



# QDENGA: TRANSFORMING DENGUE PREVENTION

Ramona Sequeira  
President, Global Portfolio Division

Derek Wallace  
Vice President, Head of Dengue Global Program

*Guest Speaker:*  
Eng Eong Ooi  
Professor, Programme in Emerging Infectious Diseases,  
Duke-NUS Medical School

March 15, 2023 EST / March 16, 2023 JST

**Better Health, Brighter Future**



This material is prepared and distributed solely for the purpose of providing information about Takeda's management or business to shareholders, investors, and analysts, and is not intended to induce purchase or prescription of any specific drugs and other products. This material is not intended for healthcare professionals, patients, or other persons other than those mentioned above. This material is prohibited from being used by persons other than those mentioned above and for the purpose other than one mentioned above.

# IMPORTANT NOTICE



For the purposes of this notice, “presentation” means this document, any oral presentation, any question and answer session and any written or oral material discussed or distributed by Takeda Pharmaceutical Company Limited (“**Takeda**”) regarding this presentation. This presentation (including any oral briefing and any question-and-answer in connection with it) is not intended to, and does not constitute, represent or form part of any offer, invitation or solicitation of any offer to purchase, otherwise acquire, subscribe for, exchange, sell or otherwise dispose of, any securities or the solicitation of any vote or approval in any jurisdiction. No shares or other securities are being offered to the public by means of this presentation. No offering of securities shall be made in the United States except pursuant to registration under the U.S. Securities Act of 1933, as amended, or an exemption therefrom. This presentation is being given (together with any further information which may be provided to the recipient) on the condition that it is for use by the recipient for information purposes only (and not for the evaluation of any investment, acquisition, disposal or any other transaction). Any failure to comply with these restrictions may constitute a violation of applicable securities laws.

The companies in which Takeda directly and indirectly owns investments are separate entities. In this presentation, “Takeda” is sometimes used for convenience where references are made to Takeda and its subsidiaries in general. Likewise, the words “we”, “us” and “our” are also used to refer to subsidiaries in general or to those who work for them. These expressions are also used where no useful purpose is served by identifying the particular company or companies.

The product names appearing in this document are trademarks or registered trademarks owned by Takeda, or their respective owners.

## **Forward-Looking Statements**

This presentation and any materials distributed in connection with this presentation may contain forward-looking statements, beliefs or opinions regarding Takeda’s future business, future position and results of operations, including estimates, forecasts, targets and plans for Takeda. Without limitation, forward-looking statements often include words such as “targets”, “plans”, “believes”, “hopes”, “continues”, “expects”, “aims”, “intends”, “ensures”, “will”, “may”, “should”, “would”, “could”, “anticipates”, “estimates”, “projects” or similar expressions or the negative thereof. These forward-looking statements are based on assumptions about many important factors, including the following, which could cause actual results to differ materially from those expressed or implied by the forward-looking statements: the economic circumstances surrounding Takeda’s global business, including general economic conditions in Japan and the United States; competitive pressures and developments; changes to applicable laws and regulations, including global health care reforms; challenges inherent in new product development, including uncertainty of clinical success and decisions of regulatory authorities and the timing thereof; uncertainty of commercial success for new and existing products; manufacturing difficulties or delays; fluctuations in interest and currency exchange rates; claims or concerns regarding the safety or efficacy of marketed products or product candidates; the impact of health crises, like the novel coronavirus pandemic, on Takeda and its customers and suppliers, including foreign governments in countries in which Takeda operates, or on other facets of its business; the timing and impact of post-merger integration efforts with acquired companies; the ability to divest assets that are not core to Takeda’s operations and the timing of any such divestment(s); the extent to which our internal energy conservation measures and future advancements in renewable energy or low carbon energy technology will enable us to reduce our greenhouse gas emissions; and other factors identified in Takeda’s most recent Annual Report on Form 20-F and Takeda’s other reports filed with the U.S. Securities and Exchange Commission, available on Takeda’s website at: <https://www.takeda.com/investors/sec-filings/> or at [www.sec.gov](http://www.sec.gov). Takeda does not undertake to update any of the forward-looking statements contained in this presentation or any other forward-looking statements it may make, except as required by law or stock exchange rule. Past performance is not an indicator of future results and the results or statements of Takeda in this presentation may not be indicative of, and are not an estimate, forecast, guarantee or projection of Takeda’s future results.

## **Financial Information and Certain Non-IFRS Financial Measures**

Takeda’s financial statements are prepared in accordance with International Financial Reporting Standards (“IFRS”).

This presentation and materials distributed in connection with this presentation include certain financial measures not presented in accordance with IFRS, such as Core Revenue, Core Operating Profit, Core Net Profit, Core EPS, Constant Exchange Rate (“CER”) change, Net Debt, EBITDA, Adjusted EBITDA and Free Cash Flow. Takeda’s management evaluates results and makes operating and investment decisions using both IFRS and non-IFRS measures included in this presentation. These non-IFRS measures exclude certain income, cost and cash flow items which are included in, or are calculated differently from, the most closely comparable measures presented in accordance with IFRS. By including these non-IFRS measures, management intends to provide investors with additional information to further analyze Takeda’s performance and core results, including when controlling for the effect of fluctuations in exchange rates. Takeda’s non-IFRS measures are not prepared in accordance with IFRS and such non-IFRS measures should be considered a supplement to, and not a substitute for, measures prepared in accordance with IFRS (which we sometimes refer to as “reported” measures). Investors are encouraged to review the definitions and reconciliations of non-IFRS financial measures to their most directly comparable IFRS measures, which are in the financial appendix appearing at the end of this presentation.

## **Exchange Rates**

In this presentation, certain amounts presented in Japanese yen have been translated to US dollars solely for the convenience of the reader. Except where otherwise noted, these convenience translations have been made at an exchange rate of 1USD = 131.81 JPY, the Noon Buying Rate certified by the Federal Reserve Bank of New York on December 30, 2022. The rate and methodologies used for these convenience translations differ from the currency exchange rates and translation methodologies under IFRS used for the preparation of Takeda’s consolidated financial statements. These translations should not be construed as a representation that the relevant Japanese yen amounts could be converted into U.S. dollars at this or any other rate.

## **Medical information**

This presentation contains information about products that may not be available in all countries, or may be available under different trademarks, for different indications, in different dosages, or in different strengths. Nothing contained herein should be considered a solicitation, promotion or advertisement for any prescription drugs including the ones under development.

