NARFA
NATIONAL AUTOMOTIVE ROADS FUEL ASSOCIATION

Moderna COVID-19 vaccine mRNA-1273 - Interim Analysis from Phase 3 Study

On Monday, November 16, 2020, Moderna announced that an independent, NIH-appointed Data Safety Monitoring Board (DSMB) identified that their COVID-19 vaccine was 94.5% effective. This is the second vaccine to demonstrate efficacy as on November 9, 2020, Pfizer, reported positive preliminary results for its vaccine candidate (BNT 162b2) which was more than 90% effective.

Highlights:

- The Phase 3 study for vaccine candidate mRNA-1273 enrolled more than 30,000 participants in the U.S.
- This first interim analysis was based on 95 cases, of which 90 cases of COVID-19 were observed in the placebo group versus 5 cases observed in the mRNA-1273 group, resulting in a 94.5% efficacy rate
  - Eleven cases of severe COVID-19 infections were analyzed as a secondary endpoint, all of which occurred in the placebo group and none in the mRNA-1273 vaccinated group
- The interim analysis did not report any significant safety concerns. Mild to moderate side effects such as site pain, fatigue, myalgia, headache were reported
- Moderna intends to submit for an Emergency Use Authorization (EUA) with the U.S. Food and Drug Administration (FDA) in the coming weeks. In addition to the evidence for effectiveness, the companies must also submit two months of safety data on at least half of the participants.
- By the end of 2020, Moderna expects to have approximately 20 million doses of mRNA-1273 ready to ship in the U.S. The Company remains on track to manufacture 500 million to 1 billion doses globally in 2021.

Considerations:

- The Moderna COVID-19 vaccine utilizes a platform that leverages synthetic generic material, mRNA, to impart immunity. This m-RNA platform is the same as the one used to develop Pfizer's vaccine candidate
- Using nanoparticle technology, Moderna has overcome the ultracold storage requirements of mRNA vaccines which may prove advantageous over the Pfizer vaccine candidate which must be stored at minus 70 degrees Celsius
  - The Moderna vaccine candidate can be safely stored at -20° C (-4°F) for up to six months, at refrigerated conditions for up to 30 days and at room temperature for up to 12 hours
- Given the expected efficacy for COVID-19 vaccines was 50 to 70%, the 94.5% efficacy reported from this interim analysis is very positive. Note as additional data is collected the efficacy may change
- Because this is a two-shot series (4 weeks apart), this vaccine will require tracking and monitoring to ensure people return for their subsequent shot. Moderna's vaccine is not interchangeable with Pfizer's vaccine, and it remains unclear if one vaccine can be substituted for another in the instance of a vaccine shortage. More data will need to be collected
- There is limited data on the length of immunity imparted by this vaccine. Continued follow-up will be required to determine if additional doses will be needed

https://investors.modernatx.com/news-releases/news-release-details/modernas-covid-19-vaccine-candidate-meets-its-primary-efficacy
https://investors.modernatx.com/news-releases/news-release-details/moderna-announces-longer-shelf-life-its-covid-19-vaccine
https://www.nytimes.com/2020/11/16/health/Covid-moderna-vaccine.html?auth=login-email&login=email

*Content comes courtesy of Cambridge Advisory Group