「 Pfizer/BioNTech's COVID-19 vaccine has 100% effectiveness in adolescents clinically」

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Pfizer and BioNTech today announced that, in a Phase 3 trial in adolescents 12 to 15 years of age with or without prior SARS-CoV-2 infection, the Pfizer-BioNTech COVID-19 vaccine BNT162b2 demonstrated 100% efficacy and robust antibody responses, exceeding those recorded earlier in vaccinated participants aged 16 to 25 years old, and was well tolerated. These are topline results from a pivotal Phase 3 trial in 2,260 adolescents.

The trial enrolled 2,260 adolescents 12 to 15 years of age in the United States. In the trial, 18 cases of COVID-19 were observed in the placebo group (n=1,129) versus none in the vaccinated group (n=1,131). Vaccination with BNT162b2 elicited SARS-CoV-2–neutralizing antibody geometric mean titers (GMTs) of 1,239.5, demonstrating strong immunogenicity in a subset of adolescents one month after the second dose. This compares well (was non-inferior) to GMTs elicited by participants aged 16 to 25 years old (705.1 GMTs) in an earlier analysis. Further, BNT162b2 administration was well tolerated, with side effects generally consistent with those observed in participants 16 to 25 years of age.

The companies plan to submit these data to the FDA and EMA for a requested amendment to the Emergency Use Authorization of BNT162b2 and the EU Conditional Marketing Authorization for COMIRNATY® to expand use in adolescents 12-15 years of age as quickly as possible. All participants in the trial will continue to be monitored for long-term protection and safety for an additional two years after their second dose.

“We share the urgency to expand the authorization of our vaccine to use in younger populations and are encouraged by the clinical trial data from adolescents between the ages of 12 and 15,” said Albert Bourla, Chairman and Chief Executive Officer, Pfizer. “We plan to submit these data to FDA as a proposed amendment to our Emergency Use Authorization in the coming weeks and to other regulators around the world, with the hope of starting to vaccinate this age group before the start of the next school year.”

“Across the globe, we are longing for a normal life. This is especially true for our children. The initial results we have seen in the adolescent studies suggest that children are particularly well protected by vaccination, which is very encouraging given the trends we have seen in recent weeks regarding the spread of the B.1.1.7 UK variant. It is very important to enable them to get back to everyday school life and to meet friends and family while protecting them and their loved ones,” said Ugur Sahin, CEO and Co-founder of BioNTech.

Mar 30, Pfizer and BioNTech dosed the first healthy children in a global Phase 1/2/3 seamless study to

further evaluate the safety, tolerability, and immunogenicity of the Pfizer-BioNTech COVID-19 vaccine in children 6 months to 11 years of age. The study is evaluating the safety, tolerability, and immunogenicity of the Pfizer-BioNTech COVID-19 vaccine on a two-dose schedule (approximately 21 days apart) in three age groups: children aged 5 to 11 years, 2 to 5 years, and 6 months to 2 years. The 5- to 11- year-old cohort started dosing last week and the companies plan to initiate the 2- to 5- year-old cohort next week. It is expected that clinical data will be released in the second half of this year, and it will be administered to children in early 2022.

Reference:

1. 2021 Mar 31 "PFIZER-BIONTECH ANNOUNCE POSITIVE TOPLINE RESULTS OF PIVOTAL COVID-19 VACCINE STUDY IN ADOLESCENTS" *Pfizer News Press.*
2. U.S. Food and Drug Administration, FDA: https://www.fda.gov/