Response to Ruiz-Alejo et al

TO THE EDITOR—We are pleased to respond to the comments by Ruiz-Alejo et al [1], regarding the need to conduct future studies of the live attenuated tetravalent dengue vaccine in areas endemic for dengue. We could not agree more that candidate dengue vaccines will need to be studied in the populations identified as targeted for eventual vaccination. Our study was a phase I clinical trial and was thus focused primarily on safety. Because preexisting immunity to ≥1 flavivirus can affect the antibody response to vaccination with live attenuated dengue vaccine candidates [2–4], we thought it would be most appropriate to conduct the first evaluation of this promising candidate vaccine in flavivirus-naive adults.

We have 2 phase 2 trials planned for dengue-endemic areas (Brazil and Thailand), and these trials will enroll flavivirus-experienced individuals. Enrollment in dengue-endemic areas will proceed in an age deescalated manner to ensure that the safety profile of the vaccine is acceptable in adults and older children before enrolling younger children.

The overall aim of these trials is to better assess the safety and immunogenicity of the candidate vaccine. Because of the surprising lack of protection against dengue virus 2 infection despite the presence of dengue virus 2 neutralizing antibody reported by Sabchareon et al [5], we have designed the trials to include immunologic assessments in all enrolled subjects, with the goal of elucidating the immune response induced by the live attenuated tetravalent vaccine. Should these phase 2 trials further establish the safety and immunogenicity profile of the vaccine, our eventual goal is to determine its efficacy in a dengue-endemic area.

Note

Potential conflicts of interest. All authors: No reported conflicts. All authors have submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest. Conflicts that the editors consider relevant to the content of the manuscript have been disclosed.

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