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Positive BARHEMSYS™ Phase 3 Treatment Data Published in Anesthesia & Analgesia

Cambridge, UK and Indianapolis, US – 14 September 2018: Acacia Pharma Group plc ("Acacia Pharma", the "Company") (EURONEXT: ACPH) announces that data and analyses from its positive Phase 3 clinical trial with BARHEMSYS™ (intravenous amisulpride) have been published in the online edition of the leading peer-reviewed journal *Anesthesia & Analgesia* (Candiotti *et al*[1]). Positive headline results were first announced by the Company in August 2016.

The pivotal Phase 3 trial met its primary endpoint, demonstrating that BARHEMSYS, at two doses tested (5 mg and 10 mg), was significantly superior to placebo at treating established post-operative nausea & vomiting (PONV) in patients at low-to-moderate risk of PONV who had not received any prior prophylaxis. BARHEMSYS at both doses also showed a safety profile similar to placebo.

A New Drug Application (NDA) for BARHEMSYS, including data from this and three other positive Phase 3 trials, is currently under review by the US Food and Drug Administration (FDA), with a target date of 5 October 2018 to complete its review. The extensive clinical trial programme has investigated the safety and efficacy of BARHEMSYS in the treatment of established PONV, whether or not prior prophylaxis was given, and the prevention of PONV, alone or in combination with other antiemetics.

"*PONV is a common complication of surgery affecting millions of patients who undergo general anaesthesia and represents an important challenge for physicians and patients. I am very encouraged by the results seen in this and other trials with BARHEMSYS, which could provide a valuable additional option for treating PONV*," said Professor Keith Candiotti MD, Professor of Anesthesiology and Interim Chair of the Anesthesiology faculty at the University of Miami's Miller School of Medicine and chief investigator of the study.

Dr Gabriel Fox, Acacia Pharma's Chief Medical Officer, added: "*This is the fourth publication to come out of our rigorous, 3,300-patient BARHEMSYS clinical programme, which demonstrated efficacy in both the prophylaxis and treatment of PONV. BARHEMSYS is the first new agent in more than 20 years to be studied in prospective, randomised trials of the treatment of active PONV and we are therefore especially excited by the possibility of giving healthcare providers and patients another choice in that setting*."

Note: The tradename BARHEMSYS™ has received conditional approval by the US FDA and has replaced the previously used BAREMSIS®.

Summary of the trial and results

The Phase 3 study (*ClinicalTrials.gov identifier: NCT02449291*) was a double-blind, randomised, placebo-controlled trial conducted at 21 sites in Europe and North America. It included 1,988 adult patients undergoing elective surgery under general anaesthesia who had a low-to-moderate risk of PONV based on the Apfel risk factor scoring system[2].

Patients who then suffered PONV were randomised equally to one of three single-dose, IV regimens: placebo or 5 mg or 10 mg amisulpride. A total of 560 patients were randomised to receive one of the study medications and were eligible for intent-to-treat analysis. The primary endpoint was complete response (CR), defined as no emesis in the period 30 minutes to 24 hours after study drug treatment and no use of rescue medication in the entire 24-hour period.

The trial met its primary endpoint: CR occurred in 39/181 patients (21.5%) in the placebo group compared to 60/191 patients (31.4%; p=0.016) and 59/188 patients (31.4%; p=0.016) in the amisulpride 5 mg and 10 mg groups, respectively. One or more treatment-emergent adverse events were experienced by 39.8% of patients in the 5 mg group and 42.0% of the 10 mg group, compared to 53.0% of the placebo group. The only adverse events to occur in 5% or more of the patients in any group were flatulence, nausea occurring more than 24 hours after treatment, constipation and infusion site pain, all of which were similar between the groups.

References

1. Candiotti KA, Kranke P, Bergese SD, et al. Randomized, Double-Blind, Placebo-Controlled Study of Intravenous Amisulpride as Treatment of Established Postoperative Nausea and Vomiting in Patients Who Have Had No Prior Prophylaxis. Anesth Analg 2018; doi: 10.1213/ANE.0000000000003733 [epub ahead of print]
2. Apfel, C.C., Läärä, E., Koivuranta, M., Greim, C.A., Roewer, N. A simplified risk score for predicting postoperative nausea and vomiting: conclusions from cross-validations between two centers. Anesthesiology 1999, 91(3):693-700.

About BARHEMSYS

BARHEMSYS comprises a low dose intravenous formulation of the marketed dopamine antagonist amisulpride, which Acacia Pharma has developed for the completely new, patent-protected uses of prevention and treatment of PONV.

A New Drug Application (NDA) submission for BARHEMSYS, including data from four positive Phase 3 studies and more than 3,300 surgical patients and healthy volunteers, is currently under review by the US Food and Drug Administration (FDA). Under the Prescription Drug User Fee Act (PDUFA), the FDA has set a target date of 5 October 2018 to complete its review.

The Company is seeking approval of BARHEMSYS for:

- Treatment of PONV in patients who have received antiemetic prophylaxis with an agent of a different class or who have not received prophylaxis; and
- Prevention of PONV, either alone or in combination with an antiemetic of a different class.

About PONV

PONV is a common complication of surgery, occurring in approximately 30% of surgical patients and up to 80% of high-risk patients. It is associated with the use of anaesthetic gases and opioid pain-killers and is particularly common following gynaecological, abdominal, breast, eye and ear operations, especially those lasting an hour or more.

The Company estimates that approximately 65 million surgical procedures are conducted in the US each year that require injectable analgesia and are eligible for antiemetic use to prevent PONV. Based on market research, Acacia Pharma estimates that the total market in the US for prophylactic and rescue treatment comprises an estimated 34 million treatment events annually.

PONV has been ranked as the most undesirable of all surgical complications by patients and contributes significantly to patient anxiety and distress. PONV can delay hospital discharge; result in re-admission after in-patient procedures; and lead to day-case patients being admitted to hospital, all of which can result in significantly increased healthcare costs.

About Acacia Pharma

Acacia Pharma is a hospital pharmaceutical company focused on the development and commercialisation of new nausea & vomiting treatments for surgical and cancer patients. The Company has identified important and commercially attractive unmet needs in nausea & vomiting and has discovered two product candidates based on the same active ingredient, amisulpride, to meet those needs.

The Company's lead product, BARHEMSYS for post-operative nausea & vomiting (PONV), has generated positive results in Phase 3 clinical studies and an NDA is currently under review by the US FDA with a PDUFA goal date of 5 October 2018. Its sister project, APD403 for chemotherapy induced nausea & vomiting (CINV), has successfully completed one proof-of-concept and one Phase 2 dose-ranging study in patients receiving highly emetogenic chemotherapy.

Acacia Pharma is based in Cambridge, UK, and its US operations are centred in Indianapolis, IN. The Company is listed on the Euronext Brussels exchange under the under ISIN code GB00BYWF9Y76 and ticker symbol ACPH. www.acaciapharma.com

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Forward looking statement

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