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ASIA EDITION

Indonesia approves Takeda's dengue vaccine

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Indonesia approval marks the first for QDENGA, Takeda's first marketed vaccine outside of Japan



Japanese firm Takeda has announced that the company's dengue vaccine, QDENGA (Dengue Tetravalent Vaccine [Live, Attenuated]) (TAK-003), has been approved by the Indonesia National Agency for Drug and Food Control, Badan Pengawas Obat dan Makanan (BPOM), for the prevention of dengue disease caused by any serotype in individuals six years to 45 years of age.

The use of QDENGA should be in accordance with official recommendations. QDENGA is the only dengue vaccine approved in Indonesia for use in individuals regardless of previous dengue exposure and without the need for pre-vaccination testing.

In recent years, Indonesia has experienced almost half of the dengue disease burden within Southeast Asia and continues to suffer from one of the highest burdens of dengue in the world. In the first half of 2022 alone, Indonesia reported over 63,000 dengue cases and nearly 600 deaths spread across 455 cities in 34 provinces.

The approval of QDENGA is based on results through three years after vaccination from the ongoing Phase 3 Tetravalent Immunization against Dengue Efficacy Study (TIDES) trial that enrolled over 20,000 healthy children and adolescents ages four to 16 years living in dengue-endemic areas in Asia and Latin America.

QDENGA is currently undergoing regulatory review for the prevention of dengue in children and adults in the European Union (EU) and in dengue-endemic countries outside the EU through the EU-M4all (previously Article 58) procedure. It is not approved for use in other countries.