September 12, 2019

Dear Joslyn,

As we continue to receive questions about the recent suspension of the open label extension portion (Part C) of our Phase 2b/3 study in the UK and France, I wanted to reach out to share another brief update based on the information we have available at this time.

We understand that there may be a desire for some study participants in the UK and France to continue the study in another country and we are actively exploring this possibility with the appropriate regulatory authorities. In the meantime, we have received written confirmation from the regulators in the UK (MHRA) and France (ANSM) that patients currently enrolled in the study can continue to be seen at their study sites to monitor their current condition and assess disease status per the current schedule of visits outlined in the study protocol. Adrabetadex cannot be administered at these visits.

The study has not been suspended in Germany. We received a written notice from the German regulatory authority (BfarM) requesting additional information, and complied with that initial request. Mallinckrodt is working on additional responses for all EU competent authorities including BfarM, ANSM and MHRA with a formal deadline for responses by September 16, 2019. Although there is no required timeline for the health authorities to respond, we will continue appropriate dialogue and follow up until they do so.

We also wanted to inform you that, as is typically done after the conclusion of the double-blind portion of a study, we have provided information to all sites participating in Study VTS301 on the treatment that patients received (adrabetadex or sham) in Study Part A and Study Part B. Patients or family members who would like to find out this information should contact their study site or investigator.

Please feel free to share this information through your networks as appropriate. We will continue to keep you abreast of new information as it becomes available. As always, feel free to reach out to me with any questions in the meantime.

Sincerely,

Shelia Talafous
Director, Advocacy Relations