

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	28-NOV-2012 07:17 PM
Author	BERKHOUSEN, KATHERINE
EDR	
Post to Web	Yes
Outside Phone Number	
FDA Originated?	No
Communication Categories	OT -
Related STNs	None
Related PMCs	None
Telecon Summary	Discussion questions for the December face to face meeting
FDA Participants	K. Berkhausen; R. Daemer; M. Major
Applicant Participants	W. Turner; E. Alambra

Telecon Body: Dynavax has corresponded with us via email to outline the discussion topics and questions for the meeting with OVRR in December.

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From: Turner, William [<mailto:wturner@dynavax.com>]

Sent: Wednesday, November 28, 2012 7:12 PM

To: Daemer, Richard J.; Berkhausen, Katherine

Cc: Major, Marian; Alambra, Elaine; Martin, Tyler

Subject: Dynavax - Discussion Questions

Importance: High

Dear Dick and Katherine,

In follow-up to our discussion on 27 November 2012, please find questions/topics that we would like to discuss with the FDA review team in light of the recent recommendations from VRBPAC.

1. As presented to VRBPAC, both FDA and Dynavax have concluded that HEPLISAV met pre-specified non-inferiority criteria for immunogenicity, as compared to ENGERIX B. At this time, does the FDA review team have any concerns regarding the immunogenicity of HEPLISAV?
2. As presented to VRBPAC, both FDA and Dynavax concluded that there were no clinically significant safety differences between recipients of HEPLISAV and ENGERIX-B. At this time, does the FDA review team have any concerns regarding the safety of HEPLISAV?
3. As discussed at the VRBPAC meeting, Dynavax proposes to do a post approval concomitant use study. Does the FDA agree?
4. As presented at the VRBPAC meeting, the immunogenicity data of HEPLISAV across all racial ethnicities is consistent. Dynavax believes that a post approval study conducted through Kaiser Permanente Northern California and Kaiser Permanente Southern California provides the best opportunity to gather additional information on ethnic and socioeconomic diversity. Does the FDA agree?
5. As with other hepatitis B vaccines the indication proposed by Dynavax is based on the age range studied throughout the clinical development program. The specific recommendations for the use of Hepatitis B vaccines in various at risk populations has historically been provided by ACIP. Does the FDA agree?
6. Dynavax proposes that a post approval pharmacovigilance study be conducted at Kaiser Permanente Northern California and Kaiser Permanente Southern California. Kaiser estimates they could enroll 30,000 HEPLISAV recipients without chronic kidney disease, between the age of 18 and 70, in 18 months. Dynavax proposes 2 methods of signal detection. First, a risk interval analysis within the HEPLISAV control and cross cohort analysis with 3 matched vaccinated controls for each HEPLISAV recipient – A postmarketing evaluation of the safety of Ann Arbor strain of live attenuated influenza vaccine in adults 18-49 years of age is attached for reference. Secondly, an expert review of pre-defined autoimmune events of special interest (AESI) would be conducted to further refine the safety assessment – Surveillance of autoimmune conditions following routine use of quadrivalent human papillomavirus vaccine is attached for reference. Dynavax proposes the analysis takes place when 5,000, 15,000 and 30,000 HEPLISAV recipients are available. Does the FDA agree with this proposal?

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Tyler Martin and I have agreed we would prefer that this be a face to face discussion – only he and I will be participating from Dynavax. We understand that it could be difficult to schedule everyone at FDA for a face to face meeting but we do believe it will be beneficial to the overall collaboration if many of us are in the same room. We can be available any day the week of December 10th with December 11th or 12th being the best days for us. Additionally, if Drs. Gruber and/or Midtun are available we think their input could be helpful.

Dynavax plans to submit the response to the 21 November 2012 Information Request via email to you tomorrow (29Nov2012). If there is any additional information we can provide to support this discussion, please let me know. Thank you for working so quickly with us on this and we look forward to speaking with you soon.

Best regards,
Bill

*William Turner
Vice President
Regulatory Affairs and
Corporate Quality Assurance*

*Dynavax Technologies
2929 Seventh St.
Suite 100
Berkeley, CA 94710*

*510-665-7296
510-717-0833 mobile*

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