DEFERRAL EXTENSION REQUEST for PREA PMR 3

GSK requests a Deferral Extension for the Post-Marketing Requirement #3, for the deferred pediatric study (V72_57) under PREA to evaluate the safety and immunogenicity of BEXSERO in North American infants 6 weeks through 12 months of age for the prevention of invasive group B meningococcal disease.

The original Schedule for Conduct and Reporting of V72_57 Study was:

Final Protocol Submission: December 31, 2014 (Actual Date: December 19, 2014)
Study Completion: June 30, 2017
Final Report Submission: March 31, 2018

GSK is requesting an extension of deferral due to the time needed to align on details of the protocol with CBER. We have been actively working with CBER to ensure that our pediatric development plans and this specific protocol will support fulfillment of the PREA commitment as well as meet expectations for licensure. This alignment has included submissions of the initial protocol as well as responses to IRs, Type C meetings, and includes a Breakthrough Therapy Designation for an interim age group (2 to 10 year olds). GSK has just received another request for information and discussion related to the protocol V57_72 from CBER on 19 April 2018.

For the record of interactions we refer to List A (the submissions from GSK to CBER in pursuit of an endorsed protocol V72_57) and List B (the record of CBER correspondence regarding these submissions).

As seen in these lists GSK initially submitted the protocol in 2014 and has accommodated CBER input and submitted revised protocols in 2015, 2016 and most recently in Q1 2018. We have positive feedback from CBER on this last version and will be meeting in May 2018 to address CBER's recent questions.

Given that we have nearly complete alignment with CBER for the protocol, our proposed Schedule for Conduct and Reporting are:

Final Protocol Submission: February 21, 2018 (assuming agreement with CBER regarding recent questions on strain testing)

Study Completion: November 15, 2023
Final Report Submission: June 30, 2024

Sincerely, /s/

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