# TODAY'S SPEAKERS



## Presenting



**Ramona Sequeira**

President,  
Global Portfolio Division



**Derek Wallace**

Vice President,  
Head of Dengue Global Program

## Q&A



**Gary Dubin**

President,  
Global Vaccines Business Unit



**Renata Campos**

President,  
Growth and Emerging Markets Business Unit

## Joined by Special Guest



**Eng Eong Ooi**


Professor,  
Programme in Emerging Infectious Diseases,  
Duke-NUS Medical School



# DENGUE – TOP 10 THREAT TO GLOBAL PUBLIC HEALTH

*Ramona Sequeira – President, Global Portfolio Division*

# DENGUE IS LISTED BY THE WORLD HEALTH ORGANIZATION AS ONE OF TEN THREATS TO GLOBAL HEALTH<sup>1</sup>



**>3.9 Billion**  
*people are at risk of dengue infection globally<sup>2</sup>*



**>125**

Endemic in over **125 countries**; 70% of the burden in Asia<sup>2</sup>




**390M**

**390M estimated infections and 500,000 hospitalizations each year**, with an estimated **death rate of 20-25,000 per year**, primarily in children<sup>2,4,5</sup>



**Growing prevalence**

Global incidence rates have **increased 30-fold** over the last 50 years due to urbanization, travel and climate change<sup>6</sup>



**Urgent need for a safe and effective vaccine for endemic and travel markets**



Severe dengue is a **leading cause of hospitalization and death** in children and adults of all ages in endemic regions,<sup>2</sup> resulting in a high burden on healthcare systems



Significant **economic burden of disease**; families in endemic regions may spend 15-23% of monthly household income for hospitalizations<sup>7,8</sup>



Dengue is a **leading cause of fever among travelers** returning from Latin America, the Caribbean & Southeast Asia  
More than **90 million arrivals** from the United States, Canada and Europe to dengue endemic countries in 2018<sup>3</sup>

1. World Health Organization. [Ten threats to global health in 2019](#). Retrieved October 2022.  
2. World Health Organization. Fact Sheet. [Dengue and Severe Dengue](#). January 2022. Retrieved October 2022.  
3. Bulugahapitiya, U., Siyambalapatiya, S., Seneviratne, S. L., & Fernando, D. 3. J. (2007). Dengue fever in travellers: A challenge for European physicians. *European journal of internal medicine*, 18(3), 185–192. <https://doi.org/10.1016/j.ejim.2006.12.002>

4. Guzman MG, Halstead SB, Artsob H, et al. Dengue: a continuing global threat. *Nat Rev Microbiol*. 2010;8(12 Suppl):S7-S16. doi:10.1038/nrmicro2460.  
5. Schaefer T, Panda P, Wolford R. [Dengue Fever](#). April 2022. Retrieved October 2022.  
6. Ebi KL, Nealon J. Dengue in a changing climate. *Environmental Research*. 2016;151:115-123. doi:10.1016/j.envres.2016.07.026

7. Tozan Y, Ratanawong P, Sewe MO, Wilder-Smith A, Kittayapong P. Household costs of hospitalized dengue illness in semi-rural Thailand. *PLoS Negl Trop Dis*. 2017;11(9):e0005961  
8. Senanayake MP, Jayasinghe SSK, Wijesundera DS, Manamperi M. Economic cost of hospitalized non-fatal Paediatric Dengue at the Lady Ridgeway Hospital for Children in Sri Lanka. *Sri Lanka Journal of Child Health*. 2014;43(4):205. doi:10.4038/sljch.v43i4.7762

# QDENGA STRATEGIC LAUNCH IMPERATIVES



**Create awareness** of the health and economic risks associated with dengue for consumers living or traveling to endemic regions



**Build confidence** with regulators, recommending bodies, HCPs and consumers by leveraging strong clinical profile



**Establish rapid and broad access** at an individual- and population-level



**Ensure launch preparedness** through increased manufacturing capacity, established supply network and proven global commercial capabilities

# TODAY'S AGENDA



***Dengue Burden and Control*** – Eng Eong Ooi BMBS, PhD, FRCPath Professor  
Programme in Emerging Infectious Diseases, Duke NUS Medical School. Singapore

***QDENGGA Program and Clinical Results*** – Derek Wallace

***QDENGGA Commercial Outlook*** – Ramona Sequeira

**Q&A** – Ramona Sequeira, Derek Wallace, Gary Dubin, Renata Campos and Eng Eong Ooi



# Dengue burden and control

Why the world needs a vaccine

Eng Eong Ooi BMBS, PhD, FRCPath

Professor

Programme in Emerging Infectious Diseases



# THE GLOBAL BURDEN OF DENGUE

- **More than 4 billion people are at risk and estimated 390 million infections per year<sup>1</sup>**
- **30 times increase in disease over the past 50 years<sup>2</sup>**

Driven by

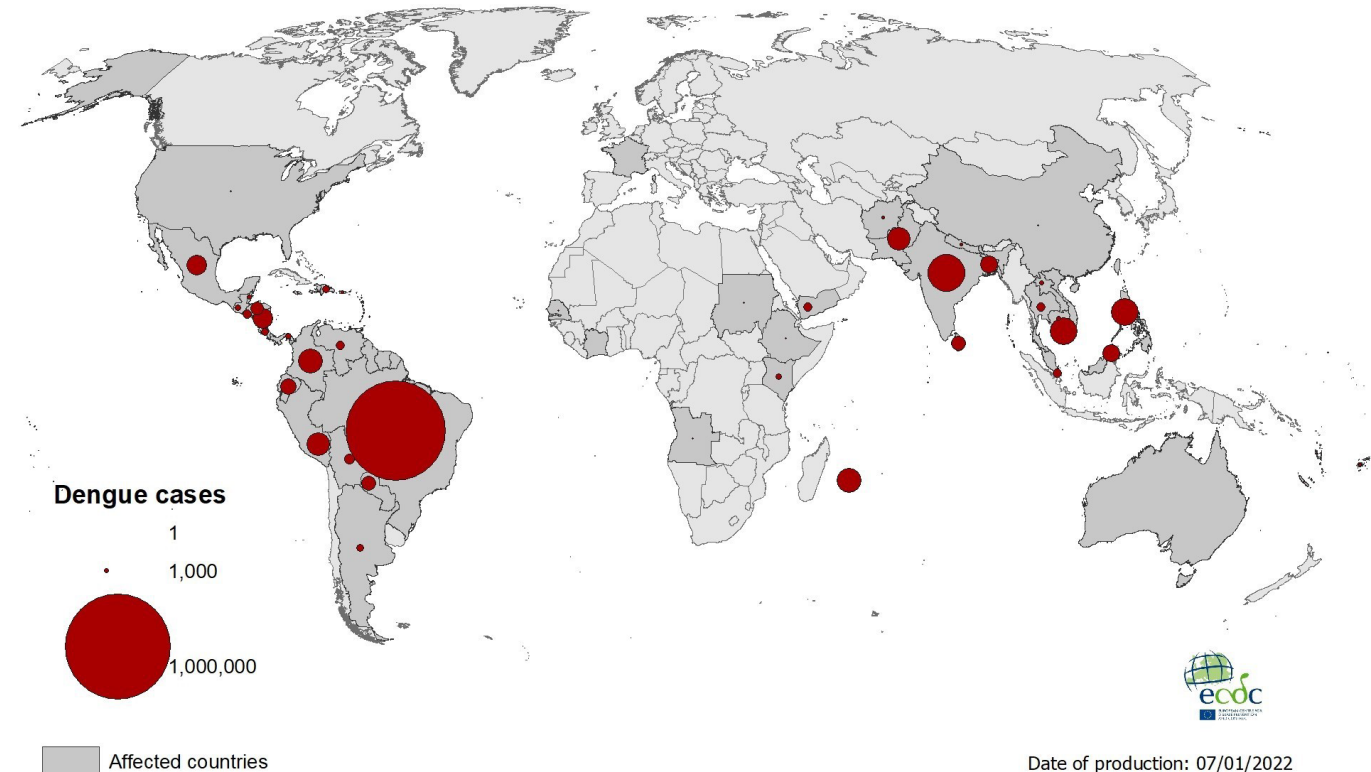
- Urbanization
- Global warming
- Increased global travel

More mosquitos

More mosquito / people contact

- **By 2080, more than 6 billion people are estimated to be at risk<sup>3</sup>**

