

## Supplementary Materials for

### **The live attenuated dengue vaccine TV003 elicits complete protection against dengue in a human challenge model**

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#### **This PDF file includes:**

Fig. S1. Components of the LATV dengue vaccines TV003 and CYD (Dengvaxia).

Table S1. Incidence of specific AEs in TV003 recipients compared to controls.

Table S2. Interval between TV003 and challenge.

#### **Other Supplementary Material for this manuscript includes the following:**

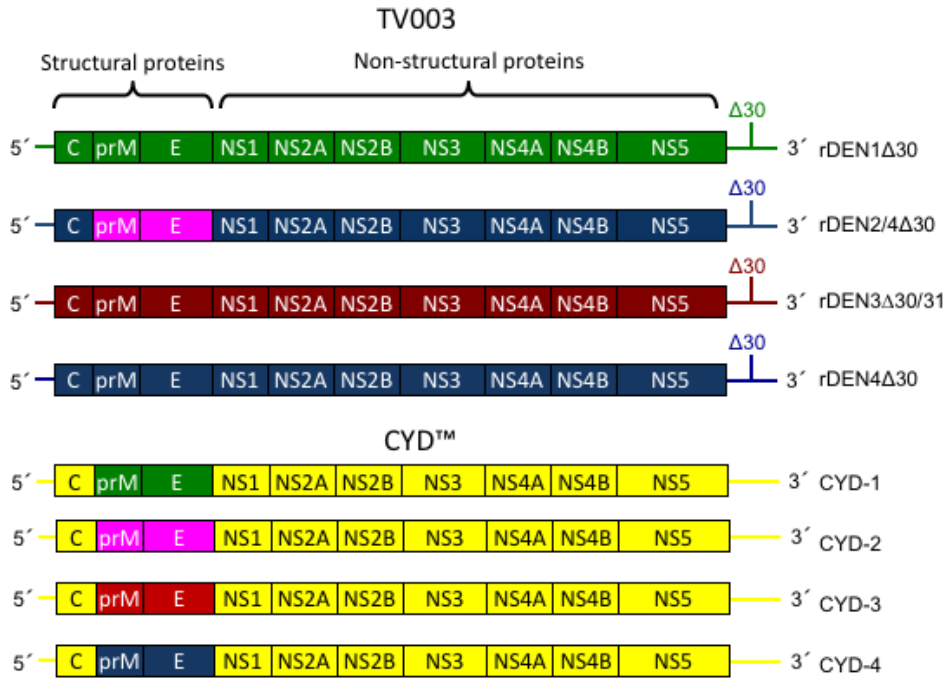
(available at [www.sciencetranslationalmedicine.org/cgi/content/full/8/330/330ra36/DC1](http://www.sciencetranslationalmedicine.org/cgi/content/full/8/330/330ra36/DC1))

Other supplemental material S1 (Microsoft Word format). Clinical protocol for the study “A Phase 1 Evaluation of the Protective Efficacy of a Single Dose of the Live Attenuated Tetravalent Dengue Vaccine TV003 to Protect Against Infection with Attenuated DENV-2, rDEN2Δ30-7169.”

Other supplemental material S1 (Microsoft Word format). Consent form for the study “A Phase 1 Evaluation of the Protective Efficacy of a Single Dose of the Live Attenuated Tetravalent Dengue Vaccine TV003 to Protect Against Infection with Attenuated DENV-2, rDEN2Δ30-7169.”

Other supplemental material S2. Excel file of screening and enrollment data.

Supplemental Figure 1



**Fig. S1. Components of the LATV dengue vaccines TV003 and CYD (Dengvaxia).**

**Table S1: Incidence of specific AEs in TV003 recipients compared to controls.**

| Adverse event          | Treatment group    |                   |
|------------------------|--------------------|-------------------|
|                        | TV003<br>(n=24)    | Placebo<br>(n=24) |
| <b>Injection site:</b> |                    |                   |
| Erythema               | 4.2%               | 0.0%              |
| Pain                   | 8.3%               | 8.3%              |
| Tenderness             | 4.2%               | 4.2%              |
| Induration             | 0.0%               | 0.0%              |
| Pruritis               | 0.0%               | 0.0%              |
| <b>Systemic:</b>       |                    |                   |
| Fever                  | 0.0%               | 0.0%              |
| Headache               | 50.0%              | 20.8%             |
| Rash                   | 79.2% <sup>1</sup> | 0.0%              |
| Neutropenia            | 4.2%               | 0.0%              |
| Elevated ALT           | 4.2%               | 4.2%              |
| Myalgia                | 4.2%               | 8.3%              |
| Arthralgia             | 4.2%               | 0.0%              |
| Retro-orbital Pain     | 16.7%              | 0.0%              |
| Fatigue                | 16.7%              | 16.7%             |
| Nausea                 | 16.7%              | 16.7%             |
| Photophobia            | 12.5%              | 0.0%              |
| Elevated PT            | 0.0%               | 16.7%             |
| Elevated PTT           | 0.0%               | 8.3%              |
| Thrombocytopenia       | 0.0%               | 0.0%              |

1.  $p < 0.0001$ , two-sided

**Table S2: Interval between TV003 and challenge.**

| Date of vaccination (n) | Date of challenge (n) | Site |
|-------------------------|-----------------------|------|
| 11/11/13 (14)           | 5/5/14 (12)           | JHU  |
| 11/11/13 (1)            | 6/9/14 (1)            | JHU  |
| 12/2/13 (8)             | 6/9/14 (8)            | JHU  |
| 12/2/13 (1)             | 8/11/14 (1)           | JHU  |
| 1/28/14 (15)            | 7/29/14 (13)          | UVM  |
| 1/28/14 (1)             | 9/9/14 (1)            | UVM  |
| 2/25/14 (8)             | 9/9/14 (5)            | UVM  |