Takeda in I-SEA: Expanding Access, Leveraging Partnerships and Tailoring Healthcare Solutions

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Dengue fever is highly endemic in almost every country in Southeast Asia, meaning that Takeda â?? having launched its dengue vaccine in 2023 â?? stands to have a massive impact on health in the region. In conversation, Takedaâ??s Area Head for India and Southeast Asia Dion Warren outlines how Takedaâ??s strategy for tackling dengue extends beyond its innovative vaccine alone; including public-private partnerships, education, surveillance, and integration into national immunisation programs. Warren also explains how Takeda is attempting to expand access to its other innovative medicines in I-SEA through tailored, sustainable patient access programs and partnerships, and why â?? in a hugely diverse region like I-SEA â?? Takeda must tailor its efforts to each countryâ??s unique healthcare needs.

Having spent much of your career in oncology, you now head up Takedaâ??s operations in the vast I-SEA country grouping. How did you get here, and what does your current role entail?

I was born and raised in the state of Maine in the US, and, after university in the Southeast of the US I found myself within the biotech community in the Boston area. It was there that I met my wife and started working at a biotech focused on oncology. In the first five to ten years of my career, I held a variety of roles, from financial planning analysis to business development, corporate strategy, marketing, and investor relations.

The company was acquired by Takeda in 2008, and I was given the opportunity to help globalise oncology within Takeda. As part of this I spent three years in Switzerland from 2012 to 2015 starting

oncology in Emerging Markets for Takeda before moving to Singapore. There my remit was setting up commercial operations in Emerging Markets with a focus on innovative medicines as well as pricing market access, and ultimately trying to ensure patient access to medicine.

I then returned to Europe to lead Takedaâ??s oncology business unit in Europe and Canada and, in my last role before my current one, spent four years leading the oncology business unit in the US. A year and a half ago, I took the opportunity to come back to Singapore with my wife and two kids to lead the I-SEA area. This group of countries is diverse and always evolving â?? two billion people live here â?? and its economies and healthcare markets are rapidly growing. In addition, weâ??re seeing a rapid shift in demographics across the region, with the population of people aged 60 and above set to reach over 1 billion people by 2050, which of course also poses challenges, especially when it comes to healthcare.

What is the rationale behind the I-SEA grouping and what are the key items on your agenda?

There are two primary reasons behind Takeda originally creating this country grouping. The first was to successfully launch Takedaâ??s dengue vaccine in this group of countries where dengue is highly endemic. India and Southeast Asia are experiencing rapid economic growth which is closely interlinked with dense â?? and often unplanned â?? urban development. These are also the countries that are bearing the brunt of climate change, which has led to severe outbreaks of dengue. We aim to have a tremendous positive impact on public health in I-SEA countries through our efforts in dengue and this serves as Takedaâ??s entrance into vaccines outside of Japan.

Secondly, there are similar challenges in these countries; most notably that patient access to innovative medicines is extremely difficult, complex and with low levels of reimbursement. Without well-established national reimbursement structures and health technology assessment (HTA) bodies, patients often need to pay out of pocket for the healthcare and therapies they need; a problematic situation compounded by a lack of diagnosis and often insufficient medical infrastructure, especially when considering highly specialized disease areas with innovative medicines.

Over the next couple of years, dengue is our top priority in I-SEA. Bringing our innovative vaccine to people who need it will of course be critical, but we firmly believe in striking partnerships with both public and private organisations in all countries in the region and across I-SEA to make a sustainable impact on dengue beyond our vaccine alone.

Our second key priority is around continuing to expand patient access to new innovative medicines in our core therapeutic areas throughout I-SEA. We have launched many products in recent years and will continue to do so in the coming months and years. Figuring out how to do that successfully and sustainably increase patient access, will be crucial to patients and the communities we serve. Here again, our partnership approach will play an important role.

Finally, as we move into areas â?? such as vaccines â?? that are relatively new to Takeda, we are really prioritising having the right talent and values-based culture in place. It is critical to have the right people who bring the right mix of expertise, diverse perspectives and a shared passion to collaborate with the aim of impacting patients.

What is the level of public health threat that dengue fever represents and why is a vaccine against the disease so important?

This is something Iâ??ve been able to connect with on a personal level since living in Southeast Asia and talking with patients, the medical community and government representatives throughout countries in I-SEA. We see about 500 million cases of dengue per year globally, mostly in Latin America and Asia, which make up about 70 percent of the global burden, and a rising number of deaths. Added to this is the enormous strain that dengue places on national healthcare systems and the economic costs of people getting sick and not being able to work. Not only is dengue quite a common disease in I-SEA, it can also be deadly, especially when you consider secondary infections. Furthermore, climate change is contributing to worsening the dengue threat, especially in tropical rainy environments such as those in Southeast Asia and Latin America â?? it is accelerating the spread of dengue by expanding mosquito habitats, especially in warmer and wetter regions. As a result, there is a marked expansion of the Aedes mosquito population, increasing the global burden of dengue and making robust, comprehensive preventative strategies, including vaccination, key to prevent, control and manage the disease.

