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â??Initial supply of dengue vaccine for India will be manufactured at Takedaâ??s facility in Germanyâ?•

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Takedaâ??s dengue vaccine, TAK-003, has been approved in India. With more than 32 million doses distributed globally, this approval marks an important step forward in strengthening dengue prevention in the Asia Pacific region. India is the 43rd country to join Malaysia, Indonesia, Thailand, and Vietnam in approving this WHO-recommended and prequalified vaccine, which, to date, has been distributed worldwide through public and private programmes across Asia, Latin America and Europe, including Brazilâ??s National Immunisation Programme and public programmes in Argentina, Colombia and Indonesia. BioSpectrum Asia took this opportunity to have a detailed conversation with Peter Streibl, Cluster General Manager, Southeast Asia and India, Takeda, about the accessibility and availability of the dengue vaccine in the country.

How is Takeda’s partnership with Biological E. Limited playing a role in strengthening dengue vaccine access in India? When are we expecting the vaccine doses to be shipped?

Our partnership with Biological E. is an important part of Takeda's long-term strategy to expand global manufacturing capacity for TAK-003 and support broader access in dengue-endemic countries in the future. We are progressing well and remain on track toward our goal of reaching a global manufacturing capacity of 100 million doses per year by 2030. As previously announced, the collaboration is expected to support production of up to 50 million doses annually through multi-dose vials for procurement in dengue endemic countries by governments to support National Immunisation Programmes.

Following marketing authorisation, there are several important steps before TAK-003 becomes available in India, including obtaining the necessary Registration Certificate and Import License from the local authorities. This is followed by manufacturing and supply of the vaccine from Takeda's facility in Singen, Germany, where the vaccines will undergo required processes, before they can be released for commercial distribution. Based on current timelines and subject to local processes, we expect TAK-003 to become available in India during the first half of 2027.

How much has been invested in the R&D of TAK-003? What is the cost of a single dose?

TAK-003 is currently the most extensively studied dengue vaccine, evaluated through a comprehensive clinical development programme involving 19 clinical trials and more than 28,000 participants across 13 countries, with long-term follow-up through 7 years.

We are pleased that TAK-003 has been approved in India for individuals aged 4 to 60 years, and are committed to supporting broad, equitable, timely and sustainable access at a cost that reflects the vaccine's value and potential health, societal and economic benefits.

Following India's marketing authorisation, our immediate priority is to complete the necessary local processes with the authorities. It would be premature to speculate on pricing before those are complete.

What steps are being taken to manage the cold chain logistics for the vaccine shipments? How many doses are being manufactured in India?

Our robust supply chain utilises a global network of internal and external manufacturing sites, with critical global manufacturing sites in the US, continental Europe and Japan.

Initial supply of dengue vaccine for India will be manufactured in Germany at Takeda's facility in Singen and through our partner IDT Biologika GmbH in Dessau-Rosslau.

Our partnership with Biological E. remains an important part of Takeda's long-term strategy to expand global manufacturing capacity for TAK-003 and support broader access in dengue-endemic countries. We are progressing well and remain on track toward our goal of reaching a global manufacturing capacity of 100 million doses per year by 2030. As previously announced, Biological E. is expected to support production of up to 50 million doses annually through multi-dose vials for procurement in dengue endemic countries by governments.

Are you partnering with multiple hospitals in India, to ensure better accessibility?

At this stage, following market authorisation, private market is likely to play an important role in enabling early access for eligible individuals while broader public pathways are established.

We welcome the recent Indian Parliamentary Committee recommendation to consider the inclusion of TAK-003 in the Universal Immunisation Programme (UIP), which reflects the growing recognition of dengue as a significant public health challenge.

Takeda's goal is to provide broad access to as many eligible people as possible through inclusion in National Immunisation Programmes. We do acknowledge that this will take time, and broader access, including through public health channels, depends on independent decisions by health authorities based on their scientific and policy assessments. This is why Takeda is working in parallel in the private, endemic, travel and public markets to ensure timely access.

In some parts of Southeast Asia, the number of dengue cases recorded has been consistently lower than those recorded in previous years. With a slowing trend of dengue, what value does dengue vaccine bring to these regions?

Dengue transmission is influenced by multiple factors, including mosquito populations, urbanisation, climate variability, population movement, and the circulation of different dengue serotypes. Because of this complexity, transmission intensity can fluctuate, especially during the El Niño event that is anticipated to last from June 2026 to early 2027, as warmer, unstable weather patterns can trigger dengue outbreaks.

As advised by WHO, effective dengue control requires an integrated approach combining mosquito control, surveillance, public awareness, vaccination, early diagnosis and appropriate clinical management. While vaccination is only one piece of the puzzle, it provides proactive, sustained protection rather than a reactive response to surges.

By reducing severe disease and hospitalisations, vaccination protects vulnerable populations and prevents healthcare facilities from being overwhelmed when the serotype shifts or climate variations trigger future outbreak cycles. These are the

outcomes that matter most because they have the greatest impact on patients, families and healthcare systems.

One of the biggest hurdles in mass immunisation programmes is operational complexity. What makes the clinical profile of TAK-003, particularly the absence of pre-vaccination testing, so valuable for endemic countries in Asia?

Based on the recent data, TAK-003 is the most extensively studied dengue vaccine to date, with long-term follow-up through 7 years. The trial data demonstrates that a two-dose schedule, administered three months apart with no booster, is sufficient in protecting against dengue. Importantly, TAK-003 is the only approved dengue vaccine for use regardless of prior disease exposure, providing an important option to help reduce the growing burden of the disease.

A broad age indication from 4 years of age (up to 60 years of age in some countries), plus the absence of need for prior dengue exposure nor pre-vaccination testing are key to driving broad usage, accessibility, and protection at scale for endemic regions. It enables governments to bypass the complex logistical and financial hurdles of diagnostic screening. Implementation then becomes far simpler for healthcare providers, enabling local governments and public health authorities to roll out vaccination campaigns with much greater efficiency. This will help ensure that protection can be delivered directly and rapidly to communities most in need across urban and rural areas.

Hospital congestion is a persistent challenge during dengue outbreaks, reported in several countries including Sri Lanka, the Philippines, and Vietnam. Can you tell us more about the clinical data and emerging real-world evidence that suggests how Takeda's dengue vaccine may ease healthcare infrastructure strain?

In the pivotal Phase III TIDES study, TAK-003 demonstrated 80.2% vaccine efficacy against virologically confirmed dengue at 12 months after the second dose, 90.4% efficacy against dengue-related hospitalization at 18 months, and 84.1% efficacy against dengue-related hospitalisation over 4.5 years of follow-up, with the completed seven-year follow-up further demonstrating sustained protection across all four dengue virus serotypes.

These clinical findings are further supported by real-world evidence from the 2024 dengue outbreak in Brazil, where a complete two-dose regimen provided approximately 61.7% efficacy in preventing dengue infection and a single dose showed 67.5% efficacy in preventing dengue-related hospitalisation.

This is particularly important where dengue outbreaks can place significant pressure on hospital beds, emergency services and healthcare resources, while creating a substantial health and economic burden for patients. Reducing hospitalisations can therefore help lessen the impact of dengue on patients and the broader healthcare system.