152 anesthesiologists and general surgeons. Question referred to "Product X" with a description matching the profile of BARHEMSYS. Note: current shares totals > 100% as responses included some combination therapy.

## **Barhemsys – Compelling Commercial Proposition**



11

### Significant unmet need

- Nausea more so than vomiting, worse than pain
- Consensus Guidelines: "When PONV prophylaxis has failed, patients should receive antiemetic treatment from a different pharmacological class to the PONV prophylaxis"<sup>1</sup>

### Only FDA-approved product for PONV rescue<sup>2</sup>

- Only drug proven in randomized clinical trial to work in PONV rescue<sup>3</sup>
- · Excellent safety profile demonstrated in clinical studies
- Also demonstrated to be effective for prevention

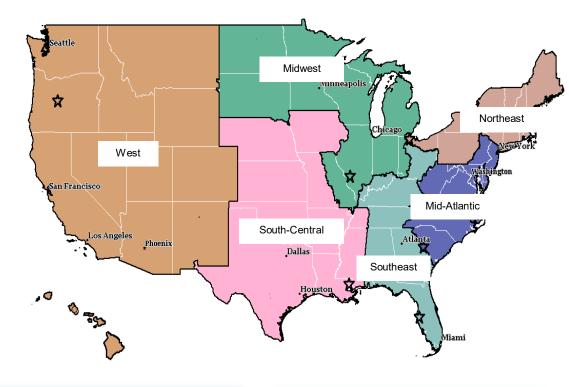
#### Throughput and health economic benefits

- Is non-sedating a common complaint of standard antiemetic agents
- 35-minute reduction in PACU stay, 6-hour reduction in hospital stay
- · Offers significant economic savings to hospital vs current standard of care



1 Fourth Consensus Guidelines for the Management of Postoperative Nausea and Vomiting; 2 FDA labels for other recommended treatments do not include treatment after failed prophylaxis. Treatment agents recommended by Society for Ambulatory Anesthesiology Consensus Guidelines (2014). Habib et al (2019): no agent has previously been shown in a prospective trial to be more effective than a placebo for treating PONV for patients who have failed prophylaxis. 3 FDA labels for other recommended treatments do not include treatment after failed prophylaxis.

## **Highly Experienced Commercial Team is Driving Formulary Adoption**



Commercial Leadership Team has 28+ years average in the industry and experience with 70+ launches

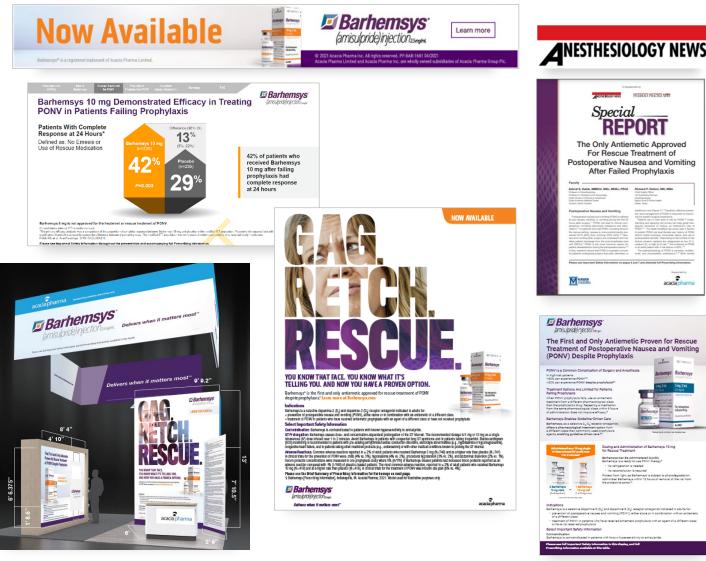
#### **Field Force Design**

- 1 SVP of Field Commercial Teams
- 1 National Accounts Group Leader
- 1 National MSL Group Leader
- 6 Sales Regions including:
  - Regional Brand Directors
  - Medical Science Liaisons
  - National Account Directors
  - Hospital Territory Managers

acacia pharma



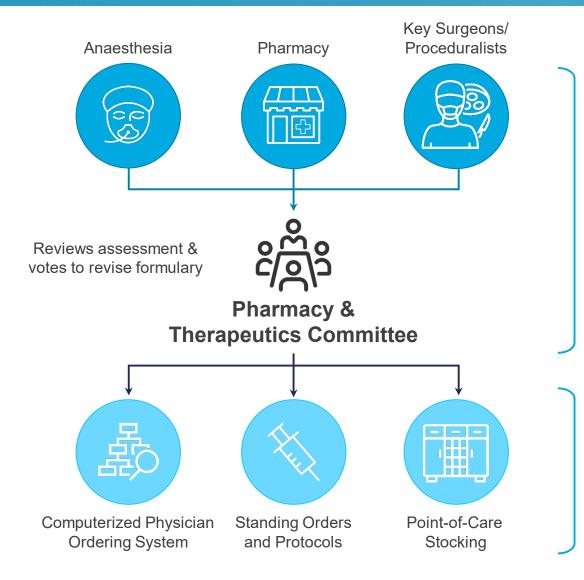
## **Barhemsys – Comprehensive Customer Engagement Plan**



