

## Vimkunya – Hope Against Chikungunya: Science, Safety, and Access

To the Editor:

Chikungunya virus (CHIKV) is a mosquito-borne alphavirus that originated over 500 years ago in Africa and was later introduced to Asia. It is contracted from the bite of a female mosquito of the *Aedes* species, particularly *Aedes aegypti* and *Aedes albopictus*,<sup>1</sup> and is endemic in regions of Africa, Asia, and the Americas. Vertical transmission—the transmission of a disease from a pregnant individual to the fetus—is rare. While 3% to 28% of the cases are asymptomatic,<sup>1</sup> symptoms are typically characterized by sudden fever associated with joint pain, headache, and skin rash. Among the infected, a significant proportion may experience severe muscle pain and long-lasting joint pain that can persist in the chronic phase of the disease.<sup>2</sup>

Until the development of Vimkunya, a chikungunya virus virus-like particle (VLP) vaccine, patients who contracted CHIKV were treated primarily with anti-inflammatory medications aimed at symptom relief.<sup>1</sup> However, the development of Vimkunya—the second vaccine approved by the US Food and Drug Administration (FDA) for CHIKV—offers a preventive intervention through induction of a seroprotective antibody response.<sup>3</sup>

Vimkunya is a novel adjuvanted recombinant vaccine containing CHIKV virus-like particles adsorbed onto aluminum hydroxide. The virus-like particles consist of envelope proteins E1 and E2 and CHIKV capsid protein (C), which are derived from the CHIKV Senegal strain 37997.<sup>3</sup> The vaccine triggers the production of neutralizing antibodies as early as 22 days after vaccination, with immunity sustained up to 183 days, offering robust protection against CHIKV disease.<sup>3</sup> Approved on February 14, 2025, under the FDA's accelerated approval pathway, the vaccine is indicated for individuals aged 12 years and older and is administered as a single 0.8-mL intramuscular dose.<sup>4</sup>

Prior to approval, 2 pivotal clinical trials evaluated the vaccine's immunogenicity: one registered as NCT05072080, enrolling 3258 individuals aged 12 to 64, and registered as NCT05349617, enrolling 413 participants aged 65 years and older in the United States. Because these trials

were conducted outside endemic regions, they assessed immunogenicity rather than clinical efficacy, using neutralizing antibody titers as the primary endpoint. High geometric mean titers and seroresponse rates demonstrated a strong immune response in both studies.<sup>4</sup> The FDA's accelerated approval was based on these antibody levels, and the indication will remain valid until August 31, 2030, unless confirmatory trials demonstrate additional clinical benefit—such as improved immune response and tolerability.<sup>4</sup>

In the NCT05072080 trial, a single dose of Vimkunya induced a robust immune response, with 97.8% of participants achieving protective antibody levels within 24 days.<sup>5</sup> Although true clinical efficacy could not be measured in a non-endemic setting, this high seroconversion rate suggests the vaccine is likely to reduce infection risk once deployed in endemic areas. The vaccine was generally well tolerated, with common side effects including headache, fatigue, muscle and joint pain, and fever—most of which were mild to moderate and resolved within a few days. Importantly, no severe adverse events were reported, reinforcing Vimkunya's favorable safety profile and acceptable risk-benefit ratio.<sup>3,6</sup> As a recently approved CHIKV vaccine, Vimkunya represents a critical advancement in combating this debilitating mosquito-borne disease.

Vimkunya is particularly important for people living in regions where mosquito-borne diseases are common, including parts of Asia, Africa, and Latin America. While CHIKV is not currently causing widespread hospital strain in these regions, populations remain at high risk of infection. This is supported by recent Centers for Disease Control and Prevention surveillance data, which document the continued presence and geographic spread of CHIKV.<sup>7</sup> However, making the vaccine widely accessible remains a challenge due to the high costs and limited supply in low- and middle-income countries. Future studies should examine the duration of immunity and evaluate whether it could be incorporated into routine vaccination programs. Although this vaccine represents a major step forward in addressing mosquito-borne diseases, expanded funding and global distribution support are essential to ensure equitable access and to help control future outbreaks.

—Muhammad Affan Abid, MBBS; Ashmat Naqvi, MBBS; Muhammad Taha Kamal, MBBS; Muhammad Ali Kamal, MBBS

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