Dengue leads to a tremendous health and economic impact for people and countries and it is important to effectively tackle dengue which has been very difficult for decades. For this reason, governments in our region have already been investing in dengue prevention and are generally open to new options such as safe and effective vaccines.

How significant a breakthrough is Takedaâ??s dengue vaccine and how widespread is access in I-SEA today?

We believe that our innovative dengue vaccine is a vitally important part of dengue prevention and control measures, along with other elements, including surveillance, clothing, and education, to name a few. In May 2024, Takedaâ??s dengue vaccine has been recommended by WHOâ??s Strategic Advisory Group of Experts (SAGE) for introduction in countries with high dengue burden and high transmission intensity to maximize public health impact. In addition to being recommended in the WHOâ??s dengue vaccines position paper, the vaccine has been included in the WHOâ??s List of Prequalified Vaccines, underscoring its quality and reliability as a helpful important dengue prevention method suitable for public programs. The recommendations by WHO underscores the vaccineâ??s potential as an important tool within an integrated strategy to help reduce the global threat of dengue.

The vaccine has already been approved in over 40 countries globally, with launches in several countries in Latin America as well as here in Southeast Asia. The first countries in this region to launch were Indonesia and Thailand last year, followed by Malaysia and Vietnam this year. We are currently working through the regulatory process in India, Philippines, and Singapore. So far, we are very pleased with the uptake country by country, and over 10 million of doses have been distributed globally.

For this vaccine, we have implemented a unique tiered pricing strategy which is adjusted by country based on affordability levels. In order for the vaccine to be effective, it needs to actually reach people and families in local communities within each country. This strategy is therefore aimed at facilitating access in low- and middle-income countries, enabling patients and national health systems to access the vaccine.

Additionally, Takeda is focusing on partnerships with local governments, NGOs, healthcare providers and communities to ensure effective deployment and adoption of preventative strategies and education. This combines our global expertise in vaccine development and deployment with local knowledge of disease transmission patterns and community needs to reduce the dengue burden

across the region.

What steps is Takeda taking on dengue prevention more broadly and what role do public-private partnerships play in this effort?

Our priority is dengue as a whole, not only the dengue vaccine. This means that we focus on healthcare collaborations and broadening while also being present on the ground to build trust among stakeholders. Doing right by patients and society will strengthen our companyâ??s reputation, lead to business results, and play a key role in combating and ultimately reducing the risk of dengue.

Our experience in countries like Indonesia, Thailand, Malaysia, and Vietnam has reinforced the understanding that vaccination alone isnâ??t enough. Due to the complexities of dengue, it must be part of a comprehensive strategy, aligned with WHOâ??s recommendation for a strong communication plan and community engagement to build public trust and ensure effective vaccine deployment. We have established strong public-private partnerships in countries like Indonesia and Thailand, where we convened over 10 stakeholders â?? from the Centers for Disease Control to the Thai Ministry of Health, other divisions of the government, and other private companies â?? through memorandums of understanding (MoUs) to strengthen dengue prevention and management. These collaborations and agreements outline clear actions and roadmaps, integrating community engagement initiatives with scientific efforts. The MoUs prioritize raising public awareness, enhancing vaccination programs, and strengthening surveillance systems, while also fostering research collaborations to tackle dengue more effectively.

The vaccine is currently available in the private sector, where individuals can purchase the vaccine, but our ultimate goal is to ensure the vaccine is included in national immunisation programs, making it available to the broadest set of eligible populations within its approved indication. Inclusion in national immunization programs will take some time and the experience and data being generated now in the private sector will be important to demonstrate real-world efficacy and safety of the vaccine.

There have already been several important milestones in this effort, not least the World Health Organisation (WHO)â??s endorsement of the vaccineâ??s suitability for public immunisation programs. In Indonesia, the vaccine is accessible through some public vaccination programs at the provincial level. Last year, an Indonesian provincial health office started a vaccination program with school-aged children, which has generated good real-world safety and efficacy data, and has since been expanded to other provinces. Meanwhile, governments in Brazil and Argentina have decided to include the vaccine in their immunisation programs.

What are the prospects for expanding access to the dengue vaccine beyond the private sector in Asia?

Demand has been extremely high for the vaccine in this region, and we have been very pleased with the uptake so far. We are now generating additional data in real-world settings which so far has been very supportive of the clinical study data. We are in active discussions with some governments around public pilot programs that show the impact of the vaccine within local communities. This effort is following on from our initial provincial public program in Indonesia that started last year.

Combatting dengue is a journey and will not be accomplished overnight, but we are confident that Takedaâ??s innovative dengue vaccine and our strategy will impact communities and countries over time. Partnerships across both public and private sectors, including with medical associations, physicians, national and local officials as well as other companies, will be critical, as no one single actor can achieve success in combating such a significant public health threat.

Asia lacks a European Medicines Agency equivalent body, meaning that the regionâ??s regulatory framework is somewhat fragmented. How are you navigating this issue?

