ACACIA PHARMA RECEIVES COMPLETE RESPONSE LETTER FROM FDA FOR BARHEMSYS®

This announcement contains inside information for the purposes of Article 7 of the Market Abuse Regulation (EU) No 596/2014.

Cambridge, UK and Indianapolis, US – 3 May 2019: Acacia Pharma Group plc ("Acacia Pharma"), a pharmaceutical company developing and commercialising hospital products for US and international markets, announces that it has received a second Complete Response Letter from the US Food and Drug Administration (FDA) regarding its New Drug Application (NDA) for BARHEMSYS® (amisulpride injection). The letter identified continuing deficiencies at the contract manufacturer of amisulpride, the active pharmaceutical ingredient used in BARHEMSYS.

As previously, no concerns were raised by FDA on any of the clinical or non-clinical data in the NDA and no further studies or data analyses will be required for approval.

"We are extremely disappointed that the amisulpride manufacturer named in our application has still not been able to meet FDA's required standards," said Dr Julian Gilbert, CEO of Acacia Pharma. "As there were no other issues raised with our application, we remain confident that BARHEMSYS is approvable. We are on track to complete the qualification of an alternative supplier of amisulpride and plan to engage with FDA as soon as possible to determine the most rapid route to obtaining approval for BARHEMSYS."

Conference Call Information

The Acacia Pharma management team will host a conference call Friday, 3 May 2019, at 14.00 CEST, 13:00 BST, 07:00 EST. Please join the event conference 5-10 min prior to the start using the confirmation code and any of the phone numbers provided below.

Password: Acacia Pharma

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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 Group 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 Group's lead project, BARHEMSYS® for post-operative nausea & vomiting (PONV), has generated positive results in four Phase 3 clinical studies. 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

Forward looking statement

This announcement includes forward-looking statements, which are based on current expectations and projections about future events. These statements may include, without limitation, any statements preceded by, followed by or including words such as "believe", "expect", "intend", "may", "plan", "will", "should", "could" and other words and terms of similar meaning or the negative thereof. Forward-looking statements may and often do differ materially from actual results. These forward-looking statements are subject to risks, uncertainties and assumptions about the Company and its subsidiaries and investments, including, among other things, the development of its business, trends in its operating industry, and future capital expenditures and acquisitions. By their nature, forward-looking statements involve risk and uncertainty because they relate to future events and circumstances. Any forward-looking statements reflect the Company's current view with respect to future events and are subject to risks relating to future events and other risks, uncertainties and assumptions relating to the Group's business, results of operations, financial position, prospectus, growth or strategies and the industry in which it operates. Save as required by law or applicable regulation, the Company and its affiliates expressly disclaim any obligation or undertaking to update, review or revise any forward-looking statement contained in this announcement whether as a result of new information, future developments or otherwise. Forward-looking statements speak only as of the date they are made.