Dengue Vaccines: An Update on Research and Development Efforts

History of Dengue and the Search for an Effective Vaccine

Dengue fever is a mosquito-borne viral disease that is common in tropical and subtropical regions around the world. With increasing globalization and urbanization, dengue virus has spread to new areas and incidence of the disease has grown dramatically in recent decades. The World Health Organization estimates that as many as 100 million dengue infections now occur annually. Four distinct, but closely related, serotypes of the virus can cause dengue (DENV-1, DENV-2, DENV-3 and DENV-4). Infection with one serotype usually provides lifelong immunity against that serotype, but only short-term protection against the others. This means a person can potentially be infected four separate times. While most cases are mild, infection in some cases leads to a more severe form of the disease called dengue hemorrhagic fever that can be lethal.

Attempts to develop a safe and effective **Dengue Vaccines** date back to the mid-20th century. However, the complex pathology of the virus presented many challenges. Traditional live attenuated and inactivated vaccine approaches showed little efficacy or led to antibody dependent enhancement where the vaccine actually increased severity of disease. In more recent decades, major pharmaceutical companies and research institutions have invested significant resources into new vaccine technologies and platforms with the goal of finally conquering this global health threat.

Leading Candidates and Regulatory Progress

Since 2014, two dengue vaccine candidates have received regulatory approvals and entered widespread use. Sanofi Pasteur's CYD-TDV, marketed as Dengvaxia, was the first dengue vaccine to win approval from several national regulatory agencies based on pivotal Phase 3 trials. However, its efficacy was later found to vary significantly based on prior dengue exposure history. In those without prior exposure, it showed a possibility of increasing severity of disease. As a result, the vaccine is now only recommended in select groups where benefit clearly outweighs risk.

Takeda's TAK-003 is a live attenuated tetravalent dengue vaccine developed using its cell

culture-based technology. Large Phase 2 and 3 studies demonstrated safety and efficacy above the WHO thresholds. In 2019-2020, it received approval in countries across Latin America and Asia making it the second dengue vaccine option. However, both CYD-TDV and TAK-003 still have limitations including the need for multiple doses and varying protection levels against different virus serotypes.

Ongoing Efforts to Improve Vaccine Candidates

Given the issues seen with the first generations, researchers continue working to develop even better next-generation dengue vaccines. Multiple candidates are currently in clinical trials. The U.S. Army is advancing TV003/TV005, an attenuated, live recombinant dengue vaccine produced in Vero cells. Phase 1 and 2 studies met primary endpoints of safety and immunogenicity and a Phase 3 trial began recruiting in 2020 across multiple Asian and Latin American countries. The NIH is supporting development of a similar approach from Inviragen using a chimeric yellow fever-dengue vaccine platform.

Several programs are also looking at novel platforms to better mimic natural immunity. India's Bharat Biotech is investigating an intranasally delivered live-attenuated vaccine candidate in early trials. Hawaii Biotech is developing an inactivated whole virus vaccine that could provide broader protection. Meanwhile, companies like Merck and Emergent BioSolutions are working on purified inactivated virus vaccine candidates.

While progress is being made, challenges remain in achieving simultaneous protection against all four serotypes, improving immunogenicity after a single dose and developing vaccines that are safe for vulnerable groups such as children, the elderly or those with underlying conditions. Continued scientific innovation and clinical collaboration will be crucial factors in finally conquering this important tropical disease.

Manufacturing and Business Considerations

With approval of the first dengue vaccines, attention is turning to the commercial and manufacturing aspects required for large-scale roll-out in endemic regions. Both Sanofi and Takeda are ramping up vaccine production capacity to meet demand across Asia and Latin America. However, procurement remains an obstacle for some lower-income countries that bear a large share of the disease burden. Industry analysts estimate the annual addressable market for dengue vaccines could exceed $1 billion once programs are established in all suitable areas.

A key question is whether the current approved vaccines will be sufficient to protect this large

population over the long run or if next-generation candidates offering improved value propositions will be needed. Global health agencies have suggested combination strategies using both available vaccines may help maximize impact. Manufacturers are seeking regional and global procurement agreements with ministries of health and organizations like PAHO and the WHO to help streamline access. While dengue vaccination programs have now begun, continued progress against this viral disease will be judged over the coming decades. Scientific advancement and effective vaccination implementation will be vital in changing the epidemiology of dengue virus infections worldwide.

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Alice Mutum is a seasoned senior content editor at Coherent Market Insights, leveraging extensive expertise gained from her previous role as a content writer. With seven years in content development, Alice masterfully employs SEO best practices and cutting-edge digital marketing strategies to craft high-ranking, impactful content. As an editor, she meticulously ensures flawless grammar and punctuation, precise data accuracy, and perfect alignment with audience needs in every research report. Alice's dedication to excellence and her strategic approach to content make her an invaluable asset in the world of market insights.
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