21 August 2017

Contains Confidential Trade Secret Information

Mitchell Mathis, M.D. Division Director
Division of Psychiatry Products
FDA/Center for Drug Evaluation and Research (CDER)
Central Document Room (CDR)
5901-B Ammendale Road
Beltsville, MD 20705-1266

RESPONSE TO PREA NON-COMPLIANCE LETTER
DEFERRAL EXTENSION REQUESTED

Re: NDA 205831 - Aptensio XR® (methylphenidate hydrochloride extended-release) capsules 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 50 mg, and 60 mg

eCTD Sequence 0053

Dear Dr. Mathis:

Reference is made to Rhodes Pharmaceuticals L.P. (Rhodes) NDA 205831 for Aptensio XR® (methylphenidate hydrochloride extended-release) capsules, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 50 mg, and 60 mg, which was approved on 17 April 2015.

Reference is also made to the Notification of Non-Compliance with PREA letter dated 12 July 2017. Rhodes hereby submits the response to this letter with an explanation for the delay in submitting the pediatric assessment for PMR 2899-2, which was deferred until 30 June 2017.

Rhodes also hereby request an extension of the deferral of the pediatric assessment for PMR 2899-2 until 30 January 2018.

PHONE: 401-262-9425 | FAX: 401-262-9450 | 498 Washington Street, Coventry, RI 02816

Aptensio Phase IV/PMR Study Status

Recruitment of preschool children into each of the Aptensio phase IV studies present a number of challenges. These are, in part, related to the subjects age (4 to 6 years old), the incidence of clinically diagnosed ADHD in preschoolers, and a requirement for a history of specific prior pharmacotherapy.

Study PMR 2899-2 (Rhodes Protocol No. RP-BP-PK003)

A total of (b) (4) subjects have participated in, and successfully completed, Protocol No. RP-BP-PK003. (b) (4) subjects were dosed on (b) (6) (b) (4) subjects were dosed on (b) (6) and (b) (4) was dosed on (b) (6). There have been no screen failures or early terminations.

To date, only one (1) adverse event has been reported in a single subject who participated in RP-BP-PK003. This adverse event (urinary infection) started prior to study treatment administration and, as such, was judged to be unrelated to study treatment. The adverse event resolved six (6) days after diagnosis without the need for any remedial intervention.

All subjects completed the study without any remarkable events. All but (b) (4) subsequently transitioned to the long-term efficacy and safety study Protocol No. RP-BP-EF004.

Table 1. Overall Subject Status for Protocol No. RP-BP-PK003

(b) (4)

Table 2. Demographics of subjects participating in RP-BP-PK003

Summary

The Aptensio phase IV (PMR) studies are currently ongoing. We acknowledge the vulnerable patient population and associated recruitment challenges that are inherently related to clinical studies in preschool children. However, we believe RP-BP-PK003 will complete this year, allowing submission of the study and data soon thereafter. Rhodes and our partner study sites remain committed to the completion of each of the PMR studies in an expeditious manner.

This electronic submission is in Electronic Common Technical Document Format (eCTD) sent through the FDA Gateway - sequence 0053. The approximate size of the electronic submission is displayed in the window of the FDA gateway. The electronic submission is virus free. The antivirus software used to check the files for viruses is Symantec Endpoint Protection – Version # 12.

Rhodes requests that all information in this file be treated as confidential within the meaning of 21 CFR 314.430 and that no information from the file be publicly released, through Freedom of Information or any other means, without prior written consent.

All communications concerning **this application** should be sent to Todd Delehant at: Rhodes Pharmaceuticals L.P., 498 Washington Street, Coventry, RI 02816. I may also be contacted by email (Todd.Delehant@pharma.com), phone (401-262-9425), or fax (401-262-9450).

Sincerely,
Rhodes Pharmaceuticals L.P.

Todd M. Delehant, Ph.D.
Director Regulatory Affairs