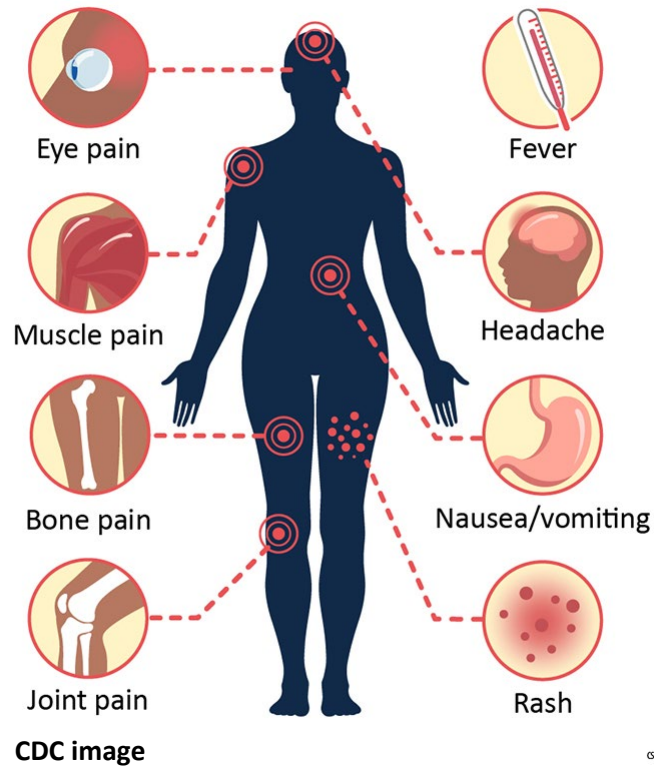
Geographical distribution of dengue cases reported worldwide, 2021<sup>4</sup>



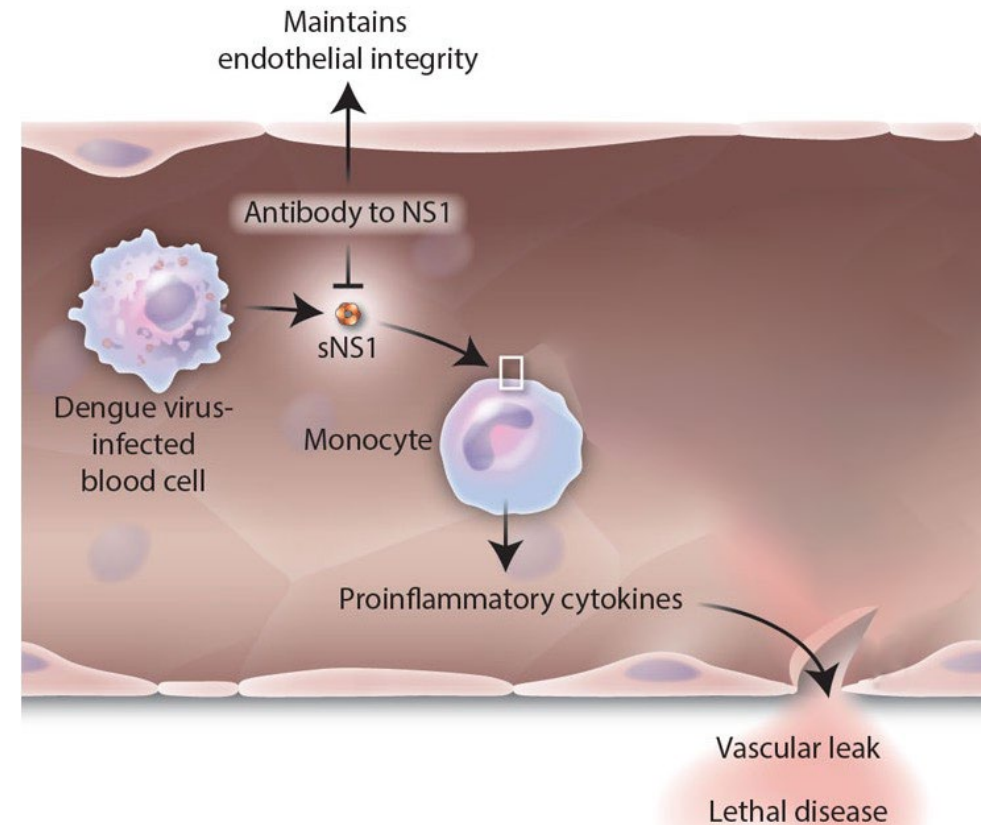
1. World Health Organization. Fact Sheet. [Dengue and Severe Dengue](#). January 2022. Retrieved October 2022.  
2. WHO. Global Strategy for Dengue Prevention and Control 2012–2020. Available at: [www.who.int/denguecontrol/9789241504034/en/](http://www.who.int/denguecontrol/9789241504034/en/)  
3. Messina, J.P., Brady, O.J., Golding, N. *et al.* The current and future global distribution and population at risk of dengue. *Nat Microbiol* 4, 1508–1515 (2019). <https://doi.org/10.1038/s41564-019-0476-8>.  
4. European Centre for Disease Prevention and Control, <https://www.ecdc.europa.eu/en/publications-data/geographical-distribution-dengue-cases-reported-worldwide-2021>

# DENGUE SYMPTOMS AND PRESENTATION VARIES

Most dengue infections are asymptomatic or lead to mild illness with flu-like symptoms<sup>1</sup>

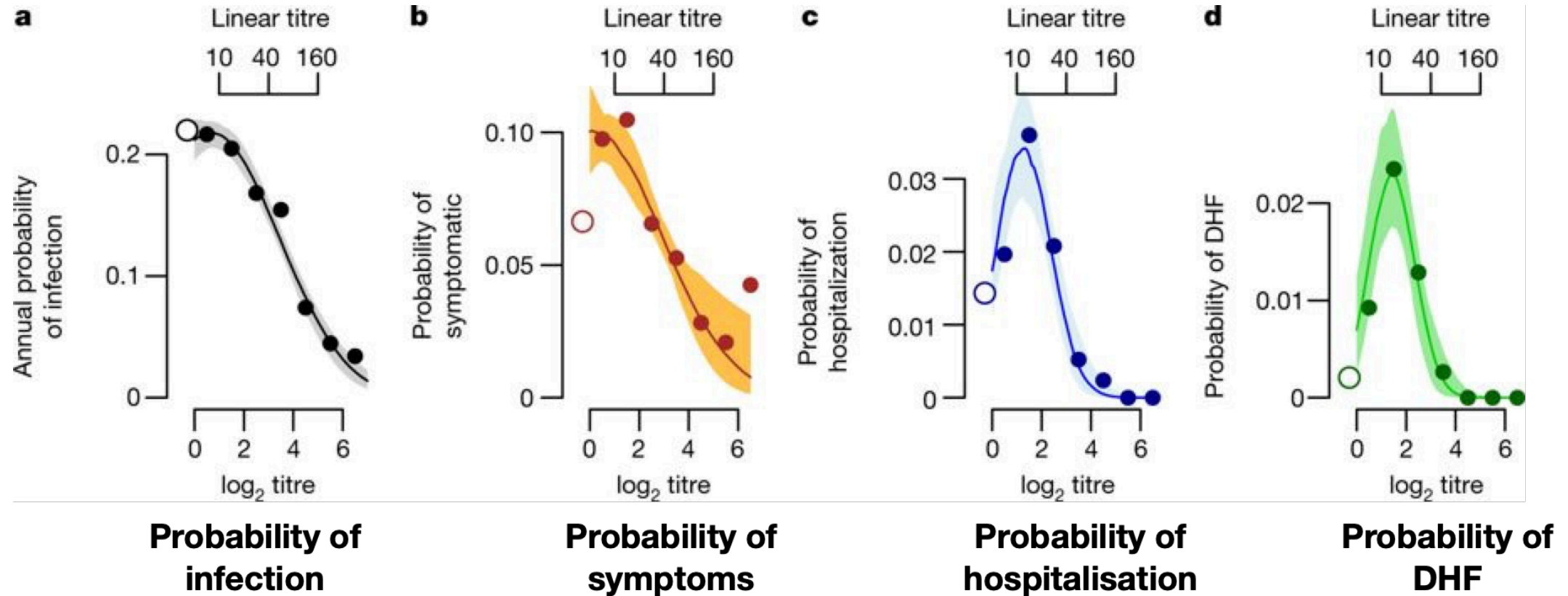


Severe dengue is present in 5% of cases<sup>2,3</sup>. High plasma viral load and NS1 levels have been associated with plasma leakage, a hallmark of severe dengue<sup>4</sup>



