

### Acacia Pharma Group plc ByFavo Licensing Agreement & Cosmo Equity and Debt Investments Mike Bolinder, CEO & Christine Soden, CFO



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### **Deal Structure**

- Acacia Pharma has acquired the rights to commercialize ByFavo<sup>™</sup> (remimazolam) in the US market from Cosmo Pharmaceuticals N.V.
- Cosmo will make a strategic equity investment in Acacia Pharma of €10m
  - 4,347,826 new ordinary shares at €2.30 per share
- Cosmo will make a loan facility of up to €35m available on achievement of milestones:
  - €10m on the US FDA approval of BARHEMSYS
  - €25m on the US approval of ByFavo
- Cosmo will receive the following in respect of the licence:



<u>On ByFavo US Approval</u> €15m in ACPH shares €15m in cash covered by 2<sup>nd</sup> loan tranche On ByFavo First US Sale €5m in ACPH shares

- Up to €105m in sales-related milestones
- Acacia Pharma to pay the agreed product royalties to Paion



### **About ByFavo<sup>™</sup> (remimazolam)**

- ByFavo is an ultra-short-acting and reversible i.v. benzodiazepine sedative/anaesthetic designed for use during invasive medical procedures, e.g. colonoscopy and bronchoscopy
- Approx. 24.5 million such procedures take place annually in the US, of which around 90% used moderate sedation
- Efficacy and safety demonstrated in extensive clinical trial programme (~2,400 volunteers and patients)
- Rapid onset and offset of action plus good cardio-respiratory safety profile
- Designed to act more quickly than alternatives of the same drug class for the same indication (e.g. midazolam) and rapidly reversible with flumazenil if necessary
- Cosmo in-licensed the US rights to ByFavo from Paion AG in 2016 and together they have progressed the product candidate through to registration
- Target review (PDUFA) date of 5 April 2020



## Why ByFavo<sup>™</sup> is a great fit

- Highly complementary commercial fit to BARHEMSYS®
  - Both products are targeted toward the same key physicians
  - Both have a very similar value proposition
    - mobilizing patients more quickly after their procedure
- ByFavo enables Acacia Pharma to further leverage the commercial infrastructure being planned and built out as the key physician targets are very aligned
- Will use the same distribution channels and networks
- Same KOLs will be targeted Acacia Pharma already has good working relationships with this key physician group
- We expect to operate with substantially the same sales and marketing infrastructure as already planned



# Key targets and newsflow for Acacia Pharma in 2020

### Q1

- BARHEMSYS PDUFA date of 26 February
  - Continue education on PONV opportunity
  - Begin education on procedural sedation
  - Begin education on BARHEMSYS
    - Conferences
    - KOLS
    - GPOs and IDNs

#### **Q2**

- ByFavo PDUFA date of 5 April
  - Begin education on ByFavo
- Onboard and train territory managers June-July
- Launch Phase 4 study for BARHEMSYS across key sites

Q3

- Launch BARHEMSYS and ByFavo
  - Report successes in formulary access
  - Report early sales
- BARHEMSYS on treatment guidelines
- Update on CINV development

#### **Q4**

- Results of BARHEMSYS Phase 4 study
  - Report progress in formulary access
  - Report early sales



### Wrap up

- Acquired access to highly complementary and highly competitive hospital product in ByFavo
- Immediate injection of cash to continue to invest in US commercial platform
- Debt facility provides financial flexibility supplements YE cash reserves (unaudited) of \$17m
- Q3 launches of BARHEMSYS and ByFavo will allow Acacia Pharma to efficiently leverage its commercial organisation
- Significant scope to create shareholder value



# **Questions?**