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Pfizer, BioNTech demonstrate 95% efficacy of COVID-19 vaccine

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Primary efficacy analysis demonstrates BNT162b2 to be 95% effective against COVID-19 beginning 28 days after the first dose

Pfizer Inc. and BioNTech have announced that, after conducting the final efficacy analysis in their ongoing Phase 3 study, their mRNA-based COVID-19 vaccine candidate, BNT162b2, met all of the study's primary efficacy endpoints. Analysis of the data indicates a vaccine efficacy rate of 95% ($p<0.0001$) in participants without prior SARS-CoV-2 infection (first primary objective) and also in participants with and without prior SARS-CoV-2 infection (second primary objective), in each case measured from 7 days after the second dose. The first primary objective analysis is based on 170 cases of COVID-19, as specified in the study protocol, of which 162 cases of COVID-19 were observed in the placebo group versus 8 cases in the BNT162b2 group. Efficacy was consistent across age, gender, race and ethnicity demographics. The observed efficacy in adults over 65 years of age was over 94%.

To date, the Data Monitoring Committee for the study has not reported any serious safety concerns related to the vaccine. "We are grateful that the first global trial to reach the final efficacy analysis mark indicates that a high rate of protection against COVID-19 can be achieved very fast after the first 30 µg dose, underscoring the power of BNT162 in providing early protection," said Ugur Sahin, M.D., CEO and Co-founder of BioNTech.

Based on current projections, the companies expect to produce globally up to 50 million vaccine doses in 2020 and up to 1.3 billion doses by the end of 2021. Four of Pfizer's facilities are part of the manufacturing and supply chain; St. Louis, MO; Andover, MA; and Kalamazoo, MI in the U.S.; and Puurs in Belgium. BioNTech's German sites will also be leveraged for global supply.

Pfizer is confident in its vast experience, expertise and existing cold-chain infrastructure to distribute the vaccine around the world. The companies have developed specially designed, temperature-controlled thermal shippers utilizing dry ice to maintain temperature conditions of -70°C±10°C. They can be used be as temporary storage units for 15 days by refilling with dry ice. Each shipper contains a GPS-enabled thermal sensor to track the location and temperature of each vaccine shipment across their pre-set routes leveraging Pfizer's broad distribution network.

In addition, Pfizer and BioNTech announced that the safety milestone required by the U.S. Food and Drug Administration (FDA) for Emergency Use Authorization (EUA) has been achieved. They plan to submit the efficacy and safety data from the study for peer-review in a scientific journal once the analysis of the data is completed.