1. World Health Organization. <https://www.who.int/news-room/fact-sheets/detail/dengue-and-severe-dengue>
2. CDC. Travelers' Health- Yellow book. New York: Oxford University Press; 2020.
3. Wilder-Smith A. Current Infectious Disease Reports. 2018;20:50
4. *Clinical Infectious Diseases*, Volume 72, Issue 12, 15 June 2021, Pages e1074–e1083, <https://doi.org/10.1093/cid/ciaa1840>

# RISK OF SEVERE DENGUE PEAKS WITHIN A NARROW RANGE OF PRE-INFECTION ANTIBODY LEVELS<sup>1</sup>



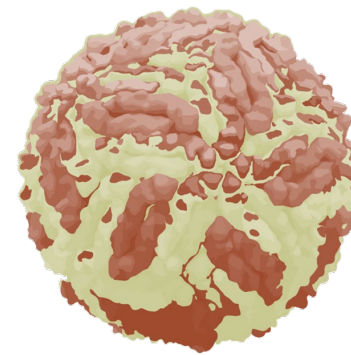
1. Salje et al, Nature 2018

# DENGUE TYPES 1 AND 2 CAUSE MAJORITY OF OUTBREAKS

Four strains of the dengue virus (DENV) 1-4 are spread by the *Aedes aegypti* and *Aedes albopictus* mosquitos worldwide

In recent years, **DENV-1** and **DENV-2** have emerged as the **most prominent strains associated with known outbreaks**<sup>1</sup>

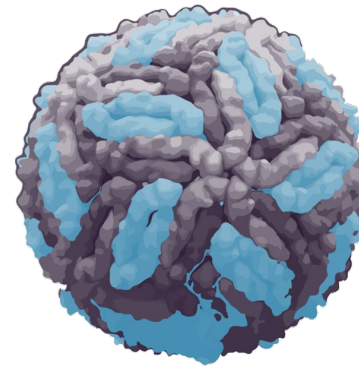
- According to empirical data, the highest pooled mortality rate has been reported during DENV-2 outbreaks<sup>1</sup>
- Studies have also shown that DENV-2 causes more severe secondary infections than other serotypes<sup>1</sup>



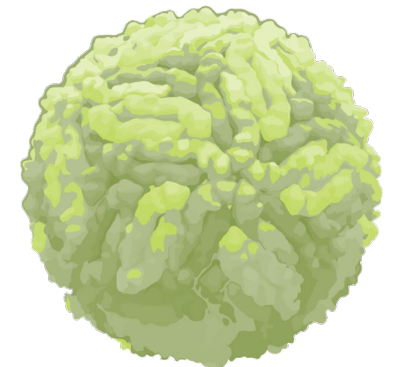
**DENV-1**



**DENV-2**



**DENV-3**



**DENV-4**

1. Yenamandra, S.P., Koo, C., Chiang, S. *et al.* Evolution, heterogeneity and global dispersal of cosmopolitan genotype of Dengue virus type 2. *Sci Rep* 11, 13496 (2021). <https://doi.org/10.1038/s41598-021-92783-y>

**Dengue outbreaks occur every few years<sup>1</sup>**

**Hospitals can become overwhelmed with the spike in cases<sup>2</sup>**



1. Clin Epidemiol. 2013; 5: 299–309.  
Published online 2013 Aug 20. doi: 10.2147/CLEP.S34440  
2. PLOS. Neglected Tropical Disease. Societal impact of dengue outbreaks: Stakeholder perceptions and related implications. A qualitative study in Brazil, 2015.

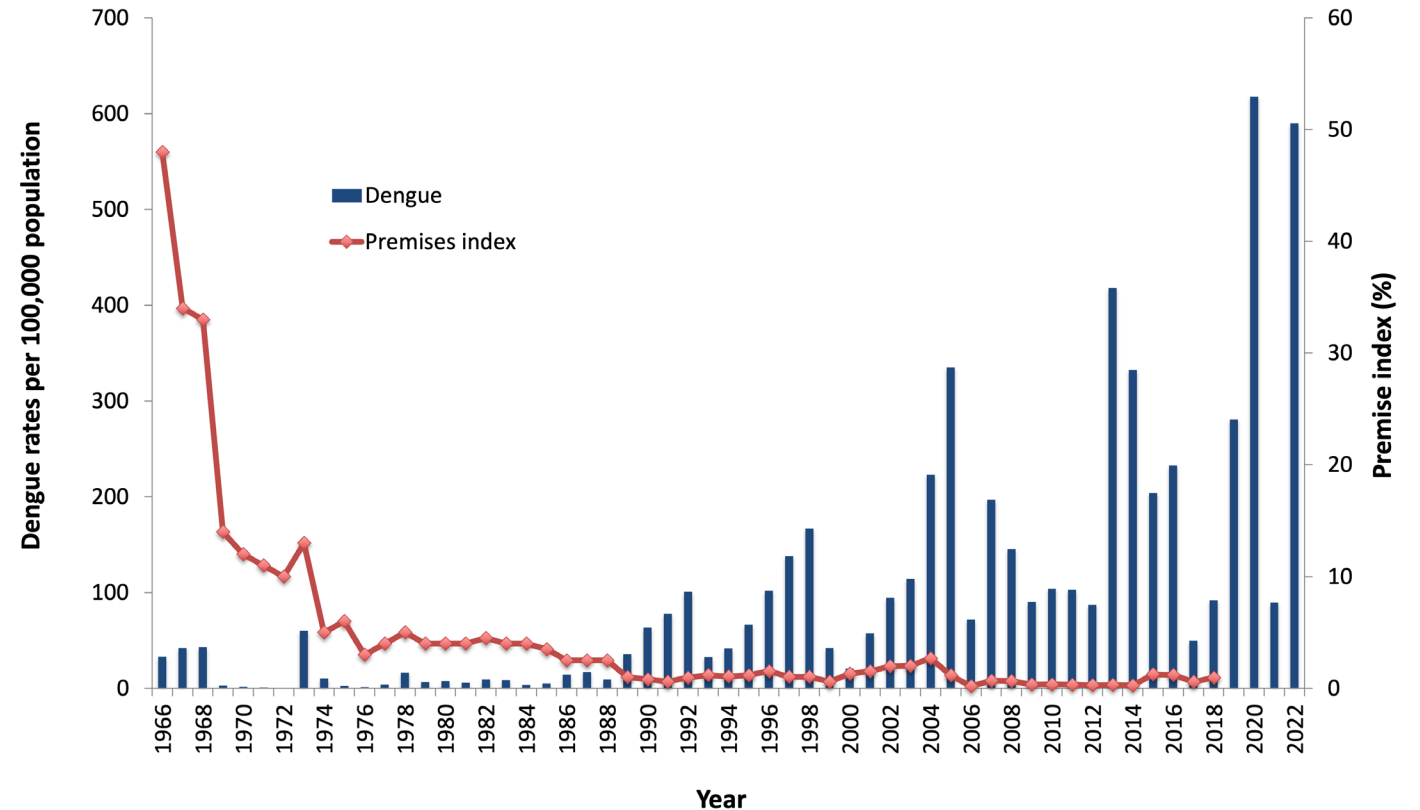
# WITHOUT VACCINATION, DENGUE CONTROL LACKS SUSTAINABILITY

Current efforts for dengue control are directed at reducing infection rate through vector control methods

