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COVID-19 Vaccines and Monoclonal Antibodies – An update

- As the COVID-19 pandemic continues to evolve, multiple decisions about prevention and treatment options are due to be announced in the next few weeks. Here is a summary of what is happening:

- **Moderna COVID-19 Vaccine**

  — **Potential Full FDA Approval:** On August 25, 2021, Moderna announced the submission of a biologics license application for their COVID-19 vaccine for people 18 years of age and older for full FDA approval.

    - Currently the Moderna COVID-19 vaccine is available in the U.S. through emergency use authorization (EUA).
    - Previously, Moderna applied for an EUA for use of its COVID-19 vaccine in adolescents 12 years to 17 years.

  — **Boosters:** On September 1, 2021, Moderna announced that they have submitted initial data to the FDA about their COVID-19 vaccine as a booster dose in people 18 years of age and older. The booster will be given as a 50 mcg dose at least 6 months after the primary series is completed.

    - The primary series uses 100 mcg doses given every 28 days times 2 doses.
    - A total of 344 participants received 50 mcg mRNA-1273 booster dose 6 months after 2nd dose. It induced robust antibody responses and significantly increased geometric mean titers (GMT) for all variants of concern including Beta (B.1.351) by 32-fold, Gamma (P.1) by 43.6-fold and Delta (B.1.617.2) by 42.3-fold.
    - A Vaccines and Related Biological Products Advisory Committee (VRBPAC) meeting has been scheduled for October 14, 2021 to discuss Moderna's booster dose.

- **Pfizer COVID-19 Vaccine**

  — **Use in Children:** On October 7, 2021, Pfizer requested EUA for their COVID-19 vaccine in children 5 years to < 12 years. The vaccine will be given at a dose of 10 mcg every 21 days times 2 doses in this age group.

    - The dose is 30 mcg every 21 days times 2 doses in people 12 years and older.
    - A total of 2,268 children 5 to < 12 years of age who received 10 mcg of vaccine every 21 days times 2 doses had non-inferior neutralizing antibody response vs. 16 - 25 years of age.
    - A VRBPAC meeting has already been scheduled for October 26, 2021 to discuss the Pfizer vaccine for children 5 to < 12 years of age.

- **Johnson & Johnson COVID-19 Vaccine**

  — **Boosters:** On October 5, 2021, Johnson and Johnson (J&J) announced that they have submitted data to the FDA about their COVID-19 vaccine as a booster dose in people 18 years of age and older.

    - Clinical trial data from ENSEMBLE 2 have shown that a second dose given 56 days after the 1st dose provided 100% protection against severe/critical COVID-19 and 94% protection against symptomatic (moderate to severe/critical) COVID-19 in the U.S.

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- Additional clinical trial data show that a booster dose given six months after the single shot demonstrated antibody levels increased nine-fold one week after the booster and continued to climb to 12-fold higher four weeks after the booster.
- A VRBPAC meeting has been scheduled for October 15, 2021 to discuss J&J's booster dose.

- **Eli Lilly's Anti-COVID-19 Monoclonal Antibodies**

  — On September 16, 2021, the FDA announced the expanded EUA approval of Eli Lilly's bamlanivimab/etesevimab for emergency use as *post-exposure* prophylaxis (prevention) for COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) who are at high risk for progression to severe COVID-19, including hospitalization or death.

  - Previously, bamlanivimab/etesevimab was approved for the treatment of mild to moderate COVID-19 in adults and pediatric patients.
  - Regeneron's REGEN-COV™ (casirivimab and imdevimab) is also EUA approved for post-exposure prophylaxis and treatment of COVID-19.
  - GlaxoSmithKline's sotrovimab is EUA approved for the treatment of COVID-19.

- **AstraZeneca's Anti-COVID-19 Monoclonal Antibodies**

  — On October 5, 2021, AstraZeneca announced it had submitted an EUA request for AZD7442 (tixagevimab/cilgavimab) for *pre-exposure* prophylaxis of symptomatic COVID-19 in people who aren't able to mount a protective response following vaccination and continue to be at risk of developing COVID-19.

  - If approved, AZD7442 will be the first monoclonal antibody approved for people who do not have COVID-19 but are at increased risk of severe disease.

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