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COVID-19 Vaccines – FDA advisors discuss Pfizer/BioNTech's vaccine for patients 5 to < 12 years

- On October 26, 2021 the FDA convened a Vaccines and Related Biological Products Advisory Committee (VRBPAC) meeting to discuss expanding the emergency use authorization (EUA) for Pfizer/BioNTech's COVID-19 vaccine to include children between 5 and < 12 years of age.
    - The dosage being considered for 5 to < 12 years of age is two 10 mcg doses given 21 days apart.
    - The dosage for patients 12 years of age and older is two 30 mcg doses given 21 days apart.
    - The FDA has not yet approved the expanded EUA for children 5 to <12 years of age.

- Pfizer-BioNTech plans to produce a new formulation specific for children.
    - The pediatric formulation uses a different buffer, Tris, that maintains pH and provides for greater stability of the product compared to Comirnaty®, which uses PBS as a buffer.
    - The Tris formulation can be stored at 2 – 8 degrees C for up to 10 weeks and does not require the same level of minus 80 degrees C required for Comirnaty.
    - The pediatric vials will use orange labels and caps to clearly distinguish them from the adult formulation which uses purple labels. The NDCs are 59267-1055-01, 59267-1055-02, and 59267-1055-04.
    - The dose will be 10 mcg/0.2 mL given as an intramuscular injection.

- The expanded EUA request is based on data from a phase 2/3 trial conducted in 2,268 children 5 to <12 years of age. Participants received the Pfizer/BioNTech's COVID-19 vaccine 10 mcg every 21 days for two doses or placebo.
    - The antibody responses in the participants given 10 mcg doses were comparable to those recorded in a previous Pfizer/BioNTech study in people 16 to 25 years of age immunized with 30 mcg doses.
    - Side effects were generally comparable to those observed in participants 16 to 25 years of age.

- Additional data was submitted to the FDA by Pfizer/BioNTech:
    - The vaccine met the predefined immunogenicity endpoints indicating that the response in individuals 5 to < 12 years receiving the 10 mcg dose was similar to the response in individuals 16 – 25 years of age receiving the 30 mcg dose of vaccine.
    - In addition, 3 participants who received the vaccine and 16 participants who received placebo developed COVID-19 ≥ 7 days after the second dose for a vaccine efficacy of 90.7% (95% CI: 67.7, 98.3).
    - The observed adverse events profile in this study did not suggest any safety concerns. The most commonly reported solicited adverse reactions were pain at the injection site, fatigue, and headache.

- The VRBPAC extensively discussed the Benefit-Risk Analysis of COVID vaccine administration in children 5 to < 12 years of age specifically considering the incidence of myocarditis.
    - Overall, the Committee felt that the benefits of the vaccine for some children outweighed any potential risks of the vaccine.
    - In addition, they felt that the existing FDA and CDC surveillance systems would pick up any early safety signals as it has done previously with vaccine use in adults.

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- After extensive discussion, the VRBPAC voted on the following question, “Based on the totality of scientific evidence available, do the benefits of the Pfizer/BioNTech COVID-19 Vaccine when administered as a 2-dose series (10 µg each dose, 3 weeks apart) outweigh its risks for use in children 5-11 years of age?”

    — The VRBPAC voted 17 in favor of the question and 1 member abstained.
    — Multiple experts justified their vote by highlighting that some children have a higher risk of complications from COVID-10 due to comorbidities, or other risk factors, and they voted in favor of authorization to allow for these children to get protection from the vaccine.
    — Several experts pointed out that some children need to be vaccinated, but were unconvinced that all children needed to be vaccinated.
    — The FDA authorization indicates if the vaccine can be used. The CDC’s ACIP determines who should be vaccinated; ACIP can define a narrower target population than the FDA authorized indication, but ACIP cannot broaden it.

What’s Next:

- The FDA will take the recommendations of the VRBPAC under advisement when determining whether to approve the request for an expanded EUA for the Pfizer/BioNTech COVID-19 vaccine for children 5 to < 12 years of age.

- The CDC’s Advisory Committee on Immunization Practices (ACIP) will meet on November 2 and 3 to discuss Pfizer/BioNTech’s COVID-19 vaccine for children 5 to < 12 years of age. An agenda has not yet been posted.

- As a reminder of the process, FDA issues the authorization, ACIP reviews the data and recommends the proper use, the CDC Director must then verify the ACIP recommendations before they become official.