In the medium to long term, this could cause lower population immunity and make them more susceptible to dengue outbreaks

**Elevating immunity levels with vaccination is the missing link in integrated dengue control**

Dengue and Aedes population density in Singapore – 1966 to 2022<sup>1</sup>



1. Data from Ministry of Health, Singapore  
Adapted from Ooi et al, Emerg Infect Dis 2006



# DEVELOPING SAFE AND EFFECTIVE VACCINE FOR A BROAD POPULATION

*Derek Wallace, MBBS – Head of Dengue Global Program*



# DENGUE VIRUS INFECTIONS HAVE A DISTINCT PATHOPHYSIOLOGY



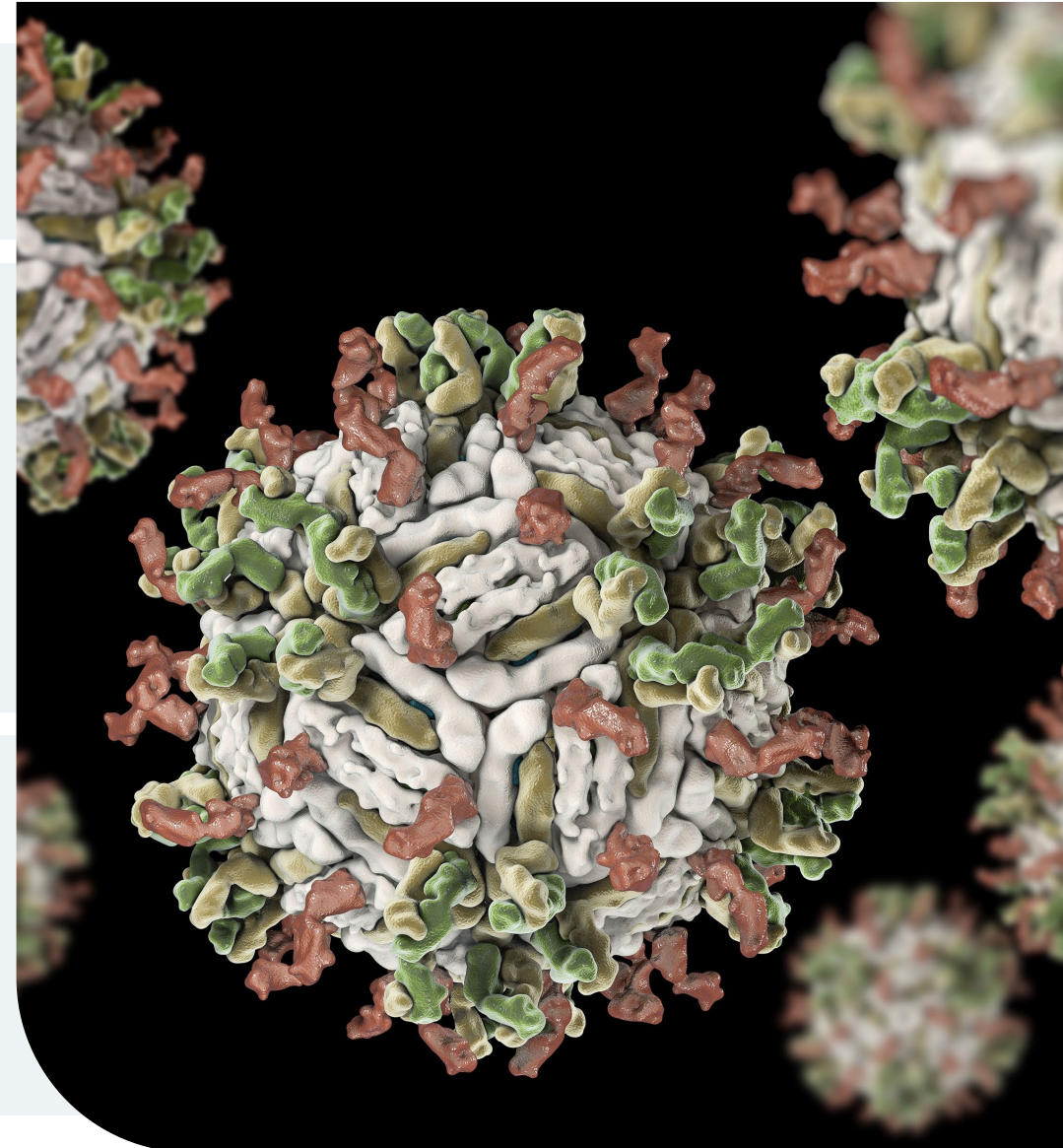
**Severe disease, although rare, is unpredictable and typically affects children<sup>1,2</sup>**

**Severe dengue infections are characterized by vascular leakage associated with a high risk of hospitalization and mortality<sup>2</sup>**

- Dengue virus non-structural (NS) protein 1 can trigger vascular leakage
- NS1 protein is highly conserved across the four dengue serotypes
- No specific treatment options exist to manage vascular leakage

**Potential for disease enhancement<sup>2</sup>**

- After an initial infection, a subsequent infection with a different serotype can lead to more severe outcomes
- There is no method of predicting or preventing disease enhancement in patients





# QDENGGA: ENGINEERED TO ELICIT A BROAD AND LASTING IMMUNE RESPONSE AGAINST ALL DENGUE SEROTYPES



## Tetravalent QDENGGA was engineered:

1

To contain the structural genes of serotypes 1 to 4

2

Built on a dengue virus serotype 2 backbone containing dengue virus non-structural genes, including NS-1 protein

## QDENGGA VACCINATION HYPOTHESIS

Activation of....

Antibodies against structural proteins for serotypes 1-4

Antibodies against NS proteins cross-reactive against all NS serotypes

T- and B-cells reactive against dengue antigens

With the objective of....

Efficiently blocking infection with wildtype virus of all serotypes

Reducing risk for severe dengue by preventing vascular leakage induced by NS1 protein

Support long-term immunity against dengue infections with different serotypes

WITH THE GOAL TO DEMONSTRATE....

