NARFA
NATIONAL AUTOMOTIVE ROADS FUEL ASSOCIATION

COVID-19 Treatment and Vaccine Updates

Updated as of December 8, 2020

Contents

*Content comes courtesy of Cambridge Advisory Group

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Treatment Update

Regeneron's antibody cocktail

On November 21, 2020, the U.S. Food and Drug Administration issued an emergency use authorization (EUA*) for Regeneron's antibody cocktail which includes 2 antibodies, casirivimab and imdevimab for the treatment of mild to moderate COVID-19 infections in high risk individuals. Monoclonal antibodies are laboratory-made proteins that mimic the immune system's ability to fight off harmful pathogens such as viruses. These antibodies are similar to Eli Lilly's bamlanivimab, that received an EUA on November 9, 2020, for the same indication as Regeneron's cocktail.

Highlights:

- In a clinical trial of 799 non-hospitalized patients with mild to moderate COVID-19, casirivimab and imdevimab, administered together, were shown to reduce viral load and COVID-19-related hospitalization or emergency room visits within 28 days after treatment in patients at high risk for disease progression.
- When compared to placebo the antibody cocktail reduced hospitalization and emergency visits from 9% to 3%. These study results were similar to those observed with Eli Lilly's bamlanivimab.
- Patients receiving the greatest benefit will be those who have not yet mounted their own immune response against SARs-CoV-2, have a lower viral load and those that receive the cocktail early after diagnosis (within 10 days of symptom onset).
- The cocktail is given as an intravenous infusion by a healthcare professional.

Considerations:

- Similar to Eli Lilly's bamlanivimab, casirivimab and imdevimab are limited in scope and not authorized for patients who are hospitalized due to COVID-19 infections or require oxygen therapy because of lack of benefit in this population.
- With a limited initial supply of 80,000 doses and a vague definition of high risk the decision as to who will receive antibody therapies may be challenging.
- Regeneron plans to increase the number of doses to 300,000 by the first week of January 2021.
    - As part of Operation Warp Speed, the first 300,000 doses will be administered at no cost to the patient. Subsequent supplies will likely be billed via the medical benefit.

*EUA allows unapproved products or unapproved uses of approved products to be used in emergency situations when no alternatives are available. The EUA is temporary and does not replace the formal FDA review and approval process.

https://newsroom.regeneron.com/news-releases/news-release-details/regenerons-regen-cov2-first-antibody-cocktail-covid-19-receive
https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-monoclonal-antibodies-treatment-covid-19
https://www.nytimes.com/2020/11/21/health/regeneron-covid-antibodies-trump.html

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Vaccine Updates

Pfizer submits for EUA

On November 20, 2020, Pfizer submitted a request to the U.S. Food and Drug Administration for an EUA of their mRNA vaccine candidate, BNT162b2 against SARS-CoV-2. This action will potentially enable use of the vaccine in high-risk populations in the U.S. by the mid to late December 2020.

Highlights:

- The EUA submission is based on a vaccine efficacy rate of 95% demonstrated in a Phase 3 clinical study in participants without prior COVID-19 infection as well as safety data noting no serious side effects from the vaccine.
- The Vaccines and Related Biological Products Advisory Committee (VRBPAC), an independent committee, will review the EUA submission on December 10 and advise the FDA who ultimately will make the decision on the EUA. It's expected the FDA's decision will be made within days of the VRBPAC's recommendation.
    - To provide transparency to the public the FDA intends to livestream the VRBPAC meeting on the agency's YouTube, Facebook and Twitter channels; the meeting will also be webcast from the FDA website.
- Pfizer expects to produce globally up to 50 million doses in 2020 and up to 1.3 billion doses by the end of 2021; the company states they will be ready to distribute the vaccine within hours after authorization. Due to the storage and distribution requirements specially designed, temperature-controlled shippers with GPS-enabled thermal sensor will be used to track the location and temperature of the vaccines during shipment.
- Per recommendations from the Centers for Disease Control and Prevention (CDC) both healthcare personnel (approximately 21 million) and residents of long-term care facilities (more than 3 million) should be offered the vaccine as part of the initial phase of the COVID-19 vaccination program (Phase 1a).
- On December 3, 2020, the United Kingdom gave regulatory approval for Pfizer's vaccine with administration to begin the week of December 7, 2020.

https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-submit-emergency-use-authorization
https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-announces-advisory-committee-meeting-discuss-covid-19-vaccine
https://www.cnn.com/2020/12/02/uk/pfizer-coronavirus-vaccine-uk-intl-hnk/index.html

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Moderna submits for EUA

On November 30, 2020, Moderna applied for an EUA for its COVID-19 vaccine candidate, mRNA-1273. This action will potentially enable use of the vaccine in high-risk populations in the U.S. by the mid to late December 2020.

Highlights:

- The Vaccines and Related Biological Products Advisory Committee (VRBPAC) is scheduled to review Moderna's EUA submission on December 17, 2020. Similar to the review of Pfizer's COVID-19 vaccine data, the VRBPAC will make a recommendation to the FDA on Moderna's EUA submission. It is expected the final decision from the FDA should follow shortly.
- Moderna's vaccine demonstrated a 94.1% efficacy rate in preventing COVID-19 infections and 100% efficacy in preventing severe infections. No serious safety concerns were identified to date. The study population was racially and ethnically diverse and included adults ages 18 and older.
- Moderna expects to have approximately 20 million doses of the vaccine available in the U.S. by year end and is on track to deliver 500 million to 1 billion doses globally in 2021.
- Storage and shipping requirements for Moderna's vaccine are less arduous than the Pfizer vaccine as Moderna's vaccine can be safely stored in freezers at about 25 degrees Fahrenheit (minus 4 degrees Celsius), a temperature easily reached by a home refrigerator freezer.

https://investors.modernatx.com/news-releases/news-release-details/moderna-announces-primary-efficacy-analysis-phase-3-cove-study
https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-announces-advisory-committee-meeting-discuss-second-covid-19-vaccine
https://www.modernatx.com/sites/default/files/content_documents/2020-COVE-Study-Enrollment-Completion-10.22.20.pdf

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AstraZeneca's vaccine candidate AZD1222

On November 23, 2020, AstraZeneca reported positive high-level results from two clinical trials noting AZD1222, a viral vector COVID-19 vaccine, was highly effective in preventing infections caused by SAR-CoV-2. Two different dosages were studied with an average efficacy of 70%. This is the third vaccine demonstrating efficacy against the SARs-CoV-2 virus albeit slightly lower than that reported for the Pfizer (95%) and Moderna (94.1%) COVID-19 vaccines.

Highlights:

- A total of 22,690 patients enrolled in two Phase 3 studies evaluating two different dosages were studied with efficacy ranging from 62% in patients who received two full doses of the vaccine and 90% effective when half of the first dose was administered followed by the full dose.
- No evidence exists to say why patients receiving half the first dose saw 90% efficacy, but one theory is that it acts as a "primer" for the immune system. There will need to be more studies in the future to understand the increase in efficacy.
- AstraZeneca's vaccine candidate uses a viral vector platform to induce immunity. Vector vaccines use another virus such as the adenovirus or common cold viurs to deliver the genetic code/instructions for the antigen or the SARs-CoV-2 spike protein. The adenovirus attaches to human cells and injects the DNA code instructing the cells to make the antigen or coronavirus spike protein which triggers an immune response. This is different from the Pfizer and Moderna vaccine candidates which use synthetic genetic material, mRNA to induce immunity.
- The combined analysis of two clinical trials resulted in an average efficacy of 70%. Due to a suspected serious adverse reaction the trials were halted for 6 weeks but then restarted once it was confirmed the reaction was not related to the vaccine. No serious safety events related to the vaccine have been confirmed to date.

Considerations

- Unlike the Pfizer and Moderna m-RNA vaccine candidates that must be frozen for long-term use, the AstraZeneca vaccine requires refrigeration at 2 to 8 C. This may be a logistical advantage over the mRNA vaccines.
- The difference in efficacy between the viral vector platform (70%) and mRNA platform (>94%) may lead patients and physicians to prefer the mRNA-based vaccine. However as more data becomes available efficacy of the viral vector vaccine may change.

https://www.astrazeneca.com/media-centre/press-releases/2020/azd1222hlr.html

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