

RECORD OF TELEPHONE CONVERSATION

Submission Information

Application Type	BLA
STN	125428/0.0
Review Office	OVRR
Applicant	Dynavax Technologies Corporation / Lic. # 1883
Product	Hepatitis B Vaccine (Recombinant), Adjuvanted
Trans-BLA Group:	No

Telecon Details

Telecon Date/Time	18-OCT-2017 02:30 PM
Author	BERKHOUSEN, KATHERINE
EDR	No
Post to Web	No
Outside Phone Number	
FDA Originated?	Yes
Communication Categories	AD - Advice
Related STNs	None
Related PMCs	None
Telecon Summary	Dynavax contacted to clarify if an interim analysis was planned for Study 26.
FDA Participants	K. Berkhausen, M. Major
Applicant Participants	R. Janssen, E. Alambra

Telecon Body:

CBER requested a telecon with Dr. Rob Janssen and Elaine Alambra (Dynavax) to clarify if Dynavax was planning to perform any interim analyses for their Post Marketing Study HBV -26 to evaluate the incidence of new onset immune mediated diseases, herpes zoster and anaphylaxis.

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- 1) Dynavax was asked if they were going to receive data for Study 26 between study start and study closure at 25 months.

Dynavax responded that as the event rate for cases would be so low, that it would not warrant doing an interim analysis; but they would be open to considering it. CBER stated that to wait until the final analysis to look at the data is too long and that Dynavax would want to have some indication *prior* to final analysis. We do not know that there will not be any events. Dynavax agreed and stated that they would be agreeable to doing an interim analysis.

- 2) CBER asked the feasibility of interim reports and at what frequency.

Dynavax stated that they would need to discuss this with Kaiser Permanente Southern California (KPSC). Kaiser Permanente would be doing all of the analysis and could possibly look at the 2 groups (KPSC and KPNC-Kaiser Permanente Northern California). Dynavax was not sure about pooling the data between the two groups and what it involves and how the number of events (or lack of) plays into it. So this would need to be discussed with Kaiser. KPSC is performing the Post Marketing Study HBV-25 (acute MI), which has interim analysis timelines already established. It is possible that for Study -26, the same or similar timelines for interim analysis could be established by KPSC. It is possible that only data from KPSC be analyzed for the interim analysis (not include KPNC). KPSC plans to enroll 50,000 subjects for HBV-26 while KPNC will only enroll 10,000 subjects. The majority of subjects in HBV-26 are coming from KPSC. The final analysis of course will be combined data from both KPSC and KPNC.

Dynavax agreed to add interim analysis for Post Marketing Study HBV-26. Details in this regard would need to first be discussed with Kaiser Permanente and later with the FDA. It was agreed that this discussion and review of the protocol would take place under the IND.