Press Releases

08 October 2018

Update on FDA regulatory review of BARHEMSYS™

- FDA issued a Complete Response letter to Acacia Pharma on Friday 5 October
- Only issue raised relates to FDA inspection of contract manufacturer of active ingredient
- No other quality or manufacturing deficiencies noted
- No clinical safety or efficacy issues identified and no requirement for further clinical studies or data analyses
- Conference call scheduled for 09.30 CEST

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 – 8 October 2018: 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 Complete Response Letter from the US Food and Drug Administration (FDA) regarding its New Drug Application (NDA) for BARHEMSYS™ (amisulpride injection).

The letter identified that deficiencies had been reported during a recent pre-approval FDA inspection of the contract manufacturer of amisulpride, the active pharmaceutical ingredient used in BARHEMSYS. No inadequacies were noted regarding the purity or stability of the active ingredient, or the manufacturing process or quality of the finished product.

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

"We are surprised to have received this Complete Response Letter, which relates solely to issues at the facility of our contract drug substance manufacturer. We intend to seek urgent clarification from FDA and the contract manufacturer as to the status and procedure for resolution of the deficiencies that have been identified. We believe that such resolution could occur quickly, and we continue to prepare for an anticipated launch in the first half of 2019. We are very encouraged that FDA has not identified any problems with the extensive clinical and non-clinical data package submitted on BARHEMSYS, nor with the quality of the finished product." said Dr Julian Gilbert, CEO of Acacia Pharma.

Conference Call Information
The Acacia Pharma management team will host a conference call Monday 8 October 2018, at 09.30 CEST. Please join the event conference 5-10 min prior to the start using the confirmation code and any of the phone numbers provided below.

Confirmation Code: 6865531

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