

RESPONSE TO CBER COMMUNICATION REGARDING CLINICAL TOPICS (IR 15)  
RECEIVED ON DECEMBER 10, 2020

The Sponsor acknowledges CBER's communication regarding Clinical topics (IR 15).

This document provides the Sponsor's responses to CBER's requests (in **Bold**).

**ITEM 1:**

**Please confirm whether Subject # P301-US350-2216 had received placebo for Dose 1 (23Oct2020) and submit all available information pertaining to adverse events occurring on 02Nov2020, including anaphylaxis and kidney stone.**

**Please confirm whether the subject received only Dose 1 or both Dose 1 & Dose 2.**

**Sponsor Response:**

The subject US3502216 a 39 year old male who received placebo, Dose 1 on 23 October and Dose 2 on 20 November. The participant reported the unsolicited AE anaphylaxis on 2 November (study day 11) assessed as severe and not related to study product by the investigator. On the same day, the participant reported an unsolicited AE of nephrolithiasis assessed as moderate and not related to study product by the investigator. On the same day both adverse events were considered resolved.