Reduction in Symptomatic Dengue

Reduction in Hospitalizations

Sustained Protection Against All Serotypes

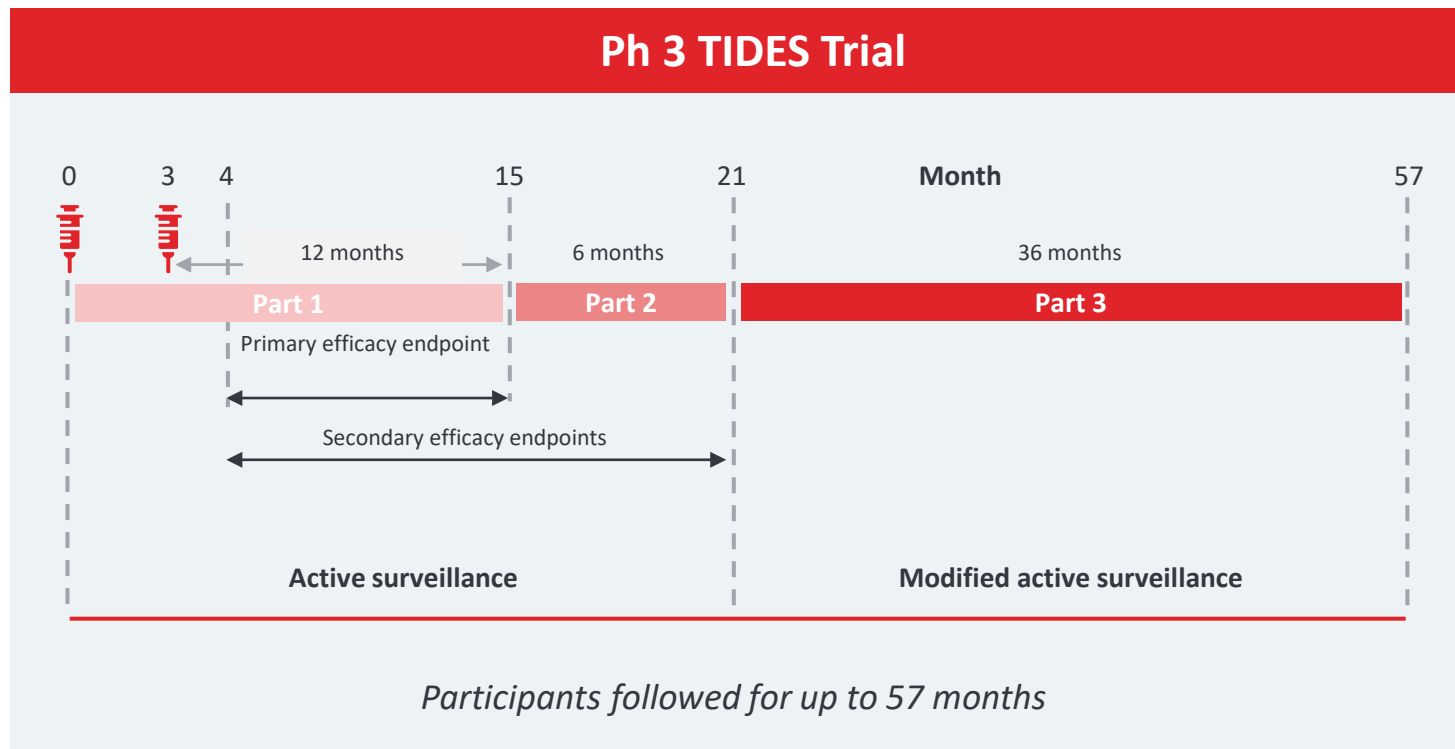
# PHASE 3 TIDES TRIAL DESIGNED TO ASSESS THE SAFETY AND EFFICACY OF TAK-003 IN BROAD POPULATION



Trial design met WHO recommendations for a second-generation dengue vaccine – 3-5 years of follow-up prior to licensure

**Broad Population**

- 20,000** children & adolescents
- 8** endemic countries
- 4/4** Includes all four serotypes
- Both** Sero-positive & Sero-negative<sup>2</sup>



**Participants stratified by serostatus<sup>1</sup>**

**Primary endpoint** – prevention of symptomatic dengue cases @ 12mo

**Key secondary endpoint** – reduction in hospitalizations @ 18mo

**Exploratory endpoint** – sustained preventions of symptomatic dengue and reduction in hospitalization @ 4.5yrs

# SUSTAINED PROTECTION AGAINST ALL DENGUE SEROTYPES & LOWER RISK OF HOSPITALIZATION REGARDLESS OF PREVIOUS EXPOSURE



## Strong efficacy across all endpoints

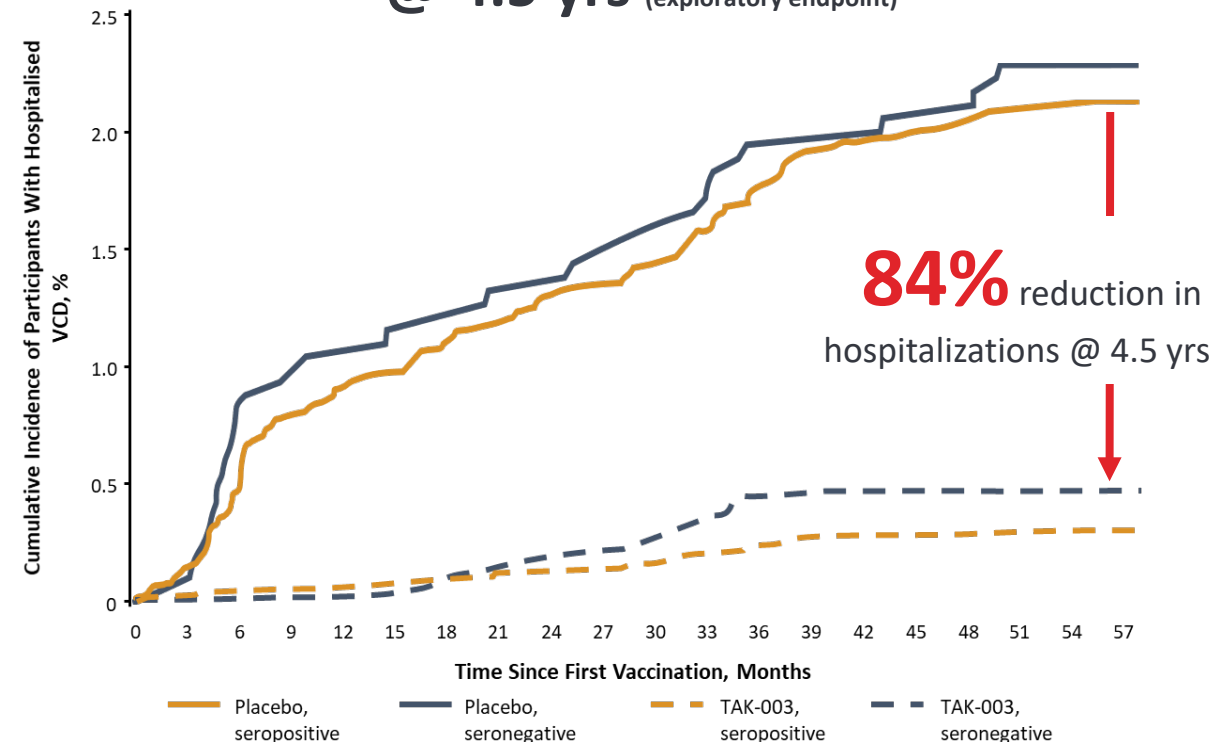
Reduction in symptomatic VCD & hospitalizations regardless of previous exposure



## No important identified safety risks<sup>3</sup>

- No evidence of disease enhancement
- Well tolerated
- Most frequently reported reactions were common to vaccines, including injection site pain, headache, myalgia, injection site erythema, malaise, asthenia and fever

## Durable Reduction in Hospitalizations @ 4.5 yrs (exploratory endpoint)<sup>3</sup>



<sup>1</sup> Biswal S, et al. Efficacy of a tetravalent dengue vaccine in healthy children and adolescents. N Engl J Med. 2019; 2019;381:2009-2019

<sup>2</sup> Biswal S, et al. Efficacy of a tetravalent dengue vaccine in healthy children aged 4-16 years: a randomized, placebo controlled, phase 3 trial. Lancet. 2020; 2020;395:1423-1433.

