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Persistence of immunogenicity of a purified inactivated Zika virus vaccine candidate in healthy adults: two years follow-up compared with natural infection

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Background: An effective Zika vaccine remains a global unmet medical need in currently endemic areas and travelers. Takeda has developed a purified, formalin-inactivated, whole Zika virus (ZIKV) vaccine candidate (TAK-426).

Methods: A randomized, observer-blind, placebo-controlled, dose-selection, phase 1 trial was performed in 18 to 49 year-old adults at nine centers (seven in the United States, two in Puerto Rico) from November 2017 to November, 2020. Primary objectives were safety, tolerability, and immunogenicity of three increasing dosages (2 µg, 5 µg and 10 µg) of TAK-426 administered as two doses 28 days apart to flavivirus-naïve (FV-naïve) and flavivirus-primed (FV-primed) adults. Here we report safety and persistence of immunity of the highest dose group (10 µg) up to two years after primary vaccination and compare neutralizing antibody responses with those observed after natural infection (two additional cohorts with confirmed ZIKV infection).

Results: The highest dose (10 µg) of TAK-426 had an acceptable safety profile in both FV-naïve and FV-primed adults up to 24 months post dose 2. Seropositivity for neutralizing antibodies was 100% at one year, and 93.8% and 76.2% at two years in FV-naïve and FV-primed groups, respectively. TAK-426 neutralizing antibody responses were comparable to those elicited by natural Zika virus infection.

Conclusion: These results support the further clinical development of TAK-426 in both FV-naïve and FV-primed populations.