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Co-administration of a tetravalent dengue vaccine (TAK-003) with hepatitis A vaccine

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Background: Vaccination against hepatitis A virus (HAV) is recommended for many travellers worldwide, including travel to dengue-endemic regions. This phase 3 randomized controlled study evaluated co-administration of HAV vaccine with 2-dose tetravalent dengue vaccine (TAK-003) in adults aged 18–60 years (NCT03525119).

Methods: 900 participants were randomized 1:1:1 to receive HAV+placebo (Group 1), TAK-003+placebo (Group 2), TAK-003+HAV (Group 3). The primary objective was non-inferiority (upper bound of 95% confidence interval of difference <10%) of the immune response to HAV in terms of seroprotection (anti-HAV >12.5 mIU/mL) in Group 3 versus Group 1 one month post-first vaccination in HAV- and dengue-naïve participants. Sensitivity analyses were performed on combinations of baseline HAV and dengue serostatus. Secondary objectives included evaluation of the immune response to HAV and TAK-003, and safety.

Results: One month after first vaccination, the immune response to HAV was non-inferior following co-administration with TAK-003 (Group 3: seroprotection 98.7%) than HAV alone (Group 1: 97.1%; difference: -1.68%, 95% confidence interval: -8.91 to 4.28). Sensitivity analyses supported this finding. HAV geometric mean concentrations one month after first vaccination were 82.1 (95% CI: 62.9 to 107.1) mIU/mL in Group 1 and 93.0 (76.1 to 113.6) mIU/mL in Group 3. By Day 120, 90.9–96.8% of TAK-003 recipients were seropositive to all four dengue serotypes. Both vaccines were well tolerated, and no important safety risks were identified.

Conclusion: No impacts on immunogenicity or safety of either vaccine were noted in this study, supporting the potential for co-administration of HAV and TAK-003.

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