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Letter to the Editor in Response to “Analysis of adverse events of potential autoimmune aetiology in a large integrated safety database of AS04 adjuvanted vaccines” by Verstraeten et al

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Dear Editor,

Verstraeten et al. recently published online results from a pooled analysis that evaluated the effect of receiving a vaccine containing the AS04 adjuvant system on rates of autoimmune conditions. The study combined data from several ongoing trials, including the autonomous, NCI-sponsored clinical trial that we are conducting in Guanacaste, Costa Rica. We would like to make two points of clarification about this publication and our trial in Costa Rica.

The report by Verstraeten et al. incorrectly states that all of the studies included in their analysis were funded by GSK Biologicals. In fact, the Costa Rica HPV Vaccine Trial (CVT) is fully supported by the NCI, with the exception that GSK Biologicals provided the HPV-16/18 vaccine (Cervarix) needed for the study and paid for costs associated with their regulatory submission and commercial licensure needs, as it was deemed that such expenses should not be financed with public funds. Further, the NCI-sponsored trial in Costa Rica is being conducted autonomously from other trials of the HPV-16/18 vaccine financed by GSK Biologicals; as such NCI and Costa Rica investigators retain the right to independently analyze and publish data from the trial. The Costa Rica HPV Vaccine Trial is the only publicly funded trial of an HPV vaccine.

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Second, we would like to clarify that we were not involved in or aware of the analysis summarized in the report by Verstraeten et al. until after it was completed. We provided GSK Biologicals with safety data from our trial while the study is ongoing to allow the company to comply with regulatory reporting requirements of the Food and Drug Administration (FDA) and other regulatory bodies (under FDA IND #BB-IND-7920), but we were not aware that results from a pooled analysis of safety data were being submitted for publication in the peer reviewed literature. Since the analysis and results from the evaluation by GSK investigators were not reviewed by NCI and Costa Rican investigators, the use of data from our trial in Costa Rica should not be construed as an indication that the NCI or the Proyecto Epidemiologico Guanacaste endorse the analysis or its conclusions.

This letter has been shared with our colleagues at GSK Biologicals.