<sup>3</sup> Tricou, V. Efficacy and Safety of Takeda's Tetravalent Dengue Vaccine Candidate (TAK-003) After 4.5 Years of Follow-Up. Presented at the 8th Northern European Conference of Travel Medicine; June 2022

VCD - Virologically confirmed dengue

# SIGNIFICANT REGULATORY MOMENTUM: QDENGA APPROVED WITH BROAD LABEL REGARDLESS OF SEROSTATUS



**August 2022**

Approved in  
Indonesia<sup>1</sup> for ages 6-  
45



**October 2022**

EU-M4all application  
receives Positive  
CHMP opinion



**November 2022**

US FDA accepts filing



**December 2022**

Approved in EU<sup>2</sup> for  
ages 4 and up



**2023**

Approved in Brazil  
for ages 4 - 60<sup>3</sup>

**Ongoing regulatory reviews in several endemic  
countries & travel markets**

1. Indonesia National Agency for Drug and Food Control, Badan Pengawas Obat dan Makanan (BPOM) [https://www.takeda.com/4a410b/siteassets/system/what-we-do/areas-of-focus/vaccines/pdf/acc\\_qdenga\\_smcp.pdf](https://www.takeda.com/4a410b/siteassets/system/what-we-do/areas-of-focus/vaccines/pdf/acc_qdenga_smcp.pdf)  
2. European Medicines Agency <https://www.ema.europa.eu/en/medicines/human/EPAR/qdenga>  
3 Anvisa approval <https://www.gov.br/anvisa/pt-br/assuntos/noticias-anvisa/2023/anvisa-aprova-nova-vacina-para-a-dengue>

QDENGA is approved in Indonesia, EU, UK, Norway, Iceland, Lichtenstein, Brazil

EU-M4all The European Medicines Agency. [Medicines for use outside the EU — EU-M4all](#). July 2020. Retrieved March 2021.



# QDENGGA COMMERCIAL OUTLOOK

*Ramona Sequeira – President, Global Portfolio Division*



# QDENGA STRATEGIC LAUNCH IMPERATIVES



**Create awareness** of the health and economic risks associated with dengue for consumers living or traveling to endemic regions



**Build confidence** with regulators, recommending bodies, HCPs and consumers by leveraging strong clinical profile



**Establish rapid and broad access** at an individual- and population-level



**Ensure launch preparedness** through increased manufacturing capacity, established supply network and proven global commercial capabilities

# COUNTRY-LEVEL ACTIVATION OF STRATEGIC IMPERATIVES INITIATED AHEAD OF EXPECTED APPROVALS



Driving  
**consumer  
awareness**  
of dengue risk  
and prevalence  
*in THAILAND*



70M+ people in country

## Public Education Partnerships

- Partnering with 11 entities to raise public awareness
- Ing-Ma virtual human video campaign launched: >35 million views
- Partnership with Kao Thailand, top consumer brand

Establishing  
**trust** in dengue  
prevention  
*in BRAZIL*



200M+ people in country

## Consumer Engagement Initiatives

- UNICEF partnership to educate 90,000 people to reduce the transmission of water and vector borne infectious diseases
- Dengue prevention social media campaign

Building a  
dengue **travel  
business**  
*in NON-ENDEMIC  
COUNTRIES*

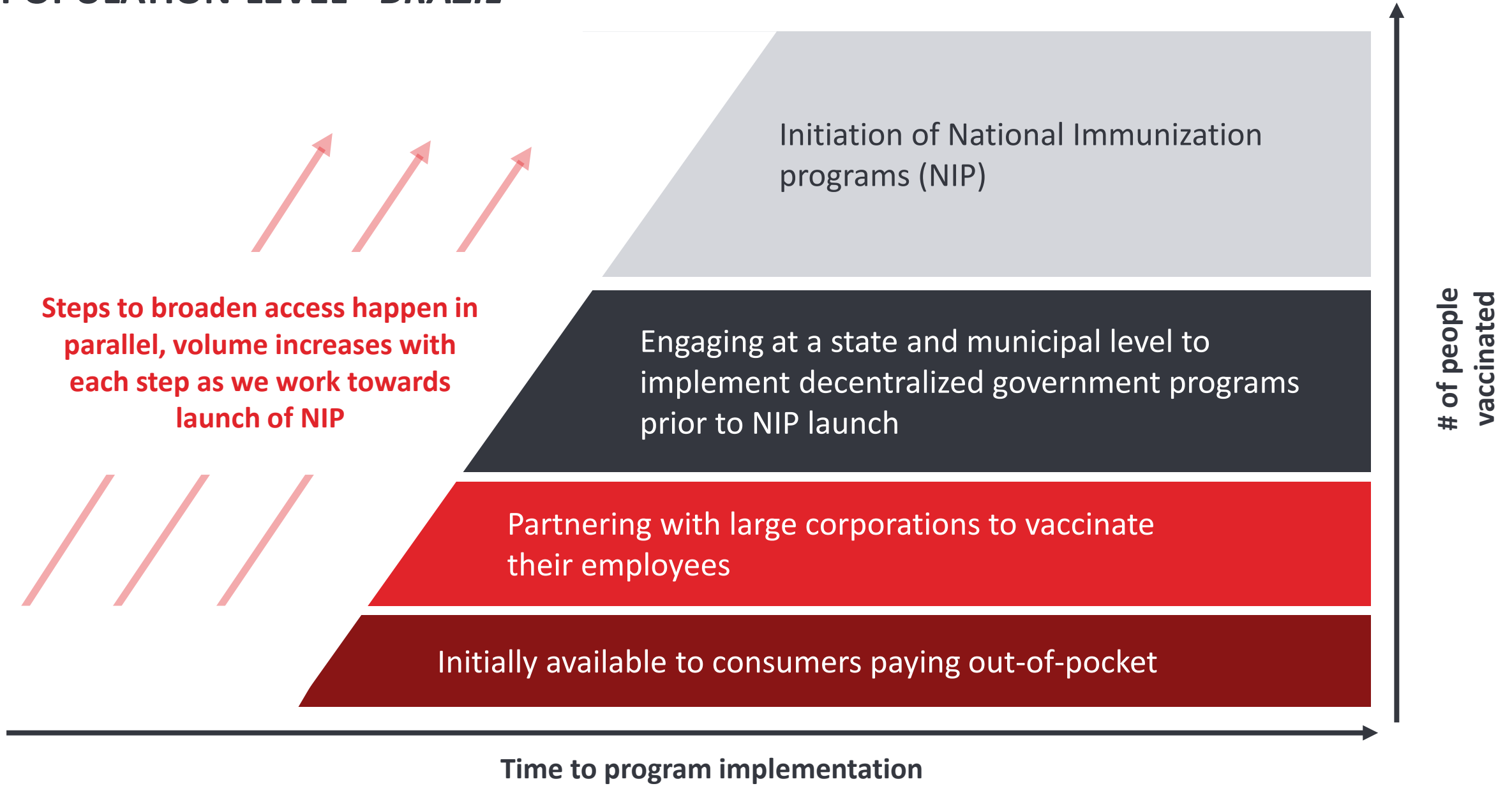


90M+ arrivals from the US, CA & EU\*

## Critical External Engagements

- Partnership with leading travel immunization clinics and HCPs
- Ongoing engagements with CDC ACIP dengue working group

# ESTABLISH RAPID AND BROAD ACCESS AT AN INDIVIDUAL- AND POPULATION-LEVEL - BRAZIL





# VARIABLE PRICING APPROACH TO MEET THE NEEDS OF INDIVIDUAL COUNTRIES & MARKET SEGMENTS



We aim to make **QDENG A available to all who are eligible for vaccination** in the countries where approved

## PRIVATE ENDEMIC

- Pricing at or below the average price for other innovative vaccines
- Tiered pricing corridors based on factors such as GDP & sophistication of healthcare system.

