



Published: 07:00 CEST 09-07-2018 /GlobeNewswire /Source: Acacia Pharma Group plc / : ACPH /ISIN: GB00BYWF9Y76

Acacia Pharma Provides Operating Update for the First Half 2018

Cambridge, UK and Indianapolis, US - 9 July 2018: Acacia Pharma Group plc ("Acacia Pharma", the "Company" or the "Group"), (EURONEXT: ACPH) provides an unaudited operating update for the first half 2018 (six months ended 30 June 2018). Acacia Pharma is a hospital pharmaceutical company focused on the development and commercialisation of new nausea & vomiting treatments for surgical and cancer patients targeting a specific unmet need to improve patient outcomes and lower hospital costs.

Dr Julian Gilbert, CEO of Acacia Pharma, commented: "The Group has made important progress during the first half 2018 preparing for the launch, if approved, of BARHEMSYS(TM) for the treatment and prevention of post-operative nausea & vomiting (PONV) in surgical patients. This condition affects millions of people in the US each year despite the use of existing antiemetics and is a major cause of patient distress, as well as often resulting in delayed recovery and increasing hospital costs. BARHEMSYS has been developed to provide anaesthetists with the first new antiemetic for many years to better manage PONV and improve patient outcomes.

"Our strategy is to launch BARHEMSYS in the US through our own commercial operation. The development of this organisation and our pre-commercialisation activities in the US are on track: we have hired experienced individuals to the leadership team across all core commercial functions and are building out the team at all levels. Our discussions with FDA since acceptance of the NDA have been encouraging and, with a strong financial position, we expect to be well-positioned to execute our launch plan pending regulatory approval."

Operational Highlights for the First Half 2018

- In January, Acacia Pharma announced that it received notice from the US Food & Drug Administration (FDA) that its New Drug Application (NDA) for intravenous amisulpride (BARHEMSYS) was accepted and indicated a target PDUFA date of 5 October 2018. If approved, BARHEMSYS could become an important new option for the 16 million surgical patients who suffer PONV despite having received prior

prophylaxis with standard antiemetics, an area where no other antiemetics have been successful in clinical studies; and in preventing PONV in combination with standard antiemetics in the 18 million patients at high risk of developing it.

- In March, Acacia Pharma raised €40 million in its Initial Global Offering in conjunction with its listing on Euronext Brussels. The funds are being deployed primarily to build the sales and marketing infrastructure and undertake marketing, supply chain and other preparatory activities to launch BARHEMSYS into the US hospital market in 2019.
- In April, Acacia Pharma announced appointments to four key positions as a step towards building its US commercial organisation. In line with its strategy, Acacia Pharma is continuing to successfully recruit experienced sales, marketing, regulatory and operations people to support the launch of BARHEMSYS, each of whom brings significant and relevant commercial experience in launching and marketing hospital pharmaceutical products in the US. The leadership team collectively has more than 155 years of industry experience and over 60 pharmaceutical launches.
- The Group is on track with its launch readiness plans. Contracts have been negotiated with suppliers to deliver the logistics, distribution and order and receivables management needs upon approval, negotiations with major wholesalers and national accounts are being planned and processes under way to ensure the Group is licensed to sell BARHEMSYS in each of the key US states. Advisory Board meetings have been held at five important medical meetings delivering insights into the marketing, positioning and pricing of the product.
- In May, FDA confirmed conditional approval to the tradename BARHEMSYS, which has replaced the previously used BAREMSIS®.
- In June, Acacia Pharma and FDA held a late-cycle review meeting on BARHEMSYS. FDA indicated that an Advisory Committee was not planned and indicated a target PDUFA date of 5 October 2018.
- On 29 June 2018, the Company secured a credit facility of up to \$30 million with Hercules Technology Growth Capital, Inc. ("Hercules") (NYSE: HTGC) providing additional funding to support the intended US launch of BARHEMSYS, drawing \$10 million under the facility at closing. As at 30 June 2018 the Group's cash and cash equivalents totalled \$47.2 million (£35.7 million).

Contacts