Without a unified regulatory framework in Asia, we have to articulate the severity of dengue and the unmet need country by country, with each and every government and with local healthcare providers.

However, there are ways of working across borders on this issue. For example, an important part of our strategy is multi-country studies. We are currently launching a real-world evidence study with 70,000 subjects in three to four countries here in Asia, which has the potential to generate even more robust data more rapidly than single-country studies.

Beyond the vaccine, what are some key strategies that countries can adopt to curb the spread of dengue?

It all starts with data and accurately understanding the problem. In many places, published data only covers hospitalised cases, so reported numbers donâ??t capture the full scale of the issue. Additionally, in some countries, data reporting is far from complete or inaccurate. A crucial part of the strategy is for governments, often in partnership with organizations like Takeda, to gain a deeper understanding of case numbers, severity, and the impact on both human lives and the economyâ??country by country and even down to local communities.

Effective strategies include action plans for dengue surveillance, search-and-destroy methods, and preventative options like fogging or Wolbachia bacteria, which are being piloted in certain areas. We support comprehensive, country and community-level plans since tackling dengue will require multiple approaches working together in unison.

Government support is essential, but in some regions, the focus remains on TB, AIDS, or other diseases. Accurate data is vital for policy discussions to highlight dengueâ??s significance alongside other national health priorities. While some countries are further along, progress is being made, especially now with new tools to address dengue effectively.

What are the other therapeutic areas where Takeda stands to have the greatest impact on patients in I-SEA in the coming years?

In addition to dengue, we have an innovative portfolio in oncology, gastroenterology (GI), plasma-derived therapies, and neuroscience. Specifically, in I-SEA, oncology, gastroenterology, and plasma-derived therapies are currently making a significant impact and are expected to grow. The majority of our neuroscience pipeline is still in earlier phases, so while itâ??s not a major focus today, it holds significant potential in the future.

In oncology and GI, for instance, we are dedicated to understanding each countryâ??s patient journeyâ??examining symptoms, diagnosis timelines, diagnosis rates, and cases of misdiagnosis. These journeys present unique challenges in India and Southeast Asia compared to countries with more developed healthcare infrastructures. Weâ??re working to identify where Takeda can make a difference, often in collaboration with public and private partners, not only through access to medicine programs but also through patient affordability programs, diagnostics, transportation, and other real-world barriers patients face daily.

Compared to the US and Europe, how different does your approach to bringing innovative products to market need to be in I-SEA?

In I-SEA, we often take a creative and holistic approach, recognizing that each country, and even regions within a country, present distinct challenges. We avoid a one-size-fits-all approach and instead focus on understanding specific local patient journeys and barriers. This allows us to determine where Takeda can truly add value and make a meaningful and sustainable impact and where we cannot.

This is where partnerships are crucial. Drawing on our 242-year heritage in Japan, we collaborate with local experts, as we did for example by partnering rare disease specialists in Japan with those in Vietnam. Together, weâ??ve built diagnostic infrastructure that now allows for HAE diagnosis in Vietnam, where previously there was none. This kind of sustainable, impactful work depends on connecting with local infrastructure and tailoring our efforts to each unique setting.

What are your main priorities in the coming years?

We only started our first dengue vaccine launches last year, so weâ??re still in the early stages of this journey. At present, weâ??re focused on obtaining additional regulatory approvals in countries like India, Philippines, and Singapore, and continuing to broaden access to the vaccine across the region. A major priority is laying the groundwork for inclusion in national immunization programs, as thatâ??s where we can make the most significant public health impact. Our ultimate goal is for people to have the broadest access to the vaccine, which can be achieved through national programs that allow for a greater reach.

Beyond dengue, weâ??re also preparing dozens of new launches in the coming years across oncology, gastroenterology, plasma-derived therapies, neuroscience, and rare diseases. Iâ??m passionate about this because our industry thrives on bringing innovative healthcare solutions to areas where they donâ??t yet exist. And ultimately, our patient and value-based culture drives us to ensure patients actually receive these treatments. This means implementing sustainable, patient-centred access programs that go beyond just priceâ??considering the entire patient journey and affordability to make our medicines as broadly available as possible. Thatâ??s both the challenge and the reward of our work.

Do you have a final message on behalf of Takeda I-SEA?

India and Southeast Asia together represent two billion peopleâ??a quarter of the worldâ??s population. With such vast numbers, there are lots of patients, many of whom remain undiagnosed or go undiagnosed for extended periods of time. Fortunately, the fundamentals in this regionâ??regulatory reforms, healthcare infrastructure, funding and innovationâ??are advancing rapidly. Although these changes wonâ??t happen overnight, the pace is moving quickly and

positively in the right direction and its great to be a small part of it.

Providing innovative vaccines and therapeutic solutions here is a huge responsibility, but the current direction of change within each country creates a unique opportunity. Our approach is deeply guided by our values-based cultureâ??focusing on patients, trust, reputation, and sustainable business growth, in that order. Patient access is absolutely fundamental to our strategy, and we aim to reach millions more patients in this region. This commitment to access sets us apart, as it is deeply woven into our strategy.

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