Maximum retail price for **Indonesia is \$40 USD<sup>6</sup> per dose<sup>1</sup>, \$26 USD<sup>6</sup> ex-factory**

*Average price for innovative vaccines in Indonesia is \$73 USD<sup>6</sup> per dose<sup>2,3</sup>*

## PUBLIC ENDEMIC

- Aim to price lower than average for innovative vaccines.
- One pricing corridor and a discount matrix.

Ensures affordability for all.

## TRAVEL

- Pricing similar to other innovative travel vaccines in their respective countries.

Retail price in Germany **\$115 USD<sup>7</sup> per dose<sup>1</sup>, \$80 USD<sup>7</sup> ex-factory**

*Average price for innovative vaccines in Germany is \$119 USD<sup>7</sup> per dose<sup>2,4</sup>*

**Implementation of QDENG A has the potential to create significant cost savings for individuals and governments taking into account economic factors such as: cost of care, missed work, lost tourism, etc<sup>5</sup>**

# LAUNCH READY: ESTABLISHED MANUFACTURING & SUPPLY CHAIN AND LEVERAGING BROAD GLOBAL FOOTPRINT



## Manufacturing capacity in place for launch and investing to expand for growth

- Early investments to established in-house manufacturing for launch
- Aim to achieve **100 mill doses per year** through in-house and strategic CMO partnerships



## Well-established distribution network

- **Cold chain distribution partner** has broad global network.
- **Existing distribution networks and commercial infrastructure** in the initial launch markets



## Proven track record In Growth & Emerging Markets (GEM)

- **150 successful commercial launches** since 2019
- **14.5% FY2022 Q3YTD revenue growth** YoY at CER

# GLOBAL EXPANSION THROUGH THE END OF THE DECADE



**Target launches in >20 countries by 2025, representing 55% of eligible at-risk population**

*Leveraging EU-M4all review process to potentially accelerate approvals in participating endemic markets*

*Indonesia, Malaysia, Thailand, Colombia, Brazil,  
Mexico, Singapore, Sri Lanka, Argentina, US, EU*

*China, India, Cuba, Honduras,  
Venezuela, GAVI, PAHO*

NEAR-TERM

MID-TERM

LONG TERM

FY22-FY24

FY25-FY27

FY28-FY30

FY30+

*Canada, Israel, Ecuador, Guatemala, Paraguay, Peru, Costa Rica,  
El Salvador, Panama, Nicaragua, Dom. Rep., Philippines, Hong Kong,  
Australia, Vietnam*

- ✓ Significant regulatory progress
- ✓ Initiating launches where approved

# STEADY REVENUE GROWTH THROUGH THE END OF THE DECADE



**\$1.6 - 2.0B**  
Peak sales

**Strong Clinical Profile** - 4.5-yr data demonstrating durable reduction in hospitalization and no important safety signals consistent with 1° & 2° endpoints

Momentum with regulators – Brazil, Indonesia & EU approvals with **broad labels, regardless of serostatus**

**Expanding manufacturing capacity** with aim to achieve annual output 100M+ doses

- Continuing to add to in-house capacity and manufacturing efficiencies
- Contracting for additional capacity with CMOs; actively exploring potential partners in India and other large endemic markets



**Previous peak sales estimate of \$700M - \$1.6B was based on:**

24-month data – prior to the 4.5-year data readout

Manufacturing assumptions of 50M+ doses annually

# SUMMARY OF QDENGA COMMERCIAL OUTLOOK



## Near-term: *Drive Early Adoption*

- Launch into key endemic and travel markets – **leveraging strong clinical profile**
- **Establish rapid access** – Private segment/local partnerships
- **Ensure affordability** through variable pricing approach

## Mid-term: *Accelerate Volume Growth*

- Initiation of **national vaccination** programs will **drive volume**
- Recognize **economies of scale** to reduce CoGS as **volume grows**

## Long-term: *Durable Sales Post Peak*

- **Continued global expansion** into the next decade
- Ensure **new generations** are being vaccinated
- **Durable sales post peak** – Vaccines face **limited generic threats** due to high barriers to entry

# QDenga – Addressing the Urgent Need for a Safe and Effective Dengue Vaccine



## Significant, Growing Global Burden



- >3.9 billion people at risk of infection<sup>1</sup>
- Growing prevalence – increasing 30-fold over the last 50yrs<sup>2</sup>
- Significant economic burden of disease both at the government, healthcare systems and patient level<sup>3,4</sup>

## Differentiated Clinical Profile<sup>5</sup>



- Demonstrated strong safety and efficacy against all dengue serotypes regardless of previous exposure
- Durable reduction in hospitalizations – 84% reduction @ 4.5yrs
- No important safety risks identified

## Delivering Steady Revenue Growth Through the End of the Decade



- Peak sales expected to grow to \$1.6 - 2.0B USD
- Innovative access strategy to drive rapid and broad access
- Established manufacturing, supply chain and global footprint to ensure launch readiness

1. World Health Organization. Fact Sheet. [Dengue and Severe Dengue](#). January 2022. Retrieved October 2022.

2. Ebi KL, Nealon J. Dengue in a changing climate. *Environmental Research*. 2016;151:115-123. doi:10.1016/j.envres.2016.07.026

3. Tozan Y, Ratanawong P, Sewe MO, Wilder-Smith A, Kittayapong P. Household costs of hospitalized dengue illness in semi-rural Thailand. *PLoS Negl Trop Dis*. 2017;11(9):e0005961

4. Senanayake MP, Jayasinghe SSK, Wijesundera DS, Manamperi M. Economic cost of hospitalized non-fatal Paediatric Dengue at the Lady Ridgeway Hospital for Children in Sri Lanka. *Sri Lanka Journal of Child Health*. 2014;43(4):205. doi:10.4038/sljch.v43i4.7762

5. QDenga was assessed across a clinical development program that included 19 Phase 1, Phase 2 and Phase 3 trials, and more than 28,000 participants, including Takeda's pivotal Tetravalent Immunization against Dengue Efficacy Study (TIDES) trial. The TIDES trial met its **primary endpoint** of overall vaccine efficacy (VE) against virologically-confirmed dengue (VCD) with 80.2% efficacy at 12-months follow-up. The trial also met all **secondary endpoints** for which there were a sufficient number of dengue cases at 18-months follow-up. The VE result in preventing hospitalization due to VCD fever was 90.4%. Through four and a half years (54 months after the second dose), QDenga demonstrated continued overall protection, with sustained overall VE of 61.2% and 84.1% VE against hospitalized dengue. Observations of VE varies by serotype and remained consistent with previously reported results. QDenga has been generally well tolerated, with no evidence of disease enhancement in vaccine recipients, and no important safety risks have been identified in the TIDES trial, to date.

---

# THANK YOU

---



**Better Health, Brighter Future**