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Pfizer and Moderna COVID-19 vaccines – FDA advisors discuss emergency use authorization request for children 6 months to 4 or 5 years

- On June 15, 2022, the Food and Drug Administration (FDA) convened a Vaccine and Biologic Products Advisory Committee (VRBPAC) to discuss an Emergency Use Authorization (EUA) to prevent COVID-19 for Moderna's vaccine in individuals 6 months to 5 years of age and Pfizer's vaccine in individuals 6 months to 4 years of age.
    - The Moderna COVID-19 vaccine is administered as a 2-dose series (25 mcg each dose) in children 6 months to 5 years of age.
    - The Pfizer COVID-19 vaccine is administered as a 3-dose series (3 mcg each dose) in children 6 months through 4 years of age.

- As of June 2, 2022, there have been 442 deaths from COVID-19 in children 0 to 4 years. This is a higher rate of deaths than seen with other vaccine preventable diseases such as influenza, varicella, etc.

- For the Moderna vaccine, one randomized, observer-blind study was conducted. Study 204 enrolled 6,403 children between 6 months and 5 years to receive Moderna COVID-19 vaccine 25 mcg (2 doses given 28 days apart) or placebo. This portion of Study 204 was conducted when the omicron variant was predominant.
    - Reported local and systemic reactions were lower in this age group vs. older children and adults. Fever was reported in ~25% of participants, mostly grade 1-2 with a short duration. Vaccine immunogenic, geometric mean neutralizing concentrations (GMCs) and seroresponse rates were non-inferior to young adults (18-25 years). Vaccine efficacy was reported as 50.6% in 6 – 23 months and 36.8% in 2 – 5 years.
    - A booster dose (or 3rd dose) of the Moderna vaccine for this age group is currently being studied. Data is expected in July 2022.

- For the Pfizer vaccine, one randomized, observer-blind study was conducted enrolling 4,526 children between 6 months and 4 years to received Pfizer COVID-19 vaccine 3 mcg (3 doses with 21 days between dose 1 and 2 and 3rd dose given at least 8 weeks after 2nd dose). Omicron was predominant during the period of dose 3.
    - Potential angioedema and hypersensitivity comprising mainly urticarias and rashes were the most predominant reactions reported, and these systemic reactions were similar to placebo. Geometric mean titer (GMT) and seroresponse rates were non-inferior to young adults (16-25 years). Vaccine efficacy was reported as 75.5% in 6 – <24 months and 82.3% in 2 – < 5 years after the third dose.

- Although these efficacy rates are lower compared to adult and adolescent vaccines, it is important to note that the trials were conducted when the omicron variant was predominant whereas the adult and adolescent vaccines were tested when the original strain of COVID was predominant. The adult and adolescent vaccines also had decreased efficacy against the omicron variant.

- No cases of myocarditis or pericarditis were reported for the Moderna or Pfizer vaccine in these age groups. Fever, other respiratory infections, and additional adverse events will continue to be monitored.

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- The Committee was asked to consider the totality of the available data supporting the vaccines for potential EUA approvals.

    — For the Moderna vaccine, the Committee voted unanimously in favor of the 2-dose series (25 mcg each dose) given 28-days apart in children 6 months to 5 years of age.
    — For the Pfizer vaccine, the Committee voted unanimously in favor of the 3-dose series (3 mcg each dose) given 21 days apart for dose 1 and 2 and at least 8 weeks after dose 2 for the 3rd dose for children 6 months to 4 years of age.

What's Next?

- The FDA will review the EUA request and the recommendations of the VRBPAC. Then the FDA will either approve or deny the EUA requests for the Moderna COVID-19 vaccine for ages 6 months – 5 years of age and the Pfizer COVID-19 vaccine for ages 6 months – 4 years of age.

- If the FDA approves the EUAs for the Moderna COVID-19 vaccine for ages 6 months – 5 years of age and the Pfizer COVID-19 vaccine for ages 6 months – 4 years of age, then the CDC will convene its Advisory Committee for Immunization Practices (ACIP) to review and make recommendations for who should receive this vaccine. The next ACIP meeting is scheduled for June 17 and 18.

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