- Full 2021 Medical congress plan
  - Regional/state congresses: 24
- Peer-to-peer programs: 150+ live and virtual programs
- Digital brand engagements in the most trusted anesthesia publications with 89% readership (51K members)
  - Special report distributed to all Anesthesia targets October '21
- Robust digital and print media plan under way across Anesthesia, Pharmacy and Surgery
- All promotional materials available both physically and digitally



## Hospital Launch: Strategic Focus on Formulary Reviews & Adoption



### **Formulary Review Process**

- Identify "champions" within each facility
- Educate and prepare "champions" for P&T Committee
- Highlight current unmet needs with existing products
- · Educate on efficacy and safety data for our products
- Barhemsys and Byfavo can provide economic savings to hospital vs current standard of care

### **Pull-Through Process**

- Ensure our brands are within the workflow of the healthcare providers
- Conduct in-service presentations to educate nurses
   and staff



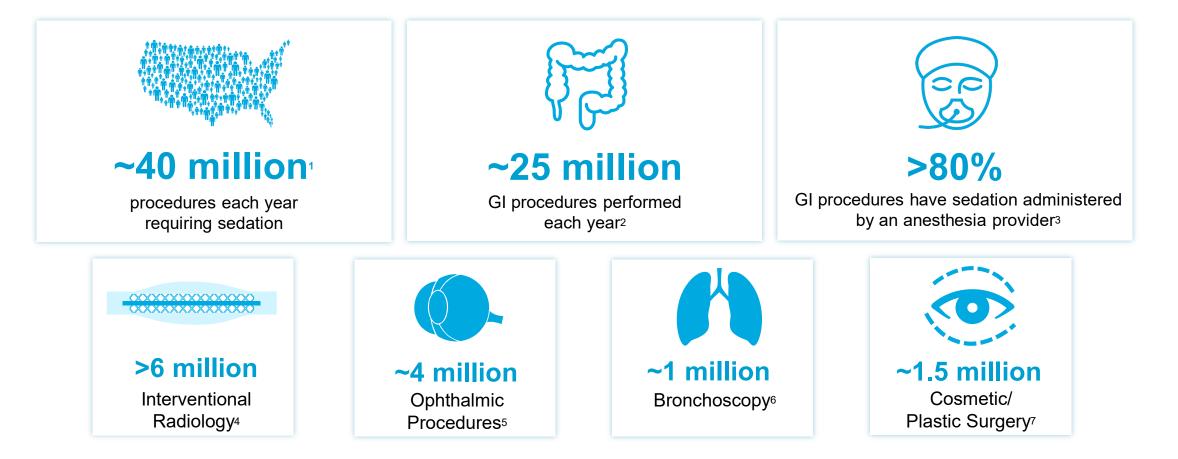
# **BYFAVO**<sup>®</sup>

(remimazolam) for injection

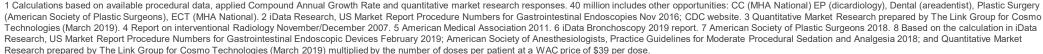
# Rapid onset/offset procedural sedative with favorable safety profile



## **Procedural Sedation Market Opportunity**



Total addressable market in procedural sedation >\$1.5B/year<sup>®</sup>





## **BYFAVO Addresses Unmet Need in Procedural Sedation**

### **Propofol**

### fast acting but significant safety issues<sup>1,2</sup>

- Rapid onset and offset anesthetic with narrow therapeutic index<sup>1</sup>
- Dose-related cardiorespiratory depression, pain at injection site<sup>1</sup>
- Non-linear dosing effects due to individual variability<sup>4</sup>
- Needs continuous monitoring by anesthesiologist, no reversal agent<sup>2</sup>
- Lipid formulation susceptible to bacterial contamination<sup>4</sup>

17

### Midazolam

better safety profile but longer onset and recovery<sup>1,2</sup>

- Benzodiazepine sedative, reversible by flumazenil<sup>1</sup>
- Slower onset and offset<sup>2,3</sup>
- Metabolized by cytochrome system; individual variability affects sedation<sup>1</sup>
- Active metabolite can accumulate and cause prolonged sedation<sup>2</sup>
- Risk of respiratory depression<sup>1</sup>

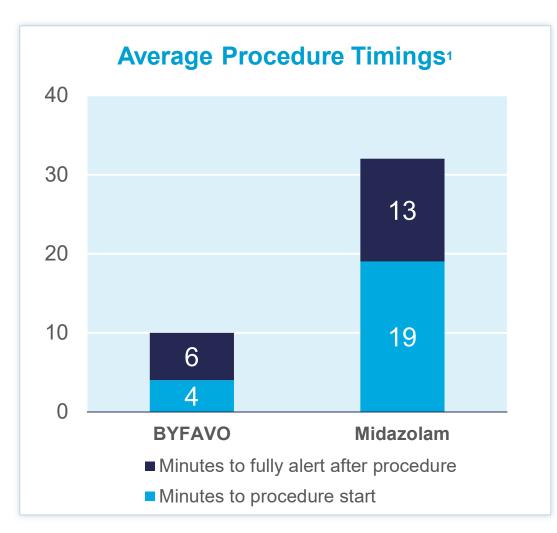
### **BYFAVO**

### fast acting AND favorable safety profile<sup>1,2</sup>

- Rapid onset/offset<sup>1,2,3</sup> benzodiazepine
- Rapid biotransformation into inactive metabolites via nonspecific tissue esterases – not dependent on liver enzymes<sup>1</sup>
- Predictable behavior, no pharmacokinetic drug interactions<sup>5</sup>
- Reliable sedation, reliable safety profile<sup>1</sup>
- Reversible by flumazenil<sup>1</sup>



## **Rapid Onset/Offset with a Favorable Safety Profile**<sup>1</sup>



### Key Adverse Events<sup>1</sup>

BYFAVO	Midazolam
74%	91%
62%	81%
18%	26%
4%	6%
	<b>74%</b> 62% 18%



## **Byfavo – Compelling Commercial Proposition**

### **Clear unmet need**

- No innovation in the sedation space for 20+ years
- Customers seeking fast onset, titratable, & rapid recovery for quick discharge
- · Shorter procedure times allow increased procedural volumes

### **Broad label & health economic benefits**

- Indicated for procedural sedation in adults in procedures lasting 30 mins or less
- Substantial clinical data package shows compelling efficacy and safety in colonoscopies and bronchoscopies, including most challenging patients
- Enables shorter procedure times and greater patient throughput

### **Commercial synergy with Barhemsys**

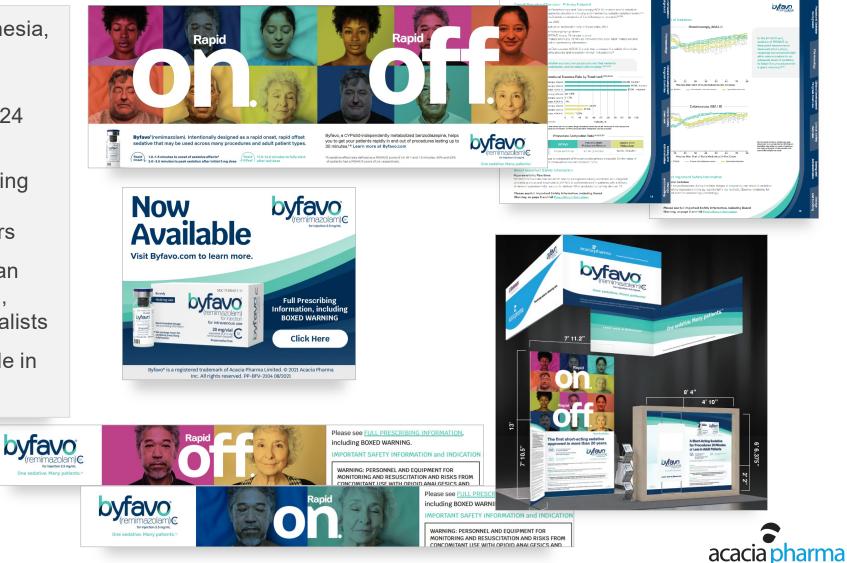
• Target prescribers: anesthesia providers and proceduralists in hospitals and ambulatory surgery centers





## Byfavo - Launching the First New Sedative in the US for 20 years

- Full congress plan across Anesthesia, Pharmacy, including key GI and Pulmonology
  - Regional/state congresses: 24
- On demand virtual and live promotional programming, featuring anesthesia, GI, and pulmonary investigators and trained speakers
- Robust digital and print media plan under way across Anesthesia, GI, Pharmacy and Surgery/proceduralists
- All promotional materials available in both digital and physical format



Efficacy of BYFAVO

## **Commercial Progress as of 30 September 2021**



### 260 accounts on formulary [Goal: 300] >80% win rate [Goal: 75%]

>185 accounts have ordered Barhemsys 73% of ordering accounts with Barhemsys on formulary have placed repeat orders









95 accounts on formulary [Goal: 150] >90% win rate [Goal: 75%]

>50 accounts have ordered Byfavo 81% of ordering accounts with Byfavo on formulary have placed repeat orders



# **Financials**



## Acacia Pharma Group – Financial Summary

Listed on Euronext Brussels exchange

- IPO in March 2018
- ~99.7m shares outstanding
- ~80% free float

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- Cash and cash equivalents as of 30 June 2021 was \$47.1m
- Equity financing in February 2021 with gross proceeds of €27m (~\$33m)

Debt• Early repayment of Hercules debt in May 2021• Cosmo ~€25m outstanding loan



# **Summary**



## **In Summary**

Our products address **unmet medical needs** in therapeutic areas with **large total addressable market opportunities** (~\$2.7B in PONV rescue, >\$1.5B in procedural sedation)

The team continues to make **tremendous progress in 2021** despite a very challenging operating environment due to the global pandemic

We continue to see a **great response from customers at launch adding our products to formulary** with continued positive customer feedback on both products

We believe we have **the right team, with the right experience** and have set the stage for significant commercial success in the years to come





