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ASIA EDITION

Takeda’s dengue tetravalent vaccine QDENGA receives approval in European Union

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Approved for use in individuals four years of age and older

Japanese pharmaceutical firm Takeda has announced that the European Commission (EC) has granted marketing authorisation for the company’s dengue vaccine QDENGA (Dengue Tetravalent Vaccine [Live, Attenuated]) (TAK-003) for the prevention of dengue disease in individuals from four years of age in the European Union (EU).

QDENGA should be used in accordance with official recommendations. The approval follows the positive recommendation from the European Medicines Agency’s Committee for Medicinal Products for Human Use (CHMP) in October 2022.

The worldwide incidence of dengue has risen eight-fold in the past 20 years, and it continues to rise, fueled by climate change and urbanisation. Today, dengue threatens about half the world’s population with a risk of infection in over 125 countries, and the disease is endemic in most of the European overseas countries, territories and departments located in tropical areas.

Approval from the EC was supported by results across 19 Phase 1, 2 and 3 trials with more than 28,000 children and adults, including four and a half years of follow-up data from the global, pivotal Phase 3 Tetravalent Immunisation against Dengue Efficacy Study (TIDES) trial.

QDENGA is also approved in Indonesia for the prevention of dengue disease by any serotype in individuals six years to 45 years of age. Takeda continues to progress regulatory filings in other dengue-endemic countries in Asia and Latin America.