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Moderna COVID-19 vaccine – FDA advisors discuss emergency use authorization request for 6 - 17 years of age

- On June 14, 2022, the Food and Drug Administration (FDA) convened a Vaccine and Biologic Products Advisory Committee (VRBPAC) to discuss an Emergency Use Authorization (EUA) for Moderna's vaccine to prevent COVID-19 in individuals 6 – 17 years of age.

    — The Moderna COVID-19 vaccine is administered as a 2-dose series (100 mcg each dose) in adolescents 12 through 17 years of age.
    — The Moderna COVID-19 vaccine is administered as a 2-dose series (50 mcg each dose) in children 6 through 11 years of age.

- Two randomized, double-blind studies were conducted: Study 203 enrolled 3,732 adolescents between 12 and 17 years of age to receive Moderna COVID-19 vaccine 100 mcg (2 doses given 28 days apart) or placebo, and Study 204 enrolled 4,016 children between 6 and 11 years of age to receive Moderna COVID-19 vaccine 50 mcg (2 doses given 28 days apart) or placebo. Study 203 was conducted when the original strain was most common. Study 204 was conducted when the delta variant was predominant.

    — For Study 203, solicited adverse reactions were mostly grade 1-2 with a median duration of 2-3 days. No deaths or myocarditis/pericarditis were reported through 11.1 months median follow-up. Geometric mean titers (GMTs) and seroresponse rates were non-inferior to young adults (18-25 years). Vaccine efficacy was reported as 93.3%.
    — For Study 204, solicited adverse reactions were mostly grade 1-2 with a median duration of 2-3 days. No deaths or myocarditis/pericarditis were reported through 5.6 months of follow-up. GMTs and seroresponse rates were non-inferior to young adults (18-25 years). Vaccine efficacy was reported as 88%.

- There was discussion about the safety of the Moderna COVID-19 vaccine in ages 6 – 17 years of age because of a potential safety signal for myocarditis/pericarditis, a reaction that has been observed with the mRNA COVID-19 vaccines (Comirnaty® and Spikevax®) especially in adolescents and young adults as well as with COVID-19 infection alone.

    — Some evidence suggests that myocarditis and pericarditis risk may be higher after Moderna COVID-19 vaccine than after Pfizer/BioNTech COVID-19 vaccine; however, findings are not consistent in all U.S. monitoring systems.
    — The Centers for Disease Control and Prevention (CDC) has verified 635 myocarditis case reports in children ages 5 – 17 years after 54.8 million Pfizer/BioNTech COVID-19 vaccine doses administered in this age group in the U.S. (The Pfizer/BioNTech vaccine is the only COVID-19 vaccine previously authorized in this age group).
    — The FDA and CDC continue to monitor myocarditis/pericarditis cases.

- Additional discussion also occurred about whether this should be a 2-dose or 3-dose vaccine.

    — Currently, the Moderna COVID-19 vaccine for ages 6 – 17 years is being proposed as a 2-dose primary vaccine. Additional data is being collected for a booster dose which will be submitted at a later date.
    — This is the same process that the Pfizer/BioNTech COVID-19 vaccine for ages 5 – 17 years of age used: a 2-dose primary vaccine followed by a booster dose.

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- The Committee was asked to consider the totality of the available data supporting the vaccine for a potential EUA approval.

    — For adolescents aged 12 – 17 years of age, the Committee voted unanimously in favor of the Moderna COVID-19 2-dose primary vaccine (100 mcg each dose) given 28 days apart.
    — For children aged 6 – 11 years of age, the Committee voted unanimously in favor of the Moderna COVID-19 2-dose primary vaccine (50 mcg each dose) given 28 days apart.

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 request for the Moderna COVID-19 vaccine for ages 6 – 17 years of age.

- If the FDA approves the EUA for the Moderna COVID-19 vaccine for ages 6 – 17 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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