13. Prospective Cohort Study of Influenza and Dengue Infection in Children and Adults, Cebu City, Philippines

To prospectively monitor a cohort of subjects (>6 months old) in Cebu City, Philippines, in order to determine age-specific incidence and clinical spectrum of influenza infection, relationship of pre-existing influenza A antibodies to incidence and disease severity of influenza A infection, transmission dynamics among household contacts, and degree and duration of respiratory viral shedding during the course of influenza A transmission.

A total of 1,000 age-stratified subjects will be enrolled and will undergo active fever surveillance. Blood samples will be collected at enrollment and at 12-month intervals for influenza antibody testing. Collection of respiratory sample, acute and convalescent blood sample will be done to measure the antibody response to influenza virus. Household contacts of cohort subjects with acute febrile illness will be asked to participate in a household contact investigation. They will also undergo clinical evaluation and baseline respiratory and blood samples, and follow-up blood samples. Serum aliquots will be frozen until ready for serological or molecular tests at AFRIMS, Bangkok, Thailand.

Protocol has been granted approval by local IRB. Study will be initiated on February 2012.

Future Plans: Study duration will be from 2 to 5 years. Initial cohort subjects will be followed by study staff for 2 to 5 years after enrollment.

14. Title of Research Project: Immunological Correlates of Clinical Outcomes in a Tetravalent Dengue Vaccine Cohort - An Ancillary Study (Cebu City, Philippines)

The overall purpose of this ancillary study is to identify immunologic correlates of clinical outcomes in participants in the parent CYD vaccine efficacy trial.

The study population will be composed of male and female Filipino children between the ages of 2 and 14 years living in Guadalupe, Cebu City, Cebu, Philippines. Up to 934 subjects will be enrolled in the parent trial. Therefore, up to 934 subjects will be screened and enrolled for the ancillary study. Visits related to this immunology ancillary study correspond to visits specified by the parent vaccine trial; two additional visits will be required for this ancillary study beyond what is required for all CYD14 subjects at 28 days after the first and second vaccine doses. The number of additional visits for this ancillary study is the same as the number of additional visits for the Sanofi sub-study.

In this reporting period, a total of 117 subjects have been enrolled into the study.

Future Plans: The current protocol will be amended and will be re-submitted to IRBs for review and approval.

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