

PRODUCT DNA vaccine for SFTSV

INDICATION

Severe fever thrombocytopenia syndrome (SFTS); infectious disease; tick virus

VALUE PROPOSITION

• First-in-class DNA vaccine to induce immune response

DEVELOPMENT STAGE

- *In vivo* proof-of-concept established.
- Animal safety and efficacy data completed

INTELLECTUAL PROPERTY

Patent application submitted

RELATED PUBLICATIONS

Kwak, Jeong-Eun et al. "Development of a SFTSV DNA vaccine that confers complete protection against lethal infection in ferrets." <u>Nature</u> <u>communications</u> vol. 10,1 3836. 23 Aug. 2019,

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DNA Vaccine for SFTSV

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UNMET NEED

Severe fever with thrombocytopenia syndrome (SFTS) first reported in 2012 is a newly emerging tick-borne infectious disease, endemic to China, South Korea, and Japan caused by the SFTS virus (SFTSV), a bunyavirus which is a single-stranded negativesense RNA virus with three genomic segments, namely L, M, and S. Similar to other bunyaviruses, the L segment encodes the viral RNA-dependent RNA polymerase, the M segment encodes the two viral envelope glycoproteins (GPs) Gn and Gc, and the S segment encodes a nucleocapsid protein (N) and non-structural proteins (NSs). SFTSV is transmitted by the tick as the predominant vector. It can also be transmitted through direct contact with blood and other body fluids from infected individuals. The clinical manifestation of SFTS is characterized by fever, thrombocytopenia, and leukocytopenia, as well as vomiting, diarrhea, and multi-system organ failure often accompanied by hemorrhage. The incidence of SFTS has rapidly increased from 2012 to present. Moreover, the spread of the tick vector to North America increases the potential for outbreaks of the disease beyond Asia. Therefore, the World Health Organization (WHO) has included SFTSV in its list of priority target pathogens requiring urgent attention. More importantly, there are no current effective vaccines against SFTSV.

SOLUTION

Researchers at Cleveland Clinic have developed a novel SFTSV DNA Vaccine and validated its immunogenicity and efficacy. Vaccine candidate induces both a neutralizing antibody response and multifunctional SFTSV-specific T cell response in mice and ferrets. An immunocompetent age-dependent ferret model was designed and used to mimic age-related clinical manifestations of SFTSV. Results indicate that the developed DNA vaccine conferred complete protection against lethal SFTSV infection in ferrets as well as the prevention of any clinical signs of SFTSV.

In conclusion, the current vaccine developed is first of its kind DNA vaccine tested both for immunogenicity and efficacy in a lethal infection ferret model. Lastly, the advantages of DNA vaccines over traditional vaccines include the relative ease of development and the ability to induce broad immunity to multiple antigens, in addition to stimulating both T cell and antibody immunity, which make them suitable for the development of vaccines against emerging pathogens.

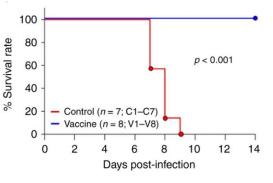


Fig 1. SFTSV vaccines confer complete protection against lethal SFTSV challenge in ferrets. Survival of vaccinated (n = 8, blue line) and non-vaccinated control (n = 7, red line) ferrets after lethal SFTSV challenge.