Zifivax (ZF2001) COVID-19 Vaccine

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Zifivax (ZF2001) COVID-19 Vaccine Description

ZifiVax ZF2001 (ZF-UZ-VAC-2001) is a protein subunit vaccine using a dimeric form of the receptor-binding domain (RBD) as the antigen, a harmless piece of the SARS-Cov-2 virus.

The ZF2001 recombined vaccine encodes the SARS-CoV-2 RBD antigen (residues 319–537, accession number YP_009724390), with two copies in tandem repeat dimeric form, and was manufactured in the CHOZN CHO K1 cell line (Sigma-Aldrich Trading; Shanghai, China) as a liquid formulation containing 25 μg or 50 μg per 0·5 mL in a vial, with aluminum hydroxide as the adjuvant.

In phase 1 and phase 2 trials, researchers found that vaccination with the ZF2001 25 or 50 μg doses and two-dose or three-dose schedules was well tolerated. The frequency of adverse events between the vaccine and placebo groups was similar in both phase 1 and phase 2. Most adverse events were mild or moderate, with the most common being injection-site pain, redness, and swelling. These adverse events are anticipated for alum-adjuvanted protein subunit vaccines and were transient and resolved within 3–4 days after vaccination.

ZF2001 has received emergency use authorization in China, Indonesia, and Uzbekistan and is rolling out a three-dose vaccination regimen.

The vaccine was jointly developed by the Institute of Microbiology, the Chinese Academy of Sciences, and Anhui Zhifei Longcom Biopharmaceutical. The vaccine was manufactured according to good manufacturing practice guidelines by Anhui Zhifei Longcom Biopharmaceutical.

DrugBank Accession Number: DB15893. This vaccine may also be referred to as RBD-Dimer, Zifivax.

Zifivax (ZF2001) COVID-19 Vaccine Indication

ZF2001 COVID-19 Vaccine is indicated to prevent COVID-19 severe disease from the SARS-CoV-2 virus.

In February 2021, lab studies of twelve serum samples taken from recipients of ZF2001 retained neutralizing activity against the Beta variant, although with weaker activity than against the original virus. For ZF-2001, geometric mean titers declined by 1.6-fold, from 106.1 to 66.6, less than antisera from mRNA vaccine recipients with a 6-folds decrease.

Zifivax (ZF2001) COVID-19 Vaccine Effectiveness Against Virus Variants

Media reported in late August 2021; a Phase III trial showed ZF 2001 had an efficacy of 93% against the Alpha variant and 78% efficacy against the Delta variant. And in July 2021, lab studies showed ZF2001 retained neutralizing effects against B.1.429, B.1.351, P.1, B.1.525, B.1.617.1; the neutralizing titers decreased from 1.1 fold to 2.1 fold.

Zifivax (ZF2001) COVID-19 Vaccine Dosage

ZF2001 COVID-19 Vaccine is currently in several clinical trials to determine the proper dosage and the number of vaccines required to obtain maximum antibodies. The safety and immunogenicity data from the phase 1 and 2 trials support using the 25 μg dose in a three-dose schedule in an ongoing phase 3 trial for large-scale evaluation of ZF2001's safety and efficacy.

The participants with an extended interval between the second and third doses (doses at 0, 1, and 4–6 months) showed higher neutralizing activity and resilience to variants than those with shorter intervals (doses at 0, 1, and 2 months; appendix pp 5–6), which is consistent with the previous study of neutralization of the SARS-CoV-2 beta variant by ZF2001-elicited antisera. The better performance of the extended interval regimen is probably because of the longer antibody maturation in the recipients than in those with the shorter interval regimen. Our data are consistent with the common practice of using the 0, 1, and 6 months regimen for subunit vaccines against diseases such as hepatitis B and guide to optimizing the vaccination regimen further.

Zifivax (ZF2001) COVID-19 Vaccine Side effects

In the phase 1 trial, six (60%) of ten participants in the placebo group, 14 (70%) of 20 in the 25 μg group, and 18 (90%) of 20 in the 50 μg group reported at least one adverse event within 30 days after vaccination, with no significant between-group differences. In the phase 2 trial, the overall frequency of adverse events was low within 30 days after vaccination.

Zifivax (ZF2001) COVID-19 Vaccine News

January 10, 2022 - The AP reported Indonesian authorities granted emergency authorization for the use of five different COVID-19 vaccines as booster shots that will prioritize vulnerable groups. Penny Lukito, head of Indonesia's Food and Drug Monitoring Agency, said the Zifivax vaccine would be distributed as a third vaccine shot in the country.

October 8, 2021 - Indonesia's drug and food authority BPOM confirmed it had issued an emergency use authorization for the Zifivax COVID-19 vaccine produced by Anhui Zhifei Longcom.

August 20, 2021 - The Lancet published - Neutralisation of ZF2001-elicited antisera to SARS-CoV-2 variants. We provide preliminary evidence of the approved RBD-based protein subunit vaccine for its neutralization profile to SARS-CoV-2 variants. The high susceptibility of these new variants to the ZF2001 vaccine supports the method of mass immunization to build herd immunity. However, the vaccine effectiveness against these variants must be validated by phase

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Zifivax (ZF2001) COVID-19 Vaccine Clinical Trials

A more extensive Phase 3 clinical trial is underway to Determine the Safety and Efficacy of ZF2001, a Recombinant Novel Coronavirus Vaccine (CHO Cell) for the Prevention of COVID-19.

ClinicalTrials.gov Identifier: NCT04646590 - A Phase III Clinical Trial to Determine the Safety and Efficacy of ZF2001 for Prevention of COVID-19. Last updated on May 7, 2021.

A Randomized, Blinded, Placebo-controlled Phase 2 Trial to Evaluate the Immunogenicity and Safety of a Recombinant New Coronavirus Vaccine (CHO Cell) With Different Doses and Different Immunization Procedures in Healthy People Aged 18 to 59 Years (/clinical-trials/clinical-study-recombinant-novel-coronavirus-vaccine)

VACCINE DATA

Condition: COVID-19

Drug Class: Adjuvanted protein subunit vaccine

NAME

Brand: Zifivax

Generic: ZF2001

Abbreviation: RBD-Dimer

MANUFACTURER

Anhui Zhifei Longcom Co., Ltd.

Country ID: CN

CODE

ChemSpider ID: 26077-31-6

ChEMBL ID: 2609662-31-7

Accession Number: DB15893

STATUS

Status: Authorized

Availability: China, Uzbekistan

CELL LINES

Design & Development: HEK293T cells

Production: CHO Hamster Cells

Confirmatory Lab Tests: Pseudovirus HEK293T cells

CLINICAL TRIALS

Clinical Trial Phase I: Phase I Trial of a Recombinant COVID-19 Vaccine (CHO Cell)

Clinical Trial Phase II: Clinical Study of Recombinant Novel Coronavirus Vaccine

Clinical Trial Phase III:
A Phase III Clinical Trial to Determine the Safety and Efficacy of ZF2001 for Prevention of COVID-19

EXTERNAL DATA

Side Effects: Phase 2 study

Ingredients: Phase 3 Study

Countries: Uzbekistan
China
Indonesia

NEW VAX DATA

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→ Novavax Nuvaxovid COVID-19 Vaccine (/vaccines/novavax-nuvaxovid-covid-19-vaccine)

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→ Prevnar 13 Pneumococcal Vaccine (/vaccines/prevnar-13-pneumococcal-vaccine)

→ PAXLOVID Oral Antiviral (PF-07321332) (/vaccines/paxlovid-oral-antiviral-pf-07321332)

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