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 May 29, 2018 and does not include countries or territories where only imported cases have been documented. [1]

References

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. Simon F, Javelle E, et al. French guidelines for the management of chikungunya (acute and persistent presentations). November 2014. Médecine Mal Infect 2015;45:243–63. doi:10.1016/j.medmal.2015.05.007.
6. 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. Valneva PR: Valneva Awarded FDA Fast Track Designation for Chikungunya Vaccine Candidate
7. Valneva PR: Valneva initiates Phase 3 clinical study for its chikungunya vaccine candidate VLA1553
8. Valneva PR: Valneva Reports Positive End-of-Phase 2 Chikungunya Meeting with the U.S. FDA; Sets Stage for Phase 3 Study
9. Valneva PR: Valneva Reports Excellent Final Phase 1 Results for Chikungunya Vaccine Vandidate
10. Valneva PR: Valneva Announces Publication in The Lancet of Complete Phase 1 Data for its Single-Shot Chikungunya Vaccine Candidate
11. Valneva PR: CEPI awards up to US$23.4 million to Valneva for late-stage development of a single-dose chikungunya vaccine
12. Valneva PR: Valneva to Partner with Instituto Butantan on Single-Shot Chikungunya Vaccine for Low- and Middle-Income Countries

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 60–80%[4] of infected humans around four to seven days after an infected mosquito bite. Complications resulting from the disease include visual, neurological, heart and gastrointestinal manifestations; fatalities have been reported[5] in newborns, adults with underlying conditions and older people.

TREATMENT & PREVENTION

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

VALNEVA'S VACCINE CANDIDATE - VLA1553

VLA1553 is a unique single-shot vaccine candidate against chikungunya.

VLA1553 is a monovalent, single dose, live-attenuated vaccine candidate for protection against chikungunya. The vaccine candidate is designed for prophylactic, active immunization against chikungunya in humans over one year old. The vaccine candidate is targeted to provide long-lasting protection and an anticipated safety profile similar to licensed vaccines for active immunization in adults and children.

The target population segments are travelers, military personnel and individuals at risk living in endemic regions.

VLA1553 was granted Fast Track designation by the FDA in December 2018[6].

Pivotal Phase 3 study initiated

- In September 2020, Valneva initiated a pivotal Phase 3 trial for VLA1553 [7], which is being conducted in the U.S. The outcome of this study, if positive, shall provide the basis for licensure of the vaccine.
- Valneva held an End-of-Phase 2 meeting with the U.S. FDA during the first quarter of 2020 [8]
- Valneva previously reported excellent Phase 1 results for VLA1553. The final Phase 1 results up to Month 13 showed an excellent immunogenicity and safety profile for Valneva's unique, single-shot vaccine candidate [9].
- Complete Phase 1 data were published in the peer-reviewed medical journal *The Lancet Infectious Diseases* in June 2020 [10].

In July 2019, Valneva received a $23.4 million funding from the Coalition for Epidemic Preparedness Innovations (CEPI) to support the development of a chikungunya vaccine in Low and Middle Income Countries (LMIC) [11]. Within the framework of this funding, Valneva and the Butantan Institute in Brazil announced the signing of a binding term sheet for the development, manufacturing and marketing of Valneva's single-shot chikungunya vaccine VLA1553 in LMIC [12].