ADVA statement regarding the CYD-TDV Dengvaxia dengue vaccine

ADVA refers to the official statement on the dengue vaccine, Dengvaxia, by the manufacturer. After studying the statement and facts put forth, ADVA is of the opinion that:

1. The results are preliminary and were made by retrospective analysis of blood samples taken a month after the third dose of the vaccine in the original CYD 14 (in Asia) and CYD 15 (in Latin America) studies.

2. The test performed is new and had been validated using PRNT as the reference. It indicates past-infection with wild dengue virus only, and excludes vaccine-induced immunity.

3. The results showed that seropositive (previously infected) individuals benefited from the vaccine. As many parts of Asia and areas in our own countries have high seropositive rates, the vaccine will have potential benefits across populations in Asia.

4. Seronegative subjects (no previous dengue infection) tend to have higher hospitalization rates – Specifically, an additional 5 hospitalisations per 1000 vaccines in five years.

5. Seronegative subjects were also observed to have more DHF Grades I and II, speficically two extra cases per 1000 vaccinees in five years. There was no shock, bleeding nor mortality in this group.

6. Serological pretesting is required, although not practical, but we need to have an appropriate, cheap, readily- and universally- available test. The gold-standard PRNT test is costly and not readily available while the test used by the manufacturer is currently only used on a research basis.
To avoid confusion, a practical approach using the most reliable laboratory testing has to be discussed and implemented.

Summary
This outcome should not cause undue panic among individuals who have already received the dengue vaccine. The severe dengue that occurred in initially seronegative vaccinees were in DHF Grades I and II and did not lead to shock, any bleeding or mortality.
The report also reinforces the fact that seropositive individuals would benefit from receiving the vaccine.

The above statement is prepared by the ADVA Steering Committee in their own professional capacity and does not reflect the views of their institutions or organisation.