CHIKUNGUNYA

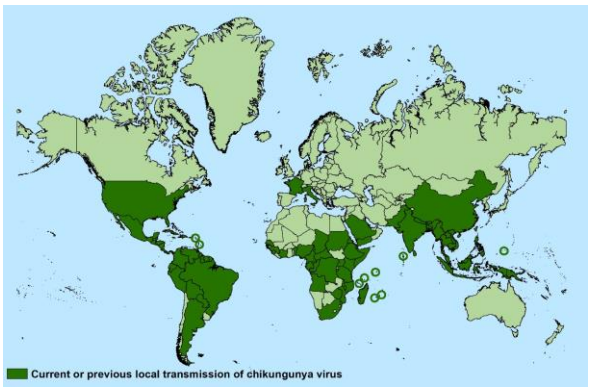
WHAT IS CHIKUNGUNYA?

Chikungunya is a mosquito-borne viral disease spreading in the Americas and to Europe[1], caused by the chikungunya virus (CHIKV), a *Togaviridae* virus transmitted by *Aedes* mosquitoes.

WHO IS AT RISK?

Chikungunya outbreaks have been reported in Asia, Africa, the Americas and recently (2017) in Europe[1]. As of September 2020, there have been more than 3 million reported cases in the Americas[2] and the economic impact is significant (e.g. Colombia outbreak 2014: $73.6m[3]). The medical and economic burden is expected to grow as mosquitos, the primary vectors of CHIKV, continue to further spread geographically.

COUNTRIES AND TERRITORIES WHERE CHIKUNGUNYA CASES HAVE BEEN REPORTED



Data as of October 30, 2020 and does not include countries or territories where only imported cases have been documented. [1]

SYMPTOMS & DIAGNOSIS

Clinical symptoms include acute onset of fever, debilitating joint and muscle pain, headache, nausea and rash, potentially developing into long-term, serious health impairments. Chikungunya virus causes clinical illness in 72–97%[4] of infected humans around four to seven days after an infected mosquito bite. Complications resulting from the disease include musculoskeletal, neurological, visual, cardiovascular, dermatological and gastrointestinal manifestations; fatalities have been reported in newborns, adults with underlying conditions and older people[5] .

TREATMENT & PREVENTION

There are no preventive vaccines or effective treatments available and, as such, chikungunya is considered to be a major public health threat [6].

VALNEVA'S VACCINE CANDIDATE - VLA1553

To Valneva's knowledge, VLA1553 is currently the only chikungunya vaccine candidate in Phase 3 clinical trials that targets long-term protection following the administration of a single dose.

VLA1553 is a live-attenuated, single dose vaccine candidate targeting the chikungunya virus. The target population segments are travelers, military personnel and individuals living in endemic regions.

VLA1553 received Fast Track designation [7] and Breakthrough Therapy designation [8] from the FDA and PRIME designation from the EMA [9].

Complete Phase 1 data were published in the peer-reviewed medical journal *The Lancet Infectious Diseases* in June 2020 [10].

POSITIVE TOPLINE RESULTS FROM PIVOTAL PHASE 3 TRIAL REPORTED [11]

- The trial, involving 4,115 adults, aged 18 years and above, across 44 sites in the U.S., met its primary endpoint inducing protective CHIKV neutralizing antibody titers in 98.5% of participants 28 days after receiving a single shot.
- VLA1553 was also highly immunogenic in elderly subjects, who achieved equally high seroprotection rates and neutralizing antibody titers as younger adults, as well as an equally good safety profile.
- VLA1553 was also generally well tolerated among the subjects evaluated for safety.
- The trial will continue towards final analysis including the 6-month safety data.

To make the vaccine candidate VLA1553 more accessible to Low and Middle Income Countries (LMIC), Valneva and Instituto Butantan in Brazil signed an agreement for the development, manufacturing and marketing of the vaccine candidate VLA1553. The collaboration falls within the framework of the funding agreement between Valneva and the Coalition for Epidemic Preparedness Innovations (CEPI) signed in July 2019, which provides funding of up to $23.4 million [12].

1. CDC – Chikungunya Virus Geographic Distribution
2. PAHO/WHO data: Number of reported cases of chikungunya fever in the Americas
3. Cardona-Ospina et al., Trans R Soc Trip Med Hyg 2015
4. CDC Yellow Book Chapter 4 Chikungunya: https://wwwnc.cdc.gov/travel/yellowbook/2020/travel-related-infectious-diseases/chikungunya
5. Weaver SC, Osorio JE, Livengood JA, Chen R, Stinchcomb DT. Chikungunya virus and prospects for a vaccine. Expert Rev Vaccines 2012;11:1087–101. doi:10.1586/erv.12.84.
6. Moizéis RNC et al. Chikungunya fever: a threat to global public health. Pathog Glob Health. 2018 Jun;112(4):182-194. doi: 10.1080/20477724.2018.1478777.
7. Valneva Awarded FDA Fast Track Designation for Chikungunya Vaccine Candidate
8. Valneva Awarded FDA Breakthrough Designation for its Single-Shot Chikungunya Vaccine Candidate
9. Valneva's Chikungunya Vaccine Candidate Awarded EMA Prime Designation
10. Valneva Announces Publication in The Lancet of Complete Phase 1 Data for its Single-Shot Chikungunya Vaccine Candidate
11. Valneva Announces Positive Phase 3 Pivotal Results for its Single-Shot Chikungunya Vaccine Candidate
12. Valneva and Instituto Butantan Sign Final Agreement on Single-Shot Chikungunya Vaccine for LMIC