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Pfizer/BioNTech COVID-19 vaccine - Interim Analysis from Phase 3 Study

On Monday, November 9, 2020, Pfizer/BioNTech released early phase 3 data on their vaccine candidate (BNT 162b2) demonstrating strong efficacy. Pfizer indicated some supply of the vaccine may be available before the end of the year. Below are highlights of the interim analysis and other considerations for the vaccine.

Highlights:

- Global Phase 3 study enrolled 43,538 participants to date, 38,955 of whom have received a second dose of the vaccine as of November 8, 2020
- Per the first interim analysis the vaccine efficacy rate was more than 90%, indicating protection against SARS-CoV-2 was achieved 28 days after initiation of vaccination
- This analysis evaluated 94 confirmed cases of COVID-19 in trial participants. Clinical trial will continue until 164 confirmed cases have accrued
- No serious safety concerns were observed to date, however safety and more efficacy data (new secondary endpoints – cases accruing 14 days after second dose) continues to be collected. Per FDA guidance, 2 additional months of safety data is required for potential Emergency Use Authorization. Pfizer expects this additional data to be available the third week of November
- Pfizer expects to produce up to 50 million vaccine doses in 2020 and up to 1.3 billion in 2021

Considerations:

- The Pfizer/BioNTech COVID-19 vaccine utilizes a new platform that leverages synthetic generic material, mRNA to impart immunity. Although there are other COVID-19 vaccines in development that utilize this same technology, it has not been used in any other FDA approved vaccine
- An advantage of mRNA vaccines is that they are made in a laboratory and quantities are quickly scalable. A potential disadvantage, but one that Pfizer is addressing, is the need for ultracold storage (minus 70 degrees Celsius) which may challenge the distribution and supply chain
- The reported efficacy rate of 90% for this vaccine is considered positive given a 50-70% efficacy rate was expected. However, as more data becomes available, this could change
- Because this is a two-shot series (3 weeks apart), this vaccine will require tracking and monitoring to ensure people return for their subsequent shot
- 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
- Pfizer is expected to request an Emergency Use Authorization from the FDA in late November and if awarded could make the vaccine available before year end

https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-announce-vaccine-candidate- against

*Content comes courtesy of Cambridge Advisory Group