



17 September 2014

Clement Lewin, MBA, PhD  
Head, Strategic Immunization Planning  
Novartis Vaccines and Diagnostics  
475 Green Oaks Parkway  
Holly Springs, NC 27540

Dear Dr. Lewin:

As you are probably aware, the New York City Department of Health and Mental Hygiene (DOHMH) is investigating a new cluster of invasive meningococcal disease among HIV-positive men who have sex with men (MSM) in New York.<sup>1</sup> A previous outbreak of meningococcal disease among MSM, involving 22 cases and seven fatalities, ended in February 2013.

DOHMH continues to recommend meningococcal conjugate vaccination—doses of either Menveo or Menactra—for all MSM living with HIV and men, regardless of HIV status, who regularly have intimate contact with other men met through websites, digital “apps,” or at bars or parties. DOHMH estimates that approximately 20 to 25 percent of individuals recommended to receive meningococcal vaccination have received at least one dose since the beginning of the outbreak in 2010.

Significant gaps in our knowledge base on the effectiveness of meningococcal vaccination with respect to preventing disease in people living with HIV make it more difficult to mount a strategic public health response to the outbreaks, both in New York City and other settings.

DOHMH’s recommendations, particularly for HIV-positive adult and adolescent MSM, are based on the assumption that two doses of the vaccine are sufficiently immunogenic. However, data are only available from studies involving limited samples of HIV-positive children, adolescents, and young adults, which noted

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<sup>1</sup> New York City Department of Health and Mental Hygiene (Press Release). Health department investigating new meningitis cases among HIV-positive men who have sex with men. 2014 September 5. <http://www.nyc.gov/html/doh/html/pr2014/pr030-14.shtml>.

correlates of protection in 70 to 80 percent of volunteers.<sup>2,3,4</sup>

Data are unavailable to confirm whether these findings are applicable to a larger population of adults living with HIV. Nor are data available for evaluations of long-term effectiveness and immunogenicity across absolute CD4 cell count, CD4 percentage, and viral load strata. Not only do these data limitations prevent effective epidemiological forecasting by DOHMH and other public health agencies, they stymie the development of evidence-based guidelines, such as those produced by the Advisory Committee on Immunization Practices, supporting routine meningococcal vaccination for all HIV-positive MSM.

It is also crucial to note that two of the recent outbreak cases in New York City had previously received meningococcal vaccination, which underscores the importance of answering these questions.

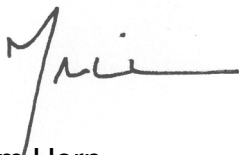
TAG would appreciate the opportunity to speak with you and other key staff at Novartis to discuss its support of the clinical research required to more fully understand the efficacy of Menveo in adolescents and adults living with HIV. We will follow up with you before the end of the week to determine your availability for a teleconference between now and the end of the month.

Thank you for your consideration and we look forward to hearing from you soon.

Sincerely,



Mark Harrington  
Executive Director



Tim Horn  
HIV Project Director

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<sup>2</sup> Lujan-Zilbermann J, Warshaw MG, Williams PL, et al. Immunogenicity and safety of one versus two doses of quadrivalent meningococcal conjugate vaccine in youth infected with HIV. *J Pediatr*. 2012 Oct;16(14):6720681. doi: 10.1016/j.jpeds.2012.04.005.

<sup>3</sup> Bertolini DV, Costa LS, van der Heijden IM, Sato HK, Marques HH. Immunogenicity of a meningococcal serogroup C conjugate vaccine in HIV-infected children, adolescents, and young adults. *Vaccine* 2012 Aug 10;30(37):5482-6. doi: 10.1016/j.vaccine.2012.06.069.

<sup>4</sup> Siberry GK, Warshaw MG, Williams PL, et al. Safety and immunogenicity of quadrivalent meningococcal conjugate vaccine in 2- to 10-year-old human immunodeficiency virus-infected children. *Pediatr Infect Dis J*. 2012 Jan;3(1):47-52. doi: 10.1097/INF.